

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549FORM S-1
(Amendment No. 2)
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

CHEMBIO DIAGNOSTICS, INC.

(Exact name of registrant as specified in its charter)

Nevada	6282	88-0425691
<i>(State or other jurisdiction of incorporation or organization)</i>	<i>(Primary Standard Industrial Classification Code Number)</i>	<i>(I.R.S. Employer Identification Number)</i>

555 Wireless Blvd., Hauppauge, New York 11788
(631) 924-1135*(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)*Richard L. Eberly
Chief Executive Officer and President
Chembio Diagnostics, Inc.555 Wireless Blvd., Hauppauge, New York 11788
(631) 924-1135*(Name, address, including zip code, and telephone number, including area code, of agent for service)*

Copies to:

Sean M. Jones
K&L Gates LLP
300 South Tryon St, Suite 1000
Charlotte, NC 28202
(704) 331-7406Robert F. Charron
Ellenoff Grossman & Schole LLP
1345 Avenue of the Americas
New York, NY 10105
(212) 370-1300

Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box: ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 7(a)(2)(B) of the Securities Act. ☐

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 (the "Securities Act") or until the registration statement shall become effective on such date as the Securities and Exchange Commission (the "SEC"), acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. The securities may not be sold until the registration statement filed with the SEC is declared effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, dated October 7, 2022

PRELIMINARY PROSPECTUS



40,476,190 Shares of Common Stock Pre-Funded Warrants to Purchase Shares of Common Stock and Warrants to Purchase up to 50,595,238 Shares of Common Stock

We are offering 40,476,190 shares of common stock, par value \$0.01 per share, together with warrants to purchase 50,595,238 shares of common stock. The common stock and warrants will be sold in a fixed combination, with each share of common stock accompanied by one and one-quarter (1.25) warrants to purchase one (1) share of common stock per whole warrant. The shares of common stock and warrants are immediately separable and will be issued separately in this offering, but must be purchased together in this offering. The assumed public offering price for each share of common stock and the accompanying warrants is \$0.42, which was the last reported sale price of our common stock on The Nasdaq Capital Market on October 5, 2022.

The warrants will be exercisable only after we receive approval from our stockholders for both (i) an increase in the number of shares of common stock we are authorized to issue and/or a reverse stock split of our outstanding shares of common stock, each in an amount to be determined by the board of directors and each sufficient for the exercise in full of all of the warrants (an increase in authorized shares or a reverse stock split, each a “Capital Event”) and (ii) the potential issuance of shares of common stock upon exercise of the warrants in accordance with Nasdaq Marketplace Rule 5635(d) (the “Nasdaq Listing Rule”) ((i) and (ii), together, the “Stockholder Approvals” and the first date on which both Stockholder Approvals are obtained, the “Stockholder Approvals Date”). If our stockholders do not approve both a Capital Event and the potential issuance of shares of our common stock upon exercise of the warrants for purposes of the Nasdaq Listing Rule, the warrants will not become exercisable. Each warrant has an initial exercise price of \$ per whole share, and will be exercisable on the Stockholder Approvals Date for a term of five years from the Stockholder Approvals Date.

We are also offering pre-funded warrants to purchase up to 40,476,190 shares of common stock to those purchasers whose purchase of shares of common stock in this offering would result in the purchaser beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the offering in lieu of the shares of common stock that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%). Each pre-funded warrant will be exercisable for one share of common stock at an exercise price of \$0.01 per share. Each pre-funded warrant is being issued together with the same warrants described above that are being issued with each share of common stock. The assumed public offering price for each such pre-funded warrant and accompanying warrants is \$0.41, which is equal to the assumed public offering price for a share of common stock and accompanying warrants less the \$0.01 per share exercise price of each such pre-funded warrant. Each pre-funded warrant will be exercisable immediately upon issuance, subject to certain limitations based on the holder’s beneficial ownership of our common stock, and may be exercised at any time until the pre-funded warrant is exercised in full. The pre-funded warrants and warrants are immediately separable and will be issued separately in this offering, but must be purchased together in this offering. For each pre-funded warrant and accompanying warrants we sell, the number of shares of common stock and the accompanying warrants we are offering will be decreased on a one-for-one basis.

We are also registering the shares of common stock issuable upon exercise of the pre-funded warrants and the warrants in this prospectus.

Our common stock is listed on The Nasdaq Capital Market under the symbol “CEMI.” On October 5, 2022, the last reported sale price of our common stock on The Nasdaq Capital Market was \$0.42 per share. The recent market price used throughout this prospectus may not be indicative of the final offering price. The final offering price will be determined through negotiation between us and the underwriter based upon a number of factors, including our history and our prospects, the industry in which we operate, our past and present operating results and the general condition of the securities markets at the time of this offering. There is no established public trading market for the pre-funded warrants or the warrants, and we do not expect a market to develop. We do not intend to apply for listing of the pre-funded warrants or the warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the pre-funded warrants and the warrants will be extremely limited.

Investing in these securities involves significant risks. See “Risk Factors” included in this prospectus and in the documents incorporated by reference in this prospectus for a discussion of the factors you should carefully consider before deciding to purchase these securities.

	Per Share and Accompanying Warrants	Per Pre-Funded Warrant and Accompanying Warrants	Total
Public offering price	\$	\$	\$
Underwriting discounts and commissions ⁽²⁾	\$	\$	\$
Proceeds, before expenses, to us ⁽³⁾	\$	\$	\$

(1) See “Underwriting” beginning on page 61 for additional information regarding underwriting compensation.

(2) The amount of proceeds, before expenses, to us does not give effect to any exercise of the pre-funded warrants or warrants.

Neither the SEC nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriter expects to deliver the shares of common stock, pre-funded warrants and warrants on or about , 2022.

Craig-Hallum

The date of this prospectus is , 2022.

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ABOUT THIS PROSPECTUS

The registration statement we filed with the Securities and Exchange Commission (the “SEC”) includes exhibits that provide more detail about the matters discussed in this prospectus. You should read this prospectus, the related exhibits filed with the SEC, and the documents incorporated by reference herein before making your investment decision. You should rely only on the information provided in this prospectus and the documents incorporated by reference herein or any amendment thereto. In addition, this prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the heading “*Where You Can Find More Information.*”

We have not, and the underwriter has not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or the documents incorporated by reference herein to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. The information contained in this prospectus or the documents incorporated by reference herein is current only as of its date, regardless of its time of delivery or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date.

This prospectus is an offer to sell only the securities offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. We are not, and the underwriter is not, making an offer to sell these securities in any state or jurisdiction where the offer or sale is not permitted.

All trademarks, trade names and service marks appearing in this prospectus or the documents incorporated by reference herein are the property of their respective owners. Use or display by us of other parties’ trademarks, trade dress or products is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owner. Solely for convenience, trademarks, tradenames and service marks referred to in this prospectus appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and trade names.

FORWARD-LOOKING STATEMENTS

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

This prospectus and the documents incorporated by reference herein contain 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 (the “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 the 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 the “Risk Factors” section beginning on page 9 of this prospectus and in Part I, Item 1A “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, and in Part II, Item 1A, “Risk Factors,” of subsequently filed Quarterly Reports on Forms 10-Q. You should interpret many of the risks identified in these reports as being heightened as a result of the ongoing and numerous adverse impacts of COVID-19. 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.

PROSPECTUS SUMMARY

This summary highlights, and is qualified in its entirety by, the more detailed information contained in other parts of this prospectus, and the documents incorporated by reference herein. This summary does not contain all of the information that may be important to you in making your investment decision. You should read this entire prospectus carefully, especially the “Risk Factors” section beginning on page 2 and in the documents incorporated by reference herein and our financial statements and the related notes incorporated by reference herein, before deciding to invest in our common stock, pre-funded warrants and warrants. As used in this prospectus, unless the context otherwise requires, references to “we,” “us,” “our” and “Chembio” refer to Chembio Diagnostics, Inc. and its subsidiaries.

Company Overview

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

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

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

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

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

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		✓

Product	U.S.	International
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		✓

We are incorporated in the State of Nevada. Our headquarters are located at 555 Wireless Blvd., Hauppauge, New York 11788, where our telephone number is (631) 924-1135. We maintain a website at www.chembio.com, where general information about us is available. We do not incorporate the information on our website into this prospectus and you should not consider that information to be part of this prospectus.

Recent Developments

Strategic Matters

The Company recently completed its future strategic planning process (the “Strategic Planning Process”), which has been approved by our board of directors. The plan is premised on a transformation of the Company that, along with other pillars, bases our commercial focus on differentiated point-of-care and over-the-counter target markets with higher average-selling prices in the United States, Europe, the Middle East, Africa and Brazil. Aligned with our Global Competitiveness Program, we are planning our sales focus opportunities to be on our core product portfolio with higher margins in growth markets and recurring revenues. We have begun implementing cost reduction programs to right-size the business, and we plan to leverage our manufacturing automation investments in recent years to scale with future higher volumes.

In addition, our board of directors has previously initiated a review of strategic alternatives, including a potential sale or merger transaction, and a review of our financing strategy. We have retained Craig-Hallum Capital Group LLC as our financial advisor to assist with this strategic review. This strategic review process is substantially complete, and we are not currently in active discussions regarding any such strategic transaction. Even if a sale, merger or financing transaction were to be consummated, it may not return any value to holders of our common stock. Regardless of whether we execute a sale, merger or financing transaction, the adverse pressures negatively impacting our business that we have experienced may continue or intensify, and we will likely continue to face all of the risks we currently face, including the risk that we may not be able to continue as a going concern.

Sale of Common Stock under the ATM Agreement

As of October 5, 2022, we have sold 14,772,190 shares of common stock, for gross proceeds of \$44.9 million and net proceeds, after giving effect to commissions and other transaction costs, of \$43.4 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 \$4.1 million and net proceeds of \$4.0 million since June 30, 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.

Contract from the CDC for Development and Clinical Validation of Dual-Path Platform Syphilis Screen & Confirm Assay

On September 6, 2022, the Company announced a \$3.2 million contract award from the Centers for Disease Control and Prevention (CDC) for the development and clinical validation of a rapid point-of-care (POC) diagnostic test for syphilis. We will undertake to develop a syphilis test and confirm assay based on our Dual Path Platform (DPP) technology and proprietary DPP Micro Reader II.

Litigation

Putative Stockholder Securities Class-Action Litigation

We and the other parties in the consolidated putative class action litigation captioned *In re Chembio Diagnostics, Inc. Securities Litigation* convened an in-person mediation before a mediator on July 14, 2022. Although the parties did not resolve the matter during that session, they continued their discussions through the mediator. On August 26, 2022, we and the other parties 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 of 1934 (the “Exchange Act”). The agreement in principle to settle contemplates an \$8.1 million payment on behalf of the defendants, approximately \$209,000 of which is to be paid by us with the remainder being funded by certain of our insurers. After the date of this prospectus, the parties will undertake to negotiate and prepare a formal stipulation or settlement setting forth the full terms of the proposed settlement, as well as the related documents which will be submitted to the court for approval together with the parties’ stipulation.

Accordingly, on August 29, 2022, we and certain other defendants filed a letter motion requesting that the court stay all proceedings to allow the parties to focus their efforts on negotiating and preparing the stipulation or settlement and related papers. The court granted the motion on August 31, 2022 and ordered the parties to file their stipulation on or before October 17, 2022. There can be no assurance that the parties will be able to reach agreement on the terms of a stipulation or settlement, or that if the parties reach agreement, the stipulation will be granted preliminary and final approval by the court.

Putative Stockholder Derivative Litigation

The parties in the actions 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* and *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* have reached an agreement in principle on the terms of a proposed settlement of both actions, other than with respect to the maximum amount of attorneys’ fees which plaintiffs may request that the court approve, and have executed a memorandum of understanding to that effect. The proposed settlement contemplates the adoption of certain corporate governance measures and does not entail any monetary compensation or payment by us other than attorneys’ fees not exceeding an amount to be negotiated.

There can be no assurance that we and the other parties to the putative stockholder derivative action will reach agreement on the maximum amount of plaintiffs’ attorneys’ fees that plaintiffs may request court approval on or on the terms of a formal stipulation or settlement, or that the court will approve the terms of a stipulation or settlement.

Liquidity Issues

We may experience significant liquidity issues in the future, and, as of October 5, 2022, we had approximately \$20.8 million in cash and cash equivalents. On September 30, 2022, we began making \$300,000 monthly principal payments on our \$20 million Credit Agreement (as defined below) with the remaining balance due on September 4, 2023. In the event the offering to which this prospectus relates does not generate sufficient liquidity or we are not able to refinance the debt owed under our Credit Agreement (whether at maturity or earlier in the event of a covenant breach and acceleration), we may be forced to pursue a reorganization under the U.S. Bankruptcy Code.

Going Concern Considerations

We continue to experience market, clinical trial and regulatory complications in seeking to develop and commercialize a portfolio of COVID-19 test systems during the continuing, but evolving, uncertainty resulting from COVID-19. For the three and six months ended June 30, 2022, we also continued to incur significant expenses in connection with pending legal matters.

We performed an assessment to determine whether there were conditions or events that, considered in the aggregate, raised substantial doubt about our ability to continue as a going concern within one year after the date of the most recent unaudited condensed consolidated financial statements incorporated by reference into this

prospectus. Initially, this assessment did not consider the potential mitigating effect of management's plans that had not been fully implemented. Because, as described below, substantial doubt was determined to exist as the result of this initial assessment, management then assessed the mitigating effect of its plans to determine if it is probable that the plans (1) would be effectively implemented within one year after the date of the most recent unaudited condensed consolidated financial statements incorporated by reference into this prospectus and (2) when implemented, would mitigate the relevant conditions or events that raise substantial doubt about the our ability to continue as a going concern.

We achieved significant revenue growth in recent years while profitability has not been at levels that we expected. We have 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. We undertook measures to increase our total revenues and improve our 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 and
- Strategic review of non-core businesses and assets.

In addition, we will continue to focus on regulatory approvals for our DPP SARS-CoV-2 Antigen test system, DPP Respiratory Antigen Panel, and DPP HIV-Syphilis test system. These measures and other plans and initiatives have been designed to provide us with adequate liquidity to meet our obligations for at least the twelve-month period following the date of the most recent unaudited condensed consolidated financial statements incorporated by reference into this prospectus. Our execution of our plans continue to depend, however, on factors and uncertainties that are beyond our control, or that may not be addressable on terms acceptable to us or at all. We considered in particular how:

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

We further considered how these factors and uncertainties could impact our ability over the next year to meet the obligations specified in our \$20.0 million Credit Agreement with Perceptive Credit Holdings II, LP (the "Lender"), entered into on September 3, 2019 (the "Credit Agreement"). Those obligations include covenants requiring: (i) a 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 range from \$45.6 million for the twelve months ending September 30, 2022, to \$50.1 million for the twelve months ending June 30, 2023. Upon an event of default under the Credit Agreement, the Lender could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. In such an event, there can be no assurance that we would have sufficient liquidity to fund payment of the amounts that would be due under the Credit Agreement or that, if such liquidity were not available, we would be successful in raising additional capital on acceptable terms, or at all, or in completing any other endeavor to continue to be financially viable and continue as a going concern. Our inability to raise additional capital on acceptable terms in the near future, whether for purposes of funding payments required under the Credit Agreement or providing additional liquidity needed for our operations, could have a material adverse effect on our business, prospects, results of operations, liquidity and financial condition.

Accordingly, management determined we could not be certain that our plans and initiatives would be effectively implemented within one year after the date of the most recent unaudited condensed consolidated financial statements incorporated by reference into this prospectus. 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 date of the most recent unaudited condensed consolidated financial statements incorporated by reference into this prospectus.

The most recent unaudited condensed consolidated financial statements incorporated by reference into this prospectus 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 the most recent unaudited condensed consolidated financial statements incorporated by reference into this prospectus. As such, the most recent unaudited condensed consolidated financial statements incorporated by reference into this prospectus 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.

Risk Factors

Our business and this offering are subject to numerous risks and uncertainties, including those in the section titled “Risk Factors” and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and subsequently filed Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, and in the other documents we file with the SEC which are incorporated by reference in this prospectus.

THE OFFERING

Securities offered by us

Up to 40,476,190 shares of common stock and warrants to purchase up to 50,595,238 shares of common stock (or pre-funded warrants to purchase shares of common stock and warrants to purchase shares of common stock in lieu thereof, as described below), at an assumed public offering price of \$0.42 per share and accompanying one and one-quarter (1.25) warrants, which was the last reported sale price of our common stock on The Nasdaq Capital Market on October 5, 2022. The shares of common stock or pre-funded warrants, respectively, and warrants are immediately separable and will be issued separately in this offering, but must initially be purchased together in this offering. Each warrant has an initial exercise price of \$ _____ per whole share of common stock. If we issue or sell any shares of common stock or securities that are convertible into shares of common stock in the future at a price per share less than the exercise price then in effect, the exercise price of the warrants will be adjusted to that lower price, subject to customary exceptions, and the number of shares issuable upon exercise of the warrants will be proportionally increased. The warrants also contain a one-time reset of the exercise price to a price equal to the lower of the exercise price then in effect and the lowest five-day volume weighted average price of the common stock for the five trading days immediately after the effective date of a reverse stock split. In connection with such a reset of the exercise price following a reverse stock split, the number of shares issuable upon exercise of the warrants will also be proportionally increased. The warrants will be exercisable only after we receive Stockholder Approvals to (i) effect a Capital Event in an amount sufficient to permit exercise in full of the warrants and (ii) potentially issue shares of our common stock upon exercise of the warrants for purposes of the Nasdaq Listing Rule. The warrants will be exercisable on the date on which both the Capital Event has occurred and Stockholder Approval for purposes of the Nasdaq Listing Rule has occurred, subject to certain limitations based on the holder's beneficial ownership of our common stock, and will expire five years from the date of the initial exercisability. If our stockholders do not approve both a Capital Event and the potential issuance of shares of our common stock upon exercise of the warrants for purposes of the Nasdaq Listing Rule, the warrants will not become exercisable and will therefore have no value. See "Description of Securities". We are also registering the shares of common stock issuable upon exercise of the pre-funded warrants and the warrants.

Description of pre-funded warrants

If the issuance of shares of common stock to a purchaser in this offering would result in such purchaser

	<p>beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding shares of common stock following the consummation of this offering, then such purchaser may purchase, if it so chooses, in lieu of the shares of common stock that would result in ownership exceeding such threshold, a pre-funded warrant to purchase shares of our common stock. Each pre-funded warrant will be immediately exercisable upon issuance and may be exercised until the pre-funded warrant is exercised in full, subject to certain limitations on the holder's beneficial ownership of our common stock. Purchasers of pre-funded warrants will also receive accompanying warrants as if such purchasers were buying shares of our common stock in this offering. The assumed public offering price of a pre-funded warrant and accompanying warrants is \$0.41, which is the assumed public offering price of one share of common stock and accompanying warrants less \$0.01, and the exercise price of the pre-funded warrant is \$0.01. For each pre-funded warrant and accompanying warrants purchased in this offering, the number of shares of common stock and accompanying warrants we are offering will be decreased on a one-for-one basis.</p>
Common stock outstanding before this offering	35,392,550 shares of common stock.
Common stock outstanding after this offering	75,868,740 shares of common stock (assuming all of the pre-funded warrants, if any, are exercised and none of the warrants issued in this offering are exercised).
Use of proceeds	<p>We estimate the net proceeds from this offering will be approximately \$15.3 million (assuming all of the pre-funded warrants and none of the warrants issued in this offering are exercised), after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, based on an assumed public offering price of \$0.42 per share and accompanying warrants, which was the last reported sale price of our common stock on The Nasdaq Capital Market on October 5, 2022. We intend to use the net proceeds from this offering to repay amounts owed to the Lender under the Credit Agreement. See "Use of Proceeds" on page 44 of this prospectus.</p>
Stockholder Approvals	<p>Promptly after this offering, we intend to call two special meetings of stockholders, one to obtain Stockholder Approval for a Capital Event and one to obtain Stockholder Approval for the potential issuance of shares of common stock upon exercise of the warrants in accordance with the Nasdaq Listing Rule. We intend to engage a proxy solicitation firm to solicit proxies in connection with obtaining such Stockholder Approvals. Investors who participate in this offering and acquire shares of common stock will be able to vote at the special meeting to obtain Stockholder Approval for a Capital Event if such investors hold their shares on the record date for such meeting. Pursuant to Nasdaq rules,</p>

	<p>investors who participate in this offering will not be able to vote at the special meeting to obtain Stockholder Approval for the potential issuance of shares of common stock upon exercise of the warrants in accordance with the Nasdaq Listing Rule. In the event that we are unable to obtain Stockholder Approvals for both a Capital Event and the potential issuance of shares of our common stock upon exercise of the warrants for purposes of the Nasdaq Listing Rule, the warrants will not be exercisable.</p>
Risk factors	<p>See “Risk Factors” beginning on page 9 and the documents incorporated by reference in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our securities.</p>
Nasdaq Symbol	<p>Our common stock is listed on The Nasdaq Capital Market under the symbol “CEMI.” There is no established trading market for the warrants or the pre-funded warrants, and we do not expect a trading market to develop. We do not intend to list the warrants or the pre-funded warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the warrants and pre-funded warrants will be extremely limited.</p>
Transfer Agent	<p>Action Stock Transfer Corp.</p>
<p>The number of shares of our common stock to be outstanding after this offering is based on 35,392,550 shares of our common stock outstanding as of October 5, 2022, and excludes:</p> <ul style="list-style-type: none"> • 3,674,045 shares issuable upon the exercise of options with a weighted-average exercise price of \$2.20 per share; • 1,722,952 shares underlying restricted and performance stock units; and • 89,030 shares reserved for future issuance under our 2019 Omnibus Incentive Plan. <p>Unless otherwise indicated, all information contained in this prospectus assumes:</p> <ul style="list-style-type: none"> • no exercise or conversion of the outstanding securities described above; and • no sale of pre-funded warrants in this offering and no exercise of the warrants in this offering. 	

RISK FACTORS

You should carefully consider the risks described below and those discussed under the section titled “Risk Factors” contained in our Annual Report on Form 10-K for the year ended December 31, 2021 and subsequently filed Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, together with other information in this prospectus, and the information and documents incorporated by reference herein. Our business, financial condition, results of operations or prospects could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our common stock could decline and you could lose all or part of your investment. Our actual results could differ materially and adversely from those anticipated in any forward-looking statements in this prospectus as a result of certain factors, including those set forth below. See “Forward-Looking Statements.”

SUMMARY OF THE RISK FACTORS

Risks Related to This Offering

- the negative impact on the market price of our common stock if a substantial number of shares of common stock are sold in the market following this offering;
- the lack of a public market for the pre-funded warrants or the warrants;
- the rights of the holders of pre-funded warrants and the warrants will not be the rights of a common stockholder until they acquire our common stock, except as set forth in the pre-funded warrants and the warrants;
- the warrants are not exercisable until we obtain both Stockholder Approvals and may not have any value;
- our broad discretion to determine how to use the funds raised in this offering;
- the volatility in the price of our common stock;
- the return on investment may be limited to the value of our common stock;
- our ability to meet the minimum bid price for continued listing on The Nasdaq Capital Market; and
- our lack of authorized shares to issue upon the exercise of all of the warrants offered hereunder.

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 the ongoing or future SEC investigation or 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;
- the ability of our review of strategic alternatives and financing strategy to result in a transaction satisfactory to our stockholders or any change at all;

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- our pursuit of strategic alternatives or financing transactions' consumption of time and attention of management and capital resources;
- 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.

RISK FACTORS

Risks Related to This Offering

A substantial number of shares of common stock may be sold in the market following this offering, which may depress the market price for our common stock.

Sales of a substantial number of shares of our common stock in the public market following this offering could cause the market price of our common stock to decline. A substantial majority of the outstanding shares of our common stock are, and the shares of common stock offered hereby or issuable upon exercise of the pre-funded warrants and, after the Stockholder Approvals, the warrants offered hereby will be, freely tradable without restriction or further registration under the Securities Act. In addition, because the pre-funded warrants and warrants are exercisable into our common stock, volatility or a reduction in the market price of our common stock could have an adverse effect on the market price of the pre-funded warrants and warrants.

There is no public market for the pre-funded warrants or the warrants being offered in this offering.

There is no established public trading market for the pre-funded warrants or the warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the pre-funded warrants or warrants on any national securities exchange or other nationally recognized trading system, including The Nasdaq Capital Market. Without an active market, the liquidity of the pre-funded warrants and the warrants will be extremely limited.

Holders of our pre-funded warrants and the warrants will have no rights as a common stockholder until they acquire our common stock, except as set forth in the pre-funded warrants and the warrants.

Until you acquire shares of our common stock upon exercise of the pre-funded warrants or the warrants, you will have no rights with respect to shares of common stock issuable upon exercise of the pre-funded warrants or the warrants, except as set forth in the pre-funded warrants and warrants. Upon exercise of your pre-funded warrants or warrants, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

The warrants offered by this prospectus are not exercisable until we obtain both Stockholder Approvals and may not have any value.

The warrants offered by this prospectus will be exercisable only after we receive Stockholder Approvals for both (i) a Capital Event and (ii) the potential issuance of shares of common stock upon exercise of the warrants for the purposes of the Nasdaq Listing Rule. We are seeking Stockholder Approval for a Capital Event because we do not have enough shares of common stock currently authorized under our articles of incorporation to issue shares of common stock upon the exercise of all of the warrants that we are issuing in this offering. We currently have 100,000,000 shares of common stock authorized under our articles of incorporation, and, as of October 5, 2022, 35,392,550 shares were outstanding and 75,868,740 shares will be outstanding after giving effect to this offering (assuming exercise in full of the pre-funded warrants issued in this offering). We are also seeking Stockholder Approval for the potential issuance of shares of common stock upon exercise of the warrants as required by the Nasdaq Listing Rule. Each warrant has an initial exercise price of \$ per whole share, and will be exercisable following receipt of both Stockholder Approvals and commencing on the Stockholder Approvals Date for a term of five years from the Stockholder Approvals Date.

Promptly after this offering, the Company intends to call two special meetings to obtain the Stockholder Approvals, and engage a proxy solicitation firm to solicit proxies in connection with obtaining such Stockholder Approvals. Investors who participate in this offering and acquire shares of common stock will be able to vote at the special meeting to obtain Stockholder Approval for a Capital Event if such investors hold their shares on the record date for such meeting. Pursuant to Nasdaq rules, investors who participate in this offering will not be able to vote at the special meeting to obtain Stockholder Approval for the potential issuance of shares of common stock upon exercise of the warrants in accordance with the Nasdaq Listing Rule. There is no assurance we will be able to obtain the Stockholder Approvals in which case the warrant holders would not be able to exercise their warrants and the warrants would have little or no value. If we do not obtain the Stockholder Approvals, we will be obligated to continue to hold meetings of our stockholders to solicit approval until the Capital Event and the potential issuance of shares of common stock upon exercise of the warrants for purposes of the Nasdaq

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Listing Rule are approved. If our stockholders do not approve both a Capital Event and the potential issuance of shares of our common stock upon exercise of the warrants for purposes of the Nasdaq Listing Rule, the warrants will not become exercisable. We will incur substantial cost, and management will devote substantial time and attention, in attempting to obtain the Stockholder Approvals.

There can be no assurance that the market price of our common stock will ever exceed the exercise price of the warrants. In the event that our common stock price does not exceed the exercise price of the warrants during the term of the warrants, the warrants may not have any value.

We have broad discretion to determine how to use the funds raised in this offering, and may use them in ways that may not enhance our operating results or the price of our common stock, pre-funded warrants or warrants.

Our management will have broad discretion over the use of proceeds from this offering, and we could spend the proceeds from this offering in ways our stockholders may not agree with or that do not yield a favorable return, if at all. We intend to use the net proceeds to repay amounts owed to the Lender under the Credit Agreement. However, our use of these proceeds may differ substantially from our current plans. If we do not invest or apply the proceeds of this offering in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline.

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

The price of our common stock has been volatile, subject to rapid and substantial decreases in stock price, and may be volatile in the future. By way of example, since September 1, 2021, our common stock has traded at a low of \$0.33 and a high of \$2.71. As a result of this volatility, investors could experience losses on their investment in our common stock.

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

Overall, the stock market has experienced price and volume fluctuations that have affected the market price of our common stock, as well as the stock of many other similar companies in our industry and of comparable size. Such price fluctuations often can be unrelated to the operating performance of the specific companies whose stock is affected.

Since the stock price of our common stock has fluctuated in the past, has been recently volatile and may be volatile in the future, investors in our common stock could incur substantial losses. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects. We are currently subject to securities class-action and stockholder derivative litigation as described in "Prospectus Summary – Recent Developments – Litigation" above and in Part II, Item 1. Legal Proceedings in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 and the information set forth under "Note 6 – Commitments, Contingencies And Concentrations – Litigation" to the consolidated financial statements included in such Quarterly Report on Form 10-Q. There can be no guarantee that our stock price will remain at current levels.

Securities of certain companies have recently experienced significant and extreme volatility in stock price due to short sellers of shares of common stock, known as a "short squeeze." Short squeezes have caused extreme volatility in the stock prices of those companies and in the market generally 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 your common stock. Sharp rises in a company's stock price may force traders with a short position to buy the stock to avoid even greater losses. Many investors who have purchased shares in those companies at an inflated rate face the risk of losing a significant portion of their original investment as the price per share has declined steadily as

interest in those stocks have abated. There can be no assurance that we will not in the future be a target of a short squeeze, and stockholders may lose a significant portion or all of their investments if they purchase our shares at a rate that is significantly disconnected from our underlying value.

We have not paid dividends in the past and do not expect to pay dividends in the future, and, as a result, any return on investment may be limited to the value of our common stock.

We have never paid dividends and do not anticipate paying dividends in the foreseeable future. The payment of dividends will depend on our earnings, capital requirements, financial condition, prospects and other factors our board of directors may deem relevant. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if our stock price appreciates and you sell our common stock thereafter.

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

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

After giving effect to this offering, we will have issued almost all of our authorized shares of common stock.

We currently have 100,000,000 shares of common stock authorized under our articles of incorporation, and, as of October 5, 2022, a total of 35,392,550 shares were outstanding, and 75,868,740 shares will be outstanding after giving effect to this offering (assuming exercise in full of the pre-funded warrants). As a result, after giving effect to this offering, we will have issued (or reserved for issuance) almost all of our authorized shares and will need Stockholder Approval to implement a Capital Event. Our articles of incorporation and Nevada law currently require the approval of stockholders holding not less than a majority of all outstanding shares of capital stock entitled to vote in order to approve an increase in our authorized shares of common stock or a reverse stock split. There are no assurances that Stockholder Approval of a Capital Event will be obtained, in which event we will be unable to raise additional capital through the issuance of shares of common stock to fund our future operations.

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

Even if we are able to obtain any such EUA or CLIA waiver, our product may not gain broad market acceptance among physicians, healthcare 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, DPP Respiratory Panel or DPP HIV-Syphilis test are not successfully commercialized as expected, we may not be able to generate sufficient revenue to become profitable. Any failure of one of these products to be successfully commercialized in the United States may have a material adverse effect on our business, operating result financial condition and cash flows, and could result in a substantial decline in the price of our common stock. In addition, the production and widely administered use of efficacious vaccines for COVID-19 may reduce the demand for diagnostic tests and, as a result, the COVID-19 diagnostic testing market may not develop or substantially grow. Our future success is substantially dependent on the manner in which the market for diagnostic testing develops and grows. If the market develops in a manner that does not facilitate demand for our products, or fails to develop or grow in the manner in which we expect or at all, our business, financial condition, results of operations and cash flows may be negatively affected.

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

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 the Biomedical Advanced Research and Development Authority (“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.

We face risks related to an ongoing SEC investigation.

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

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

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

We may incur additional costs in connection with the defense or settlement of existing and any future stockholder litigation, including the securities class-action and stockholder derivative lawsuits that have been brought against us. See “Prospectus Summary – Recent Developments – Litigation” above and “Part II, Item 1. Legal Proceedings” in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 and the information set forth under “Note 6 – Commitments, Contingencies And Concentrations – Litigation” to the consolidated financial statements included in such Quarterly Report on Form 10-Q for additional information regarding certain existing lawsuits. These lawsuits or other future litigation may adversely affect the ability of our technical and management personnel, and our directors, to perform their normal responsibilities. We could incur significant costs in connection with any such litigation, including costs associated with the indemnification of obligations to our directors, officers and other employees, as well as to third parties such as underwriters of our public offerings. We have recently engaged in settlement discussions with respect to our putative stockholder securities class action litigation and putative stockholder derivative litigation. (See “Prospectus Summary – Recent Developments – Litigation” above). We expect to continue working toward resolving these matters, but there can be no assurance that we will be able to do so, or that we will be able to do so on the terms currently being discussed.

We 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 51% of our total revenues in 2021 and 25% of our total revenues in 2020. We had another customer that accounted for 10% of our total revenues in 2021, and a third customer that accounted for 12% of our revenue in 2020. To the extent that Bio-Manguinhos or any other large customer fails to meet its purchase commitments, changes its ordering patterns or business strategy, or otherwise reduces its purchases or stops purchasing our products, or if we experience difficulty in meeting the demand by these customers for our products, our revenues and results of operations could be adversely affected.

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

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

We may face product liability claims for injuries.

The testing, manufacturing and marketing of medical diagnostic products involves an inherent risk of product liability claims. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease sales of our products. We cannot be sure that we will not

incur liabilities in excess of the policy limits of our existing product liability insurance coverage or that we will be able to continue to obtain adequate product liability insurance coverage in the future at an acceptable cost, or at all. In addition, a defect in the design or manufacture of our products could have a material adverse effect on our reputation in the industry and subject us to claims of liability for injury and otherwise. Any substantial underinsured loss resulting from such a claim could have a material adverse effect on our profitability, and the damage to our reputation in the industry could have a material adverse effect on our business.

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

Rapid point-of-care tests are beneficial because, among other things, they can be administered by healthcare providers in their own facilities or used by consumers at home without sending samples to central laboratories. 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 “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations—Going Concern Considerations” and “—Liquidity and Capital Resources,” in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, 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 date of the issuance of the most recent unaudited condensed consolidated financial statements incorporated by reference into this prospectus. 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 date of issuance of the most recent unaudited condensed consolidated financial statements incorporated by reference into this registration statement.

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.

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As of June 30, 2022 we had a loan balance, net of unamortized discounts and debt issuance costs, of \$19.1 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 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 may be forced to pursue a reorganization 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. There can be no assurance that we will be able to regain compliance with the Bid Price Requirement. Our inability to regain compliance with the Bid Price Requirement would, and the existence of the pending deficiency letter could, materially impair our ability to raise capital.

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

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

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The financial statements incorporated by reference into this prospectus 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 the most recent unaudited condensed consolidated financial statements incorporated by reference into this prospectus. As such, the financial statements incorporated by reference into this prospectus do not include any adjustments relating to the recoverability and classification of assets and their carrying amounts, or the amount and classification of liabilities that may result should we be unable to continue as a going concern.

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

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

Our board of directors has previously initiated a review of strategic alternatives, including a potential sale or merger transaction, and of our financing strategy. We have retained Craig-Hallum Capital Group LLC as our financial advisor to assist with this strategic review. This strategic review process is substantially complete, and we are not currently in active discussions regarding any such strategic transaction. Even if a sale, merger or financing transaction were to be consummated, it may not return any value to holders of our common stock. Regardless of whether we execute a sale, merger or financing transaction, the adverse pressures negatively impacting our business that we have experienced may continue or intensify, and we will likely continue to face all of the risks we currently face, including the risk that we may not be able to continue as a going concern.

The pursuit of strategic alternatives or financing transactions may consume a substantial portion of the time and attention of our management and require additional capital resources and may be disruptive to our business, which could have a material adverse effect on our business, financial condition and results of operations.

We are not able to predict with certainty the amount of time and resources necessary to successfully identify, pursue and execute any strategic transaction or obtain additional financing, if we are able to do so at all. The diversion of management's attention may materially adversely affect the conduct of our business, and, as a result, our financial condition and results of operations. The additional expense we incur in connection with our review of strategic alternatives and pursuit of strategic or financing transactions may materially adversely impact our financial condition and partially offset the value of any strategic transaction we execute or additional financing we obtain. Our recent evaluation of strategic alternatives is substantially complete, and we have not identified a transaction that we are able to determine is in the best interests of the Company and its stockholders.

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

We incurred an operating loss every year from 2014 through 2021. Under our operating plans, we have made, and plan to continue to make, significant investments in our production capacity, including in expanding facilities and automating manufacturing, and in our sales and marketing, regulatory approval, and research and development activities. Our ability to achieve profitability and generate cash flow in the future will depend on our ability to increase sales of our existing products and to successfully introduce new and enhanced products into the marketplace, all while controlling and managing our expenses consistent with our operating plan.

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

- We could reduce the level, or otherwise delay the timing, of the anticipated investments in our production capacity and other activities, which would likely curtail or delay the growth in our business

contemplated by our operating plan and could impair or defer our ability to achieve profitability and generate cash flow. Moreover, if we were to further reduce the number of our personnel, there can be no assurance that we would be able, when desirable, to successfully rehire or rebuild our workforce.

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

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

Our financial results may fluctuate.

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

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

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

On September 3, 2019, we and certain of our subsidiaries, as guarantors, entered into the Credit Agreement, under which we received a \$20.0 million senior secured term loan credit facility that was drawn in full on September 4, 2019. The Credit Agreement is secured by a first priority, perfected lien on substantially all of our property and assets, including our equity interests in our subsidiaries. See “Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Sources of Funds—Credit Agreement” in our Annual Report on Form 10-K for year ended December 31, 2021 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022.

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, which must be held in one or more accounts subject to the first priority perfected security interests of the Lender under the Credit Agreement, and (b) achieve specified minimum total revenue requirements for the twelve months preceding each quarter end. The minimum total revenue requirements range from \$45.6 million for the twelve months ending September 30, 2022 to \$50.1 million for the twelve months ending June 30, 2023. 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;

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- sell or otherwise dispose of assets, including capital stock of subsidiaries;
- enter into agreements that restrict dividends from subsidiaries;
- enter into mergers or consolidations; and
- enter into transactions with affiliates.

A breach of the minimum total revenue covenant or any other covenant in the Credit Agreement would result in a default under the Credit Agreement. Upon an event of default under the Credit Agreement, the Lender could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable and the applicable margin would increase by 4% per annum during the continuance of any event of default. In such an event, there can be no assurance that we would have sufficient liquidity to fund payment of the amounts that would be due under the Credit Agreement or that, if such liquidity were not available, we would be successful in raising additional capital on acceptable terms, or at all, or in completing any other endeavor to continue to be financially viable and continue as a going concern. Our inability to raise additional capital on acceptable terms in the near future, whether for purposes of funding payments required under the Credit Agreement or providing additional liquidity needed for our operations, could have a material adverse effect on our business, prospects, results of operations, liquidity and financial condition. If we are unable to repay amounts owed under the Credit Agreement or to raise such additional capital, we may be forced to pursue a reorganization 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 \$30.9 million in cash in 2021 and \$5.9 million through June 30, 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 may be forced to pursue a reorganization 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; (8) business acquisition; and (9) research and development costs.

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

Risks Related to Intellectual Property

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

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

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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 subsequently 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 effect on our financial condition and results of operations.

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.

As of October 5, 2022, we have sold 14,772,190 shares of common stock, for gross proceeds of \$44.9 million and net proceeds, after giving effect to commissions and other transaction costs, of \$43.4 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 \$4.1 million and net proceeds of \$4.0 million since June 30, 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 our Annual Report on Form 10-K and “Recent Development—*Sale of Common Stock under the ATM Agreement*” above.

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If 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 \$15.1 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. 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.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately \$15.3 million, assuming a public offering price of \$0.42 per share of common stock and accompanying one and one-quarter (1.25) warrants, which was the last reported sale price per share of our common stock on The Nasdaq Capital Market on October 5, 2022, after deducting underwriting discounts and commissions and estimated offering expenses payable by us and assuming no sale of pre-funded warrants in this offering and no exercise of the warrants being issued in this offering.

We intend to use the net proceeds from this offering to repay amounts owed to the Lender pursuant to our Credit Agreement. Principal installments in the amount of \$300,000 are payable on the last day of each of the eleven months from September 2022 through July 2023, and all remaining principal is payable at maturity on September 3, 2023. 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. In the event the net proceeds from this offering increase or decrease, this will result in a corresponding increase or decrease in the amount we repay the Lender pursuant to the Credit Agreement.

Pending the application of the net proceeds, we expect to invest the proceeds in investment-grade, interest-bearing instruments or other securities.

CAPITALIZATION

The following table sets forth our capitalization as of June 30, 2022:

- on an actual basis; and
- on a pro forma basis to give effect to the sale of 40,476,190 shares of common stock and accompanying warrants to purchase up to 50,595,238 shares of common stock in this offering, at an assumed public offering price of \$0.42 per share of common stock and accompanying warrants, which was the last reported sale price of our common stock on The Nasdaq Capital Market on October 5, 2022, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, assuming no exercise of the warrants being issued in this offering, and after giving effect to the repayment of amounts owed under the Credit Agreement as discussed on page 44 of this prospectus in “Use of Proceeds.”

Our capitalization following the closing of this offering will be adjusted based on the actual public offering price and other terms of this offering determined at pricing. You should read this information together with our financial statements incorporated by reference into this prospectus and the related notes and the sections entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K for the year ended December 31, 2021 and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2022 and June 30, 2022, each as incorporated by reference in this prospectus.

	As of June 30, 2022	
	Actual	Pro Forma ⁽¹⁾
	(in thousands, except share data)	
Cash and cash equivalents	\$ 22,837	\$ 18,137
Warrant liability	—	16,494
Current portion of long-term debt	3,000	—
Finance lease liabilities	74	74
Long-term finance lease liabilities	116	116
Long-term debt, net	16,127	—
Stockholders’ equity		
Preferred stock - 10,000,000 shares authorized; none outstanding	—	—
Common Stock, \$0.01 par value per share; 100,000,000 shares authorized, actual and pro forma; 30,224,606 shares issued and outstanding at June 30, 2022 actual and 70,700,796 shares issued and outstanding pro forma	303	707
Additional paid-in capital	167,041	165,442
Accumulated deficit	(146,747)	(145,862)
Treasury Stock, 48.057 shares at cost, at June 30, 2022, actual and pro forma	(207)	(207)
Accumulated other comprehensive loss	(486)	(486)
Total stockholders’ equity	\$ 19,905	\$ 19,594
Total liabilities and stockholders’ equity	\$ 56,056	\$ 51,356

- (1) Each \$0.10 increase in the assumed public offering price per share of common stock and accompanying warrants of \$0.42, which was the last reported sale price of our common stock on The Nasdaq Capital Market on October 5, 2022, would increase the pro forma amount of each of cash and cash equivalents and stockholders’ equity by approximately \$3.8 and \$0.1 million, respectively, assuming that the number of share of common stock and accompanying warrants offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each \$0.10 decrease in the assumed public offering price per share of common stock and accompanying warrants of \$0.42, which was the last reported sale price of our common stock on The Nasdaq Capital Market on October 5, 2022, would decrease the pro forma amount of each of cash and cash equivalents and stockholders’ equity by approximately \$3.8 and \$0.2 million, respectively, assuming that the number of share of common stock and accompanying warrants offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 7,500,000 shares and accompanying warrants in the number of shares and

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accompanying warrants offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma amount of each of cash and cash equivalents and stockholders' equity by approximately \$2.9 million and \$0.1 million respectively, assuming no change in the assumed public offering price and after deducting estimated underwriting discounts and commissions and estimated expenses payable by us.

The number of shares in the table above does not include:

- 3,776,436 shares issuable upon the exercise of options with a weighted-average exercise price of \$2.21 per share;
- 1,759,307 shares underlying restricted and performance stock units; and
- 43,963 shares reserved for future issuance under our 2019 Omnibus Incentive Plan.

The number of shares in the table above also assumes no sale of pre-funded warrants in this offering and no exercise of the warrants in this offering.

DILUTION

If you invest in our common stock and accompanying warrants in this offering, your ownership interest will be diluted to the extent of the difference between the public offering price per share of common stock and accompanying warrants, assuming no value is attributable to the warrants, and our as adjusted net tangible book value per share of common stock after this offering.

As of June 30, 2022, our net tangible book value was \$19.9 million, or \$0.66 per share. Our net tangible book value per share represents the amount of our total tangible assets less total liabilities, divided by the total number of shares of common stock outstanding as of June 30, 2022.

After giving further effect to our sale in this offering of 40,476,190 shares of common stock and accompanying warrants at an assumed public offering price per share of common stock and accompanying warrants of \$0.42, which was the last reported sale price of common stock on The Nasdaq Capital Market on October 5, 2022, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, and without giving effect to the exercise of the warrants issued in this offering, our as adjusted net tangible book value as of June 30, 2022 would have been \$19.6 million, or \$0.28 per share. This represents an immediate decrease in net tangible book value of \$0.38 per share to our existing stockholders and dilution of (\$0.14) to investors purchasing shares of common stock and accompanying warrants in this offering.

The following table illustrates this dilution on a per share basis:

Assumed public offering price per share of common stock and accompanying warrants	\$ 0.42
Net tangible book value per share as of June 30, 2022	0.66
Pro Forma decrease in net tangible book value per share attributable to investors purchasing in this offering	(0.38)
As adjusted net tangible book value per share as of June 30, 2022 after this offering	\$ 0.28
Dilution per share to new investors purchasing in this offering	\$(0.14)

Each \$0.10 increase (decrease) in the assumed public offering price of \$0.42 per share and accompanying warrants, which is the last reported sale price of our common stock on The Nasdaq Capital Market on October 5, 2022, would have no impact on our as adjusted net tangible book value per share and dilution to new investors would increase (decrease) by \$(0.10) and \$0.10 per share, respectively, assuming that the number of shares and accompanying warrants offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated expenses payable by us.

An increase of 7,500,000 shares and accompanying warrants in the number of shares and accompanying warrants offered by us, as set forth on the cover page of this prospectus, would decrease our as adjusted net tangible book value per share by \$0.03 per share and decrease dilution to new investors by \$0.03 per share and a decrease of 7,500,000 shares and accompanying warrants in the number of shares and accompanying warrants offered by us, as set forth on the cover page of this prospectus, would increase our as adjusted net tangible book value per share by \$0.03 per share and increase dilution to new investors by \$0.03 per share, assuming no change in the assumed public offering price and after deducting the estimated underwriting discounts and commissions and estimated expenses payable by us.

The number of shares in the table above are based on 30,224,606 shares of our common stock outstanding as of June 30, 2022 and does not include:

- 3,776,436 shares issuable upon the exercise of options with a weighted-average exercise price of \$2.21 per share;
- 1,759,307 shares underlying restricted and performance stock units; and
- 43,963 shares reserved for future issuance under our 2019 Omnibus Incentive Plan.

The number of shares in the table above also assumes no sale of pre-funded warrants in this offering and no exercise of the warrants in this offering.

DESCRIPTION OF SECURITIES

The following summary description of our common stock is based on the provisions of our Articles of Incorporation, as amended, which we refer to as our articles of incorporation or charter; our Amended and Restated Bylaws, which we refer to as our bylaws, and the applicable provisions of Nevada law. This description may not contain all of the information that is important to you and is subject to, and is qualified in its entirety by reference to, our charter, our bylaws and the applicable provisions of Nevada law. For information on how to obtain copies of our articles of incorporation and by-laws, see “Where You Can Find More Information.”

We are offering 40,476,190 shares of common stock, together with warrants to purchase up to 50,595,238 shares of common stock. Each warrant has an initial exercise price of \$ per whole share. The shares of common stock and the warrants are immediately separable and will be issued separately, but must initially be purchased together in this offering. The warrants will not be exercisable until we obtain Stockholder Approvals to (i) effect a Capital Event in an amount sufficient to permit exercise in full of the warrants and (ii) potentially issue shares of common stock upon exercise of the warrants for purposes of the Nasdaq Listing Rule. In the event we never obtain the Stockholder Approvals, the warrants will not become exercisable and will have no value. We are also offering pre-funded warrants to purchase shares of common stock to those purchasers whose purchase of shares of common stock in this offering would result in the purchaser beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering in lieu of the shares of our common stock that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%). Each pre-funded warrant will be exercisable for one share of common stock at an exercise price of \$0.01 per share. Each pre-funded warrant is being issued together with the same warrants described above being issued with each share common stock. The pre-funded warrants and warrants are immediately separable and will be issued separately in this offering, but must initially be purchased together in this offering. For each pre-funded warrant and the accompanying warrants we sell, the number of shares of common stock and the accompanying warrants we are offering will be decreased on a one-for-one basis.

Authorized and Outstanding Capital Stock

As of October 5, 2022, our authorized capital stock consisted of 100,000,000 shares of common stock, \$0.01 par value per share, and 10,000,000 shares of preferred stock, \$0.01 par value per share.

The following summary describes our capital stock, including material provisions of our charter, our bylaws and Nevada law. Because the following is only a summary, it does not contain all of the information that may be important to you. For a complete description, you should refer to our charter and bylaws, copies of which are incorporated by reference as exhibits to the registration statement of which this prospectus is a part.

Common Stock

As of October 5, 2022, there were outstanding (a) 35,392,550 shares of common stock held by approximately 113 stockholders of record, (b) options exercisable, upon vesting, to acquire 3,674,045 shares of common stock and (c) 1,722,952 shares of common stock underlying restricted and performance stock units. The actual number of stockholders is greater than the number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

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

Holders of common stock are entitled to receive dividends as may be legally declared from time to time by the board of directors, and, in the event of our liquidation, dissolution or winding up, to share ratably in all assets remaining after payment of liabilities and amounts owed with respect to any preferred stock or other senior securities.

Declaration of dividends on common stock is subject to the discretion of the board of directors and will depend upon a number of factors, including our future earnings, our capital requirements, our financial condition, and any restrictions imposed by our debt instruments or senior securities. We have not declared dividends on common stock in the past, and we currently anticipate that retained earnings, if any, in the future will be applied to our expansion and development rather than the payment of dividends.

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

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

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

The transfer agent and registrar for the common stock is Action Stock Transfer Corp.

The common stock is listed on The Nasdaq Capital Market under the symbol “CEMI”.

Preferred Stock

Under the terms of our charter, the board of directors is authorized to issue up to 10,000,000 shares of preferred stock in one or more series, to establish the number of shares to be included in each such series, and to fix the designation, powers, preferences and rights of such shares and any qualifications, limitations or restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and other provisions, any or all of which may be greater than the rights of common stock. The issuance of preferred stock with voting and conversion rights may adversely affect the voting power of the holders of common stock, including the loss of voting control to others, and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. No shares of preferred stock are currently outstanding.

Options and Other Equity Awards

As of October 5, 2022, 46,875 stock options were outstanding under the 2014 Stock Incentive Plan, or 2014 Plan. No further awards will be made under the 2014 Plan. As of October 5, 2022, stock options and other equity awards to purchase or acquire an aggregate of 4,811,545 shares of common stock were outstanding under our 2019 Omnibus Incentive Plan, or 2019 Plan, and (ii) 89,030 shares remained available for future issuance under the 2019 Plan.

Pre-Funded Warrants to be Issued as Part of this Offering

General

The pre-funded warrants offered in this offering will be issued in the form of pre-funded warrant filed as an exhibit to the registration statement of which this prospectus is a part. You should review a copy of the form of pre-funded warrant for a complete description of the terms and conditions applicable to the pre-funded warrants. The following is a brief summary of the pre-funded warrant and is subject in all respects to the provisions contained in the form of pre-funded warrant. Each pre-funded warrant will be issued in certificated form, and we do not plan to list the pre-funded warrants on The Nasdaq Capital Market, any other national securities exchange or any other nationally recognized trading system.

Duration and Exercise Price

Each pre-funded warrant represents the right to purchase one share of common stock at an exercise price per share equal to \$0.01, subject to adjustment as described below. Each pre-funded warrant will be immediately exercisable and may be exercised at any time until the pre-funded warrants are exercised in full. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The pre-funded warrants will be issued separately from the accompanying warrants, and may be transferred separately immediately thereafter.

Exercisability

The pre-funded warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). Purchasers of the

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pre-funded warrants in this offering may elect to deliver their exercise notice following the pricing of the offering and prior to the issuance of the pre-funded warrants at closing to have their pre-funded warrants exercised immediately upon issuance and receive shares of common stock underlying the pre-funded warrants upon closing of this offering. A holder (together with its affiliates) may not exercise any portion of the pre-funded warrant to the extent that the holder would own more than 4.99% (or, upon election by a holder prior to the issuance of any pre-funded warrants, 9.99%) of the outstanding common stock immediately after exercise, except that, upon notice from the holder to us, the holder may increase or decrease the amount of ownership of outstanding stock after exercising the holder's pre-funded warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants, provided that any increase in the ownership limitation shall not be effective until 61 days following notice to us. Purchasers of pre-funded warrants in this offering may also elect prior to the issuance of the pre-funded warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock. No fractional shares of common stock will be issued in connection with the exercise of a pre-funded warrant. In lieu of fractional shares, we will round up to the next whole share.

Cashless Exercise

The pre-funded warrants may also be exercised, in whole or in part, at such time by means of a "cashless exercise." In lieu of making the cash payment upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the number of shares of pre-funded warrants determined according to a formula set forth in the pre-funded warrants.

Transferability

Subject to applicable laws, a pre-funded warrant may be transferred at the option of the holder upon surrender of the pre-funded warrant to us together with the appropriate instruments of transfer.

Exchange Listing

There is no trading market available for the pre-funded warrants on any securities exchange or nationally recognized trading system. We do not intend to list the pre-funded warrants on any securities exchange or nationally recognized trading system.

Fractional Share; Right as a Stockholder

No fractional shares of common stock will be issued in connection with the exercise of a pre-funded warrant. As to any fraction of a share which the holder would otherwise be entitled to purchase upon such exercise, we will round up to the next whole share or pay a cash adjustment equal to such fraction multiplied by the exercise price to the holder. Prior to the exercise of any pre-funded warrants to purchase common stock, holders of the pre-funded warrants will not have any of the rights of holders of the common stock purchasable upon exercise, including the right to vote, except as set forth therein.

Adjustments; Fundamental Transaction.

The exercise price and the number of shares underlying the pre-funded warrants are subject to appropriate adjustment in the event of stock splits, stock dividends on our common stock, stock combinations or similar events affecting our common stock. In addition, in the event we consummate a fundamental transaction, as described in the pre-funded warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of more than 50% of the voting power represented by our outstanding common stock, the holders of the pre-funded warrants will be entitled to receive upon exercise of the pre-funded warrants the number of shares of common stock for which the pre-funded warrant is exercisable immediately prior to such fundamental transaction. Any successor to us or surviving entity will assume the obligations under the pre-funded warrants.

Amendment and Waiver

Amendments and waivers of the terms of the pre-funded warrants require the written consent of the holder of such pre-funded warrant and us.

Warrants to Purchase Shares of Common Stock to be Issued as Part of this Offering

General

The warrants offered in this offering will be issued in the form of warrant filed as an exhibit to the registration statement of which this prospectus is a part. The warrants will not be exercisable until we obtain Stockholder Approvals to (i) effect a Capital Event in an amount sufficient to permit exercise in full of the warrants and (ii) potentially issue shares of common stock upon exercise of the warrants for purposes of the Nasdaq Listing Rule. You should review a copy of the form of warrant for a complete description of the terms and conditions applicable to the warrants. The following is a brief summary of the warrant and is subject in all respects to the provisions contained in the form of warrant. Pursuant to a warrant agency agreement between us and Action Stock Transfer Corp., as warrant agent, or a successor warrant agent, the warrants will be issued in book-entry form and shall be initially represented by one or more global warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC. You should review a copy of the warrant agency agreement, which is filed as an exhibit to the registration statement of which this prospectus is a part, for complete description of the terms and conditions applicable to the warrants. We do not plan to list the warrants on The Nasdaq Capital Market, any other national securities exchange or any other nationally recognized trading system.

Duration and Exercise Price

The warrants will be issued in book-entry form. Each warrant represents the right to purchase one share of common stock at an initial exercise price equal to \$ _____ per whole share, subject to adjustment and limitations as described below. The warrants will not be exercisable until we obtain Stockholder Approvals to (i) effect a Capital Event in an amount sufficient to permit exercise in full of the warrants and (ii) potentially issue shares of common stock upon exercise of the warrants for purposes of the Nasdaq Listing Rule. After the Stockholder Approvals are obtained, each warrant may be exercised through and including the close of business on the fifth anniversary of the date of the Stockholder Approvals Date.

Exercisability

After obtaining the Stockholder Approvals, the warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to the warrant agent a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). No fractional shares of common stock will be issued in connection with the exercise of a warrant. In lieu of fractional shares, we will round up to the next whole share. A holder (together with its affiliates) may not exercise any portion of the warrant to the extent that the holder would own more than 4.99% (or, upon election by a holder prior to the issuance of any warrants, 9.99%) of the outstanding common stock immediately after exercise, except that upon notice from the holder to us, the holder may increase or decrease the amount of ownership of outstanding stock after exercising the holder's warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants, provided that any increase in the ownership limitation shall not be effective until 61 days following notice to us. Purchasers of warrants in this offering may also elect prior to the issuance of the warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock.

Cashless Exercise

If at the time of the a holder exercises its warrant, a registration statement registering the issuance of common stock underlying the warrants under the Securities Act is not then effective or available, in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the number of shares of warrants determined according to a formula set forth in the warrants.

Transferability

Subject to applicable laws, a warrant may be transferred at the option of the holder upon surrender of the warrant to us together with the appropriate instruments of transfer.

Exchange Listing

There is no trading market available for the warrants on any securities exchange or nationally recognized trading system. We do not intend to list the warrants on any securities exchange or nationally recognized trading system.

Fractional Shares; Rights as a Stockholder

No fractional shares of common stock will be issued in connection with the exercise of a warrant. As to any fraction of a share which the holder would otherwise be entitled to purchase upon such exercise, we will round up to the next whole share or pay a cash adjustment equal to such fraction multiplied by the exercise price to the holder. A warrant may be transferred by a holder, upon surrender of the warrant, properly endorsed (by the holder executing an assignment in the form attached to the warrant). Prior to the exercise of any warrants to purchase common stock, holders of the warrants will not have any of the rights of holders of the common stock purchasable upon exercise, including the right to vote, except as set forth therein.

Adjustments; Fundamental Transaction

If we issue or sell any shares of common stock or securities that are convertible into shares of common stock in the future at a price per share less than the exercise price of the warrants then in effect, the exercise price will be adjusted to that lower price, subject to customary exceptions, and the number of shares issuable upon exercise of the warrants will be proportionally increased. The warrants also contain a one-time reset of the exercise price to a price equal to the lower of the exercise price then in effect and the lowest five day volume weighted average price of the common stock for the five trading days immediately after the effective date of a reverse stock split. In connection with such a reset of the exercise price following a reverse stock split, the number of shares issuable upon exercise of the warrants will also be proportionally increased. The exercise price and the number of shares underlying the warrants are also subject to appropriate adjustment in the event of stock splits, stock dividends on our common stock, stock combinations or similar events affecting our common stock.

In addition, in the event we consummate a fundamental transaction, as described in the warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of more than 50% of the voting power represented by our outstanding common stock, the holders of the warrants will be entitled to receive upon exercise of the warrants the number of shares of common stock for which the warrant is exercisable immediately prior to such fundamental transaction. Any successor to us or surviving entity will assume the obligations under the warrants. Notwithstanding the foregoing, in the event of a fundamental transaction, the holders of the warrants have the right to require us or a successor entity to redeem the warrants for cash in the amount of the Black-Scholes Value (as defined in the warrant) of the unexercised portion of the warrants concurrently with or within 30 days following the consummation of a fundamental transaction. However, in the event of a fundamental transaction which is not in our control, including a fundamental transaction not approved by our board of directors, the holders of the warrants will only be entitled to receive from us or our successor entity, as of the date of consummation of such fundamental transaction the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of the warrant that is being offered and paid to the holders of our common stock in connection with the fundamental transaction, whether that consideration is in the form of cash, stock or any combination of cash and stock, or whether the holders of our common stock are given the choice to receive alternative forms of consideration in connection with the fundamental transaction.

The warrant holders do not have the rights or privileges of holders of common stock and any voting rights until they exercise their warrants and receive shares of common stock, except as set forth in the warrants. After the issuance of shares of common stock upon exercise of the warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

Amendment and Waiver

Amendments and waivers of the terms of the warrants require the written consent of the holders of more than 50% of the warrants then outstanding and us.

Stockholder Approvals

We have agreed to hold two stockholders meetings in order to seek Stockholder Approvals to (i) effect a Capital Event and (ii) potentially issue shares of common stock upon exercise of the warrants in accordance with the Nasdaq Listing Rule. Promptly after this offering, the Company intends to call such meetings and engage a proxy solicitation firm to solicit proxies in connection with obtaining such Stockholder Approvals. Investors who participate in this offering and acquire shares of common stock will be able to vote at the special meeting to obtain Stockholder Approval for a Capital Event if such investors hold their shares on the record date for such meeting. Pursuant to Nasdaq rules, investors who participate in this offering will not be able to vote at the special meeting to obtain Stockholder Approval for the potential issuance of shares of common stock upon exercise of the warrants in accordance with the Nasdaq Listing Rule. In the event that we are unable to obtain such Stockholder Approvals, the warrants will not be exercisable and will have no value.

Nevada Law

Transactions with Interested Persons

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

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

Control Share Acquisition Provisions

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

Combinations with Interested Stockholders

Under Nevada law, except under certain circumstances, a corporation is not permitted to engage in a business combination with any "interested stockholder" for a period of two years following the date such stockholder became an interested stockholder. An "interested stockholder" is a person or entity who owns ten percent or more of the outstanding shares of voting stock. Nevada law permits a corporation to opt out of the application of these business combination provisions by so providing in the charter. We have not opted out of the application of these business combination provisions in our charter.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES

The following discussion describes certain material U.S. federal income tax consequences of the acquisition, ownership and disposition of our common stock, pre-funded warrants and warrants acquired in this offering. This discussion is based on the current provisions of the Internal Revenue Code of 1986, as amended (the “Code”), existing and proposed U.S. Treasury regulations promulgated thereunder, and administrative rulings and court decisions in effect as of the date hereof, all of which are subject to change at any time, possibly with retroactive effect. No ruling has been or will be sought from the Internal Revenue Service (the “IRS”) with respect to the matters discussed below, and there can be no assurance the IRS will not take a contrary position regarding the tax consequences of the acquisition, ownership or disposition of our common stock, pre-funded warrants or warrants, or that any such contrary position would not be sustained by a court.

We assume in this discussion that the shares of our common stock, pre-funded warrants and warrants will be held as capital assets (generally, property held for investment). This discussion does not address all aspects of U.S. federal income taxes, does not discuss the potential application of the Medicare contribution tax or the alternative minimum tax, and does not deal with state or local taxes or U.S. federal gift and estate tax laws, or any non-U.S. tax consequences that may be relevant to holders in light of their particular circumstances. This discussion also does not address the special tax rules applicable to particular holders, such as:

- a bank, insurance company, or other financial institution;
- a tax-exempt entity, organization, or arrangement;
- a government or any agency, instrumentality, or controlled entity thereof;
- a real estate investment trust;
- an S corporation or other pass-through entity (or an investor in an S corporation or other pass-through entity);
- a regulated investment company;
- a “controlled foreign corporation” or a “passive foreign investment company”;
- a dealer or broker in stocks and securities, or currencies;
- a trader in securities that elects mark-to-market treatment or any other holder subject to mark-to-market treatment;
- a holder of our common stock, pre-funded warrants, or warrants that is liable for the alternative minimum tax;
- a holder of our common stock, pre-funded warrants, or warrants that holds such security in a tax-deferred account (such as an individual retirement account or a plan qualifying under Section 401(k) of the Code);
- a holder of our common stock, pre-funded warrants, or warrants that has a functional currency other than the U.S. dollar;
- a holder of our common stock, pre-funded warrants, or warrants that holds such security as part of a hedge, straddle, constructive sale, conversion or other integrated transaction;
- a holder of our common stock, pre-funded warrants, or warrants required to accelerate the recognition of any item of gross income with respect to such security, as a result of such income being recognized on an applicable financial statement;
- a holder of our common stock, pre-funded warrants, or warrants that is a U.S. expatriate or former citizen or long-term resident of the United States;
- a holder of our common stock, pre-funded warrants, or warrants that does not hold such security as a capital asset within the meaning of Section 1221 of the Code (generally, for investment purposes);
- a holder of our common stock, pre-funded warrants, or warrants whose security may constitute “qualified small business stock” under Section 1202 of the Code or “Section 1244 stock” for purposes of Section 1244 of the Code; or
- a holder of our common stock, pre-funded warrants, or warrants that acquired such security in a transaction subject to the gain rollover provisions of Section 1045 of the Code;

In addition, this discussion does not address the tax treatment of partnerships or other pass-through entities or persons who hold our common stock, pre-funded warrants or warrants through partnerships or other entities which are pass-through entities for U.S. federal income tax purposes. A partner in a partnership or other pass-through entity that will hold our common stock, pre-funded warrants or warrants should consult his, her or its own tax advisor regarding the tax consequences of the ownership and disposition of our common stock, pre-funded warrants or warrants through a partnership or other pass-through entity, as applicable.

The discussion of U.S. federal income tax considerations is for information purposes only and is not tax advice. Investors should consult their own tax advisors regarding the U.S. federal, state, local and non-U.S. income and other tax considerations of acquiring, holding and disposing of our common stock, pre-funded warrants and warrants.

For the purposes of this discussion, a “U.S. Holder” means a beneficial owner of our common stock, pre-funded warrants or warrants that is for U.S. federal income tax purposes (a) an individual citizen or resident of the United States, (b) a corporation (or other entity treated as a corporation for U.S. federal income tax purposes), organized in or under the laws of the United States, any state thereof or the District of Columbia, (c) an estate the income of which is includable in gross income for U.S. federal income tax purposes regardless of its source, or (d) a trust if it (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons (within the meaning of Section 7701(a)(30) of the Code) has the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person. A “Non-U.S. Holder” is, for U.S. federal income tax purposes, a beneficial owner of common stock, pre-funded warrants or warrants (other than a partnership or other entity or arrangement classified as a partnership for U.S. federal income tax purposes) that is not a U.S. Holder.

Treatment of Pre-Funded Warrants

Although the U.S. federal income tax characterization of the pre-funded warrants is not free from doubt, we intend to take the position for U.S. federal income tax purposes that a pre-funded warrant is treated as equity and a holder of pre-funded warrants should generally be taxed in the same manner as a holder of common stock as described below. Accordingly, for U.S. federal income tax purposes, no gain or loss should be recognized upon the exercise of a pre-funded warrant (except in the case of a cashless exercise, the treatment of which for U.S. federal income tax purposes is not clear), and upon exercise, the holding period of the share of common stock received should include the holding period of the pre-funded warrant. Similarly, the tax basis of a share of common stock received upon exercise of a pre-funded warrant should include the tax basis of the pre-funded warrant (discussed below) increased by the exercise price of \$0.01. Each holder should consult his, her or its own tax advisor regarding the risks associated with the acquisition of an investment unit pursuant to this offering (including potential alternative characterizations). The balance of this discussion generally assumes that the characterization described above is respected for U.S. federal income tax purposes.

Allocation of Purchase Price to Common Stock, Pre-Funded Warrants and Warrants

For U.S. federal income tax purposes, a holder’s acquisition of the warrants and common stock or pre-funded warrants, as applicable, will be treated as the acquisition of an “investment unit” consisting of one share of common stock (or one pre-funded warrant, as applicable) and one and one-quarter (1.25) warrants to acquire one (1) share of our common stock per warrant, subject to adjustment. The purchase price for each investment unit will be allocated between these two components in proportion to their relative fair market values at the time the investment unit is purchased by the holder. This allocation of the purchase price for each investment unit will establish the holder’s initial tax basis for U.S. federal income tax purposes in the common stock (or pre-funded warrant, as applicable) and the warrants included in each investment unit. The separability of the share of common stock (or pre-funded warrant, as applicable) and the warrants included in each investment unit should not in itself result in the recognition of income or gain for U.S. federal income tax purposes. Each holder should consult his, her or its own tax advisor regarding the allocation of the purchase price for an investment unit.

Tax Considerations Applicable to U.S. Holders

Exercise and Expiration of Warrants

In general, a U.S. Holder will not recognize gain or loss for U.S. federal income tax purposes upon exercise of warrants. The U.S. Holder will take a tax basis in the shares acquired on the exercise of warrants equal to the exercise prices of the warrants, increased by the U.S. Holder’s adjusted tax basis in the warrants exercised (as

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determined pursuant to the rules discussed above). The U.S. Holder's holding period in the shares of our common stock acquired on exercise of the warrants will begin on the date of exercise of the warrants, and will not include any period for which the U.S. Holder held the warrants.

In certain limited circumstances, a U.S. Holder may be permitted to undertake a cashless exercise of warrants into our common stock. Although there is no direct legal authority as to the U.S. federal income tax treatment of an exercise of a warrant on a cashless basis, we intend to take the position that such exercise will not be taxable, either because the exercise is not a gain realization event or because it qualifies as a tax-free recapitalization. In the former case, the holding period of the shares of our common stock received upon exercise of warrant should commence on the day after the warrant are exercised. In the latter case, the holding period of the shares of our common stock received upon exercise of warrant would include the holding period of the exercised warrant. However, our position is not binding on the IRS, and the IRS may treat a cashless exercise of a warrant as a taxable exchange. U.S. Holders are urged to consult their tax advisors as to the consequences of an exercise of a warrant on a cashless basis, including with respect to their holding period and tax basis in the common stock received.

The lapse or expiration of warrants will be treated as if the U.S. Holder sold or exchanged the warrants and recognized a capital loss equal to the U.S. Holder's tax basis in the warrants. The deductibility of capital losses is subject to limitations.

Constructive Dividends on Pre-Funded Warrants and Warrants

We do not expect to pay any cash dividends on our capital stock in the foreseeable future. However, if the exercise price of the pre-funded warrants and warrants is adjusted as a result of certain events affecting our common stock (or in certain circumstances, there is a failure to make adjustments), such adjustments may result in the deemed payment of a taxable dividend to a U.S. Holder. U.S. holders should consult their tax advisors regarding the proper treatment of any adjustments to the exercise price of the pre-funded warrants and warrants.

We are currently required to report the amount of any deemed distributions on our website or to the IRS and to holders not exempt from reporting. The IRS has proposed regulations addressing the amount and timing of deemed distributions, as well as obligations of withholding agents and filing and notice obligations of issuers in respect of such deemed distributions. If adopted as proposed, the regulations would generally provide that (i) the amount of a deemed distribution is the excess of the fair market value of the right to acquire stock immediately after the exercise price adjustment over the fair market value of the right to acquire stock (after the exercise price adjustment) without the adjustment, (ii) the deemed distribution occurs at the earlier of the date the adjustment occurs under the terms of the instrument and the date of the distribution of cash or property that results in the deemed distribution and (iii) we are required to report the amount of any deemed distributions on our website or to the IRS and to all holders (including holders that would otherwise be exempt from reporting). The final regulations will be effective for deemed distributions occurring on or after the date of adoption, but holders and withholding agents may rely on them prior to that date under certain circumstances.

Distributions

We currently anticipate that we will retain all available funds and any future earnings for use in the operation of our business and do not anticipate declaring or paying any cash dividends on our common stock for the foreseeable future. In the event that we do make distributions on our common stock or pre-funded warrants to a U.S. Holder, those distributions generally will constitute dividends for U.S. tax purposes to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Distributions to a U.S. Holder that are not derived from our current or accumulated earnings and profits will constitute a return of capital that is applied against and reduces, but not below zero, the U.S. Holder's adjusted tax basis in our common stock or pre-funded warrant, as applicable, and to the extent in excess of such basis, will be treated as gain realized on the sale or exchange of our common stock or pre-funded warrants, as applicable, as described below under the section titled "*Disposition of Our Common Stock, Pre-Funded Warrants or Warrants*."

Disposition of Our Common Stock, Pre-Funded Warrants or Warrants

Upon a sale or other taxable disposition of our common stock, pre-funded warrants or warrants, a U.S. Holder generally will recognize capital gain or loss in an amount equal to the difference between the amount realized and the U.S. Holder's adjusted tax basis in the applicable common stock, pre-funded warrants or warrants.

Capital gain or loss will constitute long-term capital gain or loss if the U.S. Holder's holding period for the applicable common stock, pre-funded warrant or warrants exceeds one year. The deductibility of capital losses is subject to certain limitations. U.S. Holders who recognize losses with respect to a disposition of our common stock, pre-funded warrants or warrants should consult their own tax advisors regarding the tax treatment of such losses.

Information Reporting and Backup Withholding

Information reporting requirements generally will apply to payments of dividends (including constructive dividends) on our common stock, pre-funded warrants and warrants and to the proceeds of a sale or other disposition of common stock, warrants and pre-funded warrants by a U.S. Holder unless such U.S. Holder is an exempt recipient, such as a corporation. Backup withholding will apply to those payments if the U.S. Holder fails to provide the holder's taxpayer identification number, or certification of exempt status, or if the holder otherwise fails to comply with applicable requirements to establish an exemption. Backup withholding is not an additional tax. Rather, amounts withheld as backup withholding may be credited against a person's U.S. federal income tax liability, and a holder generally may obtain a refund of any excess amounts withheld under the backup withholding rules by timely filing the appropriate claim for refund with the IRS and furnishing any required information.

Tax Considerations Applicable to Non-U.S. Holders

Exercise and Expiration of Warrants

In general, a Non-U.S. Holder will not be subject to U.S. federal income tax on the exercise of the warrants into shares of common stock. As described under "*— U.S. Holders — Exercise and Expiration of Warrants*," the U.S. federal income tax treatment of a cashless exercise of warrants into our common stock is unclear. A Non-U.S. Holder should consult his, her, or its own tax advisor regarding the U.S. federal income tax consequences of a cashless exercise of warrants.

The expiration of warrants will be treated as if the Non-U.S. Holder sold or exchanged the warrants and recognized a capital loss equal to the Non-U.S. Holder's tax basis in the warrants. However, a Non-U.S. Holder will not be able to utilize a loss recognized upon expiration of a warrant against the Non-U.S. Holder's U.S. federal income tax liability unless the loss is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if an income tax treaty applies, is attributable to a permanent establishment or fixed base in the United States) or is treated as a U.S.-source loss and the Non-U.S. Holder is an individual nonresident and present 183 days or more in the taxable year of disposition in the United States and certain other conditions are met.

Certain Adjustments to and Distributions on the Warrants

As described under "*— U.S. Holders — Certain Adjustments to and Distributions on the Warrants*," an adjustment to the warrants could result in a constructive distribution to a Non-U.S. Holder, which would be treated as described under "*Distributions*" below, and the tax treatment of a distribution on a warrant is unclear. Any resulting withholding tax attributable to deemed dividends would be collected from other amounts payable or distributable to the Non-U.S. Holder. Non-U.S. Holders should consult their tax advisors regarding the proper treatment of any adjustments to or distributions on the warrants.

Distributions

As discussed above, we currently anticipate that we will retain all available funds and any future earnings for use in the operation of our business and do not anticipate declaring or paying any cash dividends on our common stock for the foreseeable future. In the event that we do make distributions on our common stock or pre-funded warrants to a Non-U.S. Holder, those distributions generally will be treated as dividends, as return of capital or as gain on the sale or exchange of common stock or pre-funded warrants for U.S. federal income tax purposes as described in "*— U.S. Holders — Distributions*."

Subject to the discussions below under the sections titled "*— Information Reporting and Backup Withholding*" and "*— Foreign Accounts*," any distribution (including constructive distributions) on our common stock or pre-funded warrants that is treated as a dividend paid to a Non-U.S. Holder that is not effectively connected with

the holder's conduct of a trade or business in the United States will generally be subject to withholding tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and the Non-U.S. Holder's country of residence. To obtain a reduced rate of withholding under a treaty, a Non-U.S. Holder generally will be required to provide the applicable withholding agent with a properly executed IRS Form W-8BEN, IRS Form W-8BEN-E or other appropriate form, certifying the Non-U.S. Holder's entitlement to benefits under that treaty. Such form must be provided prior to the payment of dividends and must be updated periodically.

We generally are not required to withhold tax on dividends paid (or constructive dividends deemed paid) to a Non-U.S. Holder that are effectively connected with such holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment or fixed base that the holder maintains in the United States) if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to us. In general, such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular rates applicable to U.S. persons. A corporate Non-U.S. Holder receiving effectively connected dividends may also be subject to an additional "branch profits tax," which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable treaty) on the corporate Non-U.S. Holder's effectively connected earnings and profits, subject to certain adjustments.

Distributions to a Non-U.S. Holder that are not derived from our current or accumulated earnings and profits generally will be treated as a return of capital that will be applied against and reduce (but not below zero) the Non-U.S. Holder's basis in its common stock or pre-funded warrants, as applicable, and to the extent in excess of such basis, will be treated as gain from the sale or exchange of such common stock or pre-funded warrants, as applicable, as described under "— Disposition of Our Common Stock, Pre-Funded Warrants or Warrants" below.

If a Non-U.S. Holder holds stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to such agent. The holder's agent may then be required to provide certification to the applicable withholding agent, either directly or through other intermediaries.

Disposition of Our Common Stock, Pre-Funded Warrants or Warrants

Subject to the discussions below under the sections titled "— Information Reporting and Backup Withholding" and "— Foreign Accounts," a Non-U.S. Holder generally will not be subject to U.S. federal income or withholding tax with respect to gain realized on a sale or other disposition of our common stock, pre-funded warrants or warrants unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business in the United States (and, if required by an applicable income tax treaty between the United States and such Non-U.S. Holder's country of residence, the gain is attributable to a permanent establishment or fixed base maintained by the Non-U.S. Holder in the United States), in which case the Non-U.S. Holder will be taxed on a net income basis at the regular rates and in the manner applicable to U.S. persons, and if the Non-U.S. Holder is a corporation, an additional branch profits tax at a rate of 30%, or a lower rate as may be specified by an applicable income tax treaty, may also apply;
- the Non-U.S. Holder is a nonresident alien present in the United States for 183 days or more in the taxable year of the disposition and certain other requirements are met, in which case the Non-U.S. Holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence) on the net gain derived from the disposition, which may be offset by certain U.S.-source capital losses of the Non-U.S. Holder, if any, provided that the Non-U.S. Holder has timely filed U.S. federal income tax returns reporting those losses; or
- we are, or have been, a "United States real property holding corporation," or USRPHC, for U.S. federal income tax purposes during the five-year period preceding such disposition (or the Non-U.S. Holder's holding period, if shorter). We do not believe that we are or have been a USRPHC and, even if we are or were a USRPHC, dispositions will not be subject to tax for a Non-U.S. Holder that has not held more than 5% of our common stock, actually or constructively, during the five-year period preceding such Non-U.S. Holder's disposition (or the Non-U.S. Holder's holding period, if shorter). Special rules may apply to the determination of the 5% threshold in the case of a holder of warrants.

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See the sections titled “— Information Reporting and Backup Withholding” and “— Foreign Accounts” below for additional information regarding withholding rules that may apply to proceeds of a disposition of our common stock, pre-funded warrants or warrants paid to foreign financial institutions or non-financial foreign entities.

Information Reporting and Backup Withholding

We must report annually to the IRS and to each Non-U.S. Holder the gross amount of the distributions (including constructive distributions) on our common stock, pre-funded warrants or warrants paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. Holders may have to comply with specific certification procedures to establish that the holder is not a U.S. person (as defined in the Code) in order to avoid backup withholding at the applicable rate, currently 24%. Generally, a Non-U.S. Holder will comply with such procedures if it provides a properly executed applicable IRS Form W-8 or by otherwise establishing an exemption. Dividends paid to Non-U.S. Holders subject to withholding of U.S. federal income tax, as described above under the heading “— Distributions,” will generally be exempt from U.S. backup withholding.

Information reporting and backup withholding generally will apply to the proceeds of a disposition of our common stock, pre-funded warrants or warrants by a Non-U.S. Holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the Non-U.S. Holder certifies its status as a Non-U.S. Holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a Non-U.S. Holder where the transaction is effected outside the United States through a non-U.S. office of a non-U.S. broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. Holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the Non-U.S. Holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a Non-U.S. Holder can be refunded or credited against the Non-U.S. Holder’s U.S. federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act (“FATCA”)) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends (including deemed dividends) on, or (subject to the proposed Treasury Regulations discussed below) gross proceeds from the sale or other disposition of, pre-funded warrants, warrants or our common stock paid to, a “foreign financial institution” or a “non-financial foreign entity” (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any “substantial United States owners” (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain “specified United States persons” or “United States owned foreign entities” (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends (including deemed dividends). While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of pre-funded warrants, warrants or our common stock on or after January 1, 2019, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until

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final Treasury Regulations are issued. Because we may not know the extent to which a distribution is a dividend for U.S. federal income tax purposes at the time it is made, for purposes of these withholding rules we or the applicable withholding agent may treat the entire distribution as a dividend. Prospective investors should consult their tax advisors regarding the potential application of these withholding provisions.

The preceding discussion of material U.S. federal tax considerations is for information only. It is not tax advice. Prospective investors should consult their own tax advisors regarding the particular U.S. federal, state, local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, pre-funded warrants or warrants, including the consequences of any proposed changes in applicable laws.

UNDERWRITING

We entered into an underwriting agreement with Craig-Hallum Capital Group LLC on , 2022. Craig-Hallum Capital Group LLC is acting as the sole book-running manager for this offering. The underwriting agreement provides for the purchase of a specific number of shares of common stock and/or pre-funded warrants and accompanying warrants to purchase shares of common stock by the underwriter. Subject to the terms and conditions of the underwriting agreement, the underwriter has agreed to purchase the number of shares set forth below:

Underwriter	Number of Shares of Common Stock	Number of Pre- Funded Warrants	Number of Warrants
Craig-Hallum Capital Group LLC			

The underwriter has agreed to purchase all of the shares of common stock and/or pre-funded warrants and accompanying warrants offered by this prospectus, if any are purchased.

The shares of common stock and/or pre-funded warrants and accompanying warrants offered hereby are expected to be ready for delivery on or about , 2022 against payment in immediately available funds.

The underwriter is offering the shares of common stock and/or pre-funded warrants and accompanying warrants subject to various conditions and may reject all or part of any order. The underwriter proposes initially to offer the shares of common stock and/or pre-funded warrants and accompanying warrants to purchase shares of common stock to the public at the public offering price set forth on the cover page of this prospectus and to dealers at the public offering price less a concession not in excess of \$ per share and accompanying warrants or \$ per pre-funded warrant and accompanying warrants. If the shares of common stock and/or pre-funded warrants and accompanying warrants are not sold at the public offering price, the underwriter may change the offering price, the concession, and other selling terms.

The following table provides information regarding the amount of the discounts and commissions to be paid to the underwriter by us, before expenses:

	Per Share and Accompanying Warrants	Per Pre-Funded Warrant and Accompanying Warrants	Total
Public offering price	\$	\$	\$
Underwriting discounts and commissions ⁽¹⁾	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

(1) We have agreed to pay the underwriter an underwriting discount equal to 7.0% of the gross proceeds of this offering.

In addition to the underwriting discount, we have agreed to pay up to \$100,000 of the fees and expenses of the underwriter, which includes the fees and expenses of counsel to the underwriter. We estimate that our total expenses of the offering, excluding the estimated underwriting discounts and commissions, will be approximately \$510,000, which includes the fees and expenses for which we have agreed to reimburse the underwriter.

Determination of Offering Price

Our common stock is currently traded on The Nasdaq Capital Market under the symbol “CEMI.” On October 5, 2022, the closing price of our common stock was \$0.42 per share.

The public offering price of the securities offered by this prospectus will be determined by negotiation between us and the underwriter. Among the factors considered in determining the public offering price of the shares were:

- our history and our prospects;
- the industry in which we operate;
- our past and present operating results;
- the previous experience of our executive officers; and
- the general condition of the securities markets at the time of this offering.

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The offering price stated on the cover page of this prospectus should not be considered an indication of the actual value of the securities. That price is subject to change as a result of market conditions and other factors, and we cannot assure you that the securities can be resold at or above the public offering price.

Lock-Up Agreements

Our officers and directors have agreed with the underwriter to be subject to a lock-up period until the earlier of the date that the Stockholder Approvals are obtained and the warrants become exercisable and the date that is the six month anniversary of the closing date of this offering. This means that, during the applicable lock-up period, such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any shares of our common stock or any securities convertible into, or exercisable or exchangeable for, shares of our common stock. Certain limited transfers are permitted during the lock-up period if the transferee agrees to these lock-up restrictions. We have also agreed, in the underwriting agreement, to similar lock-up restrictions on the issuance and sale of our securities until the earlier of the date that the Stockholder Approvals are obtained and the warrants become exercisable and the date that is the six month anniversary of the closing date of this offering, although we will be permitted to issue stock options or stock awards to directors, officers and employees under our existing plans. In addition, we have agreed to not issue any securities that are subject to a price reset based on the trading prices of our common stock or upon a specified or contingent event in the future or enter into any agreement to issue securities at a future determined price for a period of twelve months following the closing of this offering, subject to an exception. The underwriter may, in its sole discretion and without notice, waive the terms of any of these lock-up agreements and prohibition.

Stabilization

In connection with this offering, the underwriter may engage in stabilizing transactions.

Stabilizing transactions permit bids to purchase shares of common stock so long as the stabilizing bids do not exceed a specified maximum and are engaged in for the purpose of preventing or retarding a decline in the market price of the common stock while the offering is in progress.

Other Relationships

Craig-Hallum Capital Group LLC and its respective affiliates has from time to time in the past and may in the future provide various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they have received and may continue to receive customary fees and commissions. Craig-Hallum Capital Group LLC is currently acting as sales agent under our existing at-the-market offering, which commenced in July 2021, and is engaged to assist us in our review of strategic alternatives, including a potential sale or merger transaction, and of our financing strategy.

Transfer Agent, Warrant Agent and Registrar

The transfer agent and registrar for our common stock, and the warrant agent for our warrants, is Action Stock Transfer Corp. whose mailing address is 2469 E. Fort Union Blvd, Suite 214, Salt Lake City, Utah 84121.

Indemnification

We have agreed to indemnify the underwriter and selected dealers against certain liabilities, including certain liabilities arising under the Securities Act, or to contribute to payments that the underwriter or selected dealers may be required to make for these liabilities.

LEGAL MATTERS

Certain matters concerning this offering will be passed upon for us by K&L Gates LLP. The validity of the securities offered hereby has been passed upon for us by Ballard Spahr LLP. Certain legal matters in connection with this offering may be passed upon for the underwriter by Ellenoff Grossman & Schole LLP.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2021, as set forth in their report (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 2 to the consolidated financial statements), which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements are incorporated by reference in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

Available Information

We file reports, proxy statements and other information with the SEC. Information we file can be inspected and copied at the Public Reference Room maintained by the SEC at 100 F Street, N.E., Washington, D.C. 20549. You may also obtain copies of this information by mail from the Public Reference Room of the SEC at prescribed rates. Further information on the operation of the SEC's Public Reference Room in Washington, D.C. can be obtained by calling the SEC at 1-800-SEC-0330. The SEC also maintains a website at www.sec.gov that contains reports, proxy and information statements and other information about issuers, such as us, who file electronically with the SEC.

Our website address is www.chembio.com. The information on our website, however, is not, and should not be deemed to be, a part of this prospectus. We have included our website address as an inactive textual reference only.

This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits filed therewith or the documents incorporated by reference herein. For further information about us and the common stock, pre-funded warrants and warrants offered hereby, we refer you to the registration statement and the exhibits filed thereto and to the documents incorporated by reference herein. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement or to a document incorporated by reference herein are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement or a document incorporated by reference herein. You may inspect a copy of the registration statement at the SEC's Public Reference Room in Washington, D.C. or through the SEC's website, as provided above.

INCORPORATION BY REFERENCE

The SEC's rules allow us to "incorporate by reference" information into this prospectus, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information incorporated by reference is deemed to be part of this prospectus, and subsequent information that we file with the SEC will automatically update and supersede that information. Any statement contained in this prospectus or a previously filed document incorporated by reference will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or a subsequently filed document incorporated by reference modifies or replaces that statement.

We incorporate by reference our documents listed below and any future filings made by us with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act between the date of this prospectus and the termination of the offering of the securities described in this prospectus. We are not, however, incorporating by reference any documents or portions thereof, whether specifically listed below or filed in the future, that are not deemed "filed" with the SEC, including any Compensation Committee report or any information furnished pursuant to Item 2.02 or 7.01 of Form 8-K or related exhibits furnished pursuant to Item 9.01 of Form 8-K.

This prospectus incorporates by reference the documents set forth below that have previously been filed with the SEC:

- our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on [March 3, 2022](#);
- the information specifically incorporated by reference into our Annual Report on Form 10-K for the year ended December 31, 2021 from our Definitive Proxy Statement on Schedule 14A, filed with the SEC on [April 11, 2022](#);
- our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2022, filed with the SEC on [May 5, 2022](#) and for the quarter ended June 30, 2022, filed with the SEC on [August 5, 2022](#); and
- our Current Reports on Form 8-K filed with the SEC on [January 6, 2022](#), [February 14, 2022](#), [April 7, 2022](#), [May 26, 2022](#), [September 7, 2022](#), and [October 4, 2022](#).

All reports and other documents we subsequently file pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the termination of this offering, including all such documents we may file with the SEC after the date of the initial registration statement and prior to the effectiveness of the registration statement, but excluding any information furnished to, rather than filed with, the SEC, will also be incorporated by reference into this prospectus and deemed to be part of this prospectus from the date of the filing of such reports and documents.

You may request a free copy of any of the documents incorporated by reference in this prospectus by writing or telephoning us at the following address:

Chembio Diagnostics, Inc.
555 Wireless Blvd.
Hauppauge, New York 11788
(631) 924-1135
Attention: Corporate Secretary

Exhibits to the filings will not be sent, unless those exhibits have been specifically incorporated by reference in this prospectus.

PART II**INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution**

The following (other than the fees of the SEC and the Financial Industry Regulatory Authority (“FINRA”)) are estimates of the expenses that the registrant may incur in connection with the offering and sale of the securities being registered hereby. All such expenses are to be paid by the registrant.

SEC registration fee	\$ 4,215
FINRA filing fee	\$ 3,950
Accounting fees and expenses	\$125,000
Legal fees and expenses	\$260,000
Printing expenses	\$ 10,000
Transfer agent fees and expenses	\$ 5,000
Miscellaneous	\$ 1,835
Total	\$410,000

Each of the amounts set forth above, other than the SEC registration fee and FINRA filing fee, is an estimate.

Item 14. Indemnification of Directors and Officers

Our bylaws provide that we will indemnify any of our directors, officers, other employees or agents against expenses (including attorneys’ fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such director, officer, other employee or agent in connection with any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, relating to service for or at the request of the Company. We will not indemnify a director, officer, other employee or agent if in relation to matters such director, officer, other employee or agent is adjudged in the action, suit or proceeding to not have acted in good faith and in a manner reasonably believed to be in or not opposed to the best interests of the Company in the performance of the individual’s duties.

Our bylaws also provide that we will advance expenses (including attorneys’ fees) incurred by an officer or director defending an action, suit or proceeding, upon receipt of an undertaking by or on behalf of such officer or director to repay such amount if that officer or director is determined to not be entitled to indemnification. Such expenses incurred by other employees and agents may be paid in advance by us upon certain terms and conditions deemed appropriate by our board of directors.

Our articles of incorporation provide that no director will be personally liable to the Company or our stockholders for monetary damages for breach of fiduciary duty as a director, except that the director’s liability will not be eliminated or limited: (A) for acts or omissions involving intentional misconduct, fraud or a knowing violation of the law; or (B) for the payment of any distribution in violation of Nevada law.

Nevada law permits a Nevada corporation, such as the Company, to indemnify its directors and officers in certain circumstances. Specifically, Section 78.7502 of the Nevada Revised Statutes provides as follows:

“(1) A corporation may indemnify pursuant to this subsection any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, except an action by or in the right of the corporation, by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise or as a manager of a limited-liability company, against expenses, including attorneys’ fees, judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with the action, suit or proceeding if the person: (a) is not liable pursuant to Nevada Revised Statutes 78.138 or (b) acted in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its

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equivalent, does not, of itself, create a presumption that the person is liable pursuant to Nevada Revised Statutes 78.138 or did not act in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the corporation, or that, with respect to any criminal action or proceeding, he or she had reasonable cause to believe that the conduct was unlawful.

(2) A corporation may indemnify pursuant to this subsection any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise or as a manager of a limited-liability company, against expenses, including amounts paid in settlement and attorneys' fees actually and reasonably incurred by the person in connection with the defense or settlement of the action or suit if the person: (a) is not liable pursuant to Nevada Revised Statutes 78.138; or (b) acted in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the corporation. Indemnification pursuant to this section may not be made for any claim, issue or matter as to which such a person has been adjudged by a court of competent jurisdiction, after exhaustion of any appeals taken therefrom, to be liable to the corporation or for amounts paid in settlement to the corporation, unless and only to the extent that the court in which the action or suit was brought or other court of competent jurisdiction determines upon application that in view of all the circumstances of the case, the person is fairly and reasonably entitled to indemnity for such expenses as the court deems proper.

(3) Any discretionary indemnification pursuant to this section, unless ordered by a court or advanced pursuant to subsection 2 of Nevada Revised Statutes 78.751, may be made by the corporation only as authorized in each specific case upon a determination that the indemnification of a director, officer, employee or agent of a corporation is proper under the circumstances. The determination must be made by: (a) The stockholders; (b) The board of directors, by majority vote of a quorum consisting of directors who were not parties to the action, suit or proceeding; or (c) Independent legal counsel, in a written opinion, if: (1) A majority vote of a quorum consisting of directors who were not parties to the action, suit or proceeding so orders; or (2) A quorum consisting of directors who were not parties to the action, suit or proceeding cannot be obtained."

Item 15. Recent Sales of Unregistered Securities

From November 25, 2019 through the date hereof, we have issued, in the aggregate, 90,849 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.

Item 16. Exhibits and Financial Statements Schedules

(a) Exhibits

EXHIBIT NO.	DESCRIPTION
1.1†	Form of Underwriting Agreement
3.1	Articles of Incorporation, as amended, of Chembio Diagnostics, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on July 29, 2010)
3.2	Amended and Restated Bylaws of Chembio Diagnostics, Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed with the SEC on September 17, 2018)
3.3	Amendment No. 1 to Amended and Restated Bylaws of Chembio Diagnostics, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2021)
4.4†	Form of Warrant
4.5*	Form of Pre-Funded Warrant
4.6*	Form of Warrant Agency Agreement
5.1†	Opinion of Ballard Spahr LLP
5.2†	Opinion of K&L Gates LLP

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EXHIBIT NO.	DESCRIPTION
<u>10.1(a)</u>	2008 Stock Incentive Plan, as amended (incorporated herein by reference to Attachment B to the Proxy Statement on Form DEF 14A filed on August 3, 2012)
<u>10.1(b)</u>	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)
<u>10.2(a)</u>	2014 Stock Incentive Plan (incorporated herein by reference to Attachment A to the Proxy Statement on Form DEF 14A filed on April 29, 2014)
<u>10.2(b)</u>	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)
<u>10.3</u>	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)
<u>10.4</u>	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)
<u>10.5</u>	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)
<u>10.6(a)</u>	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)
<u>10.6(b)</u>	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)
<u>10.7(a)</u>	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)
<u>10.7(b)</u>	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)
<u>10.7(c)</u>	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)
<u>10.8(a)</u>	Employment Agreement dated December 18, 2017 between Chembio Diagnostics, Inc. and Neil A. Goldman (incorporated herein by reference to Exhibit 10.4 to the Annual Report on Form 10-K filed on March 8, 2018)
<u>10.8(b)</u>	Amendment No. 1 dated January 21, 2019 between Chembio Diagnostics, Inc. and Neil A. Goldman, amending Employment Agreement dated December 18, 2017 (incorporated herein by reference to Exhibit 10.01 to the Current Report on Form 8-K filed on January 25, 2019)
<u>10.9</u>	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)
<u>10.10</u>	Offer Letter dated October 19, 2016 between Worldwide Workplace Ireland and Robert Passas, with respect to employment by Chembio Diagnostics Systems, Inc. (incorporated herein by reference to Exhibit 10.4 to the Current Report on Form 8-K filed on October 22, 2018)
<u>10.11</u>	Separation and Release Agreement, dated January 7, 2020, between Chembio Diagnostics, Inc. and John J. Sperzel III (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on January 9, 2020)
<u>10.12(a)</u>	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)

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EXHIBIT NO.	DESCRIPTION
10.12(b)	Agreement of Sublease dated February 5, 2019 between Chembio Diagnostic Systems Inc., as sublessor, and Reliance Communications of New Jersey, LLC, as sublessee, with respect to 3661 Horseblock Road, Medford, New York, as amended (incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on February 11, 2019)
10.13	Lease Agreement, dated February 4, 2013, between Sherwood Corporate Center LLC and Chembio Diagnostics, Inc. with respect to 91-1A Colin Drive, Holbrook, New York, as amended on September 19, 2017 (incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on October 22, 2018)
10.14	Lease Agreement dated February 5, 2019 between Myra Properties, LLC, as lessor, and Chembio Diagnostic Systems Inc., as lessee, with respect to 555 Wireless Boulevard, Hauppauge, New York (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on February 11, 2019)
10.15	Credit Agreement and Guaranty dated as of September 3, 2019, among Chembio Diagnostics, Inc., as the Borrower, the Guarantors from time to time party thereto, and Perceptive Credit Holdings II, LP and its successors and assigns party thereto, as Administrative Agent and as a Lender (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on September 5, 2019)
10.16	At the Market Offering Agreement, dated July 19, 2021, between Chembio Diagnostics, Inc. and Craig-Hallum Capital Group LLC (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on July 19, 2021)
23.1†	Consent of Ernst & Young LLP
23.2	Consent of Ballard Spahr LLP (included in Exhibit 5.1)
23.3	Consent of K&L Gates LLP (included in Exhibit 5.2)
24.1*	Powers of Attorney (included on the signature page)
107†	Filing Fee Table

† Filed herewith.

* Previously filed.

(b) Financial Statement Schedules

All financial statement schedules have been omitted because they are not required or because the required information is given in the financial statements or notes to those statements.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

- (a)(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
 - (i) to include any prospectus required by section 10(a)(3) of the Securities Act of 1933;
 - (ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and
 - (iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

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provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (4) The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
 - (i) any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
 - (ii) any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
 - (iii) the portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
 - (iv) any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.
- (b) The undersigned registrant hereby undertakes that:
 - (i) for purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b) (1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective; and
 - (ii) for purposes of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (c) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (d) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or

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controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-1 and has duly caused this amendment to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Hauppauge, State of New York, on October 7, 2022.

CHEMBIO DIAGNOSTICS, INC.

By: /s/ Richard L. Eberly

Richard L. Eberly

Chief Executive Officer and President

Pursuant to the requirements of the Securities Act, this amendment has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated.

Signature	Title	Date
<u>/s/ Richard L. Eberly</u> Richard L. Eberly	Chief Executive Officer and President (Principal Executive Officer)	October 7, 2022
<u>/s/ Lawrence J. Steenvoorden</u> Lawrence J. Steenvoorden	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	October 7, 2022
<u>*</u> David W.K. Acheson	Director	October 7, 2022
<u>*</u> David W. Bepalko	Director	October 7, 2022
<u>*</u> Katherine A. Davis	Chair of the Board	October 7, 2022
<u>*</u> John G. Potthoff	Director	October 7, 2022
<u>*</u> Leslie Teso-Lichtman	Director	October 7, 2022

* By: /s/ Lawrence J. Steenvoorden

Lawrence J. Steenvoorden

Attorney-in-Fact

____ SHARES OF COMMON STOCK,
____ PRE-FUNDED WARRANTS (EXERCISABLE FOR ____
WARRANT SHARES) AND
____ COMMON WARRANTS (EXERCISABLE FOR ____ WARRANT
SHARES)
OF
CHEMBIO DIAGNOSTICS, INC.
UNDERWRITING AGREEMENT

____, 2022

Craig-Hallum Capital Group LLC
As the Representative of the

Several underwriters, if any, named in Schedule I hereto
222 South Ninth Street, Suite 350
Minneapolis, Minnesota 55402

Ladies and Gentlemen:

The undersigned, Chembio Diagnostics, Inc., a company incorporated under the laws of Nevada (collectively with its subsidiaries and affiliates, including, without limitation, all entities disclosed or described in the Registration Statement as being subsidiaries or affiliates of Chembio Diagnostics, Inc., the “Company”), hereby confirms its agreement (this “Agreement”) with the several underwriters (such underwriters, including the Representative (as defined below), the “Underwriters” and each an “Underwriter”) named in Schedule I hereto for which Craig-Hallum Capital Group LLC is acting as representative to the several Underwriters (the “Representative” and if there are no Underwriters other than the Representative, references to multiple Underwriters shall be disregarded and the term Representative as used herein shall have the same meaning as Underwriter) on the terms and conditions set forth herein.

It is understood that the several Underwriters are to make a public offering of the Closing Securities (as defined below) as soon as the Representative deems it advisable to do so. The Closing Securities are to be initially offered to the public at the public offering price set forth in the Prospectus. The Representative may from time to time thereafter change the public offering price and other selling terms.

It is further understood that you will act as the Representative for the Underwriters in the offering and sale of the Closing Securities in accordance with this Agreement.

ARTICLE I. DEFINITIONS

1.1 Definitions. In addition to the terms defined elsewhere in this Agreement, for all purposes of this Agreement, the following terms have the meanings set forth in this Section 1.1:

“Action” shall have the meaning ascribed to such term in Section 3.1(k).

“Affiliate” means with respect to any Person, any other Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with such Person as such terms are used in and construed under Rule 405 under the Securities Act.

“Applicable Time” means ____ (New York City time) on ____, 2022.

“Authorization Increase” means, subject to Stockholder Approval, an increase in the number of authorized shares of Common Stock of the Company by the Company’s filing of the Certificate of Amendment with the Secretary of State of the State of Nevada and the acceptance thereof, provided that the amount of such increase shall be determined by the Board of Directors and the amount of such increase shall be sufficient for the issuance of all of the Common Warrant Shares upon exercise in full of the Common Warrants.

“Board of Directors” means the board of directors of the Company.

“Business Day” means any day other than Saturday, Sunday or other day on which commercial banks in The City of New York are authorized or required by law to remain closed; provided, however, for clarification, commercial banks shall not be deemed to be authorized or required by law to remain closed due to “stay at home”, “shelter-in-place”, “non-essential employee” or any other similar orders or restrictions or the closure of any physical branch locations at the direction of any governmental authority so long as the electronic funds transfer systems (including for wire transfers) of commercial banks in The City of New York generally are open for use by customers on such day.

“Certificate of Amendment” means the amendment to the Company’s Articles of Incorporation that effects the Reverse Stock Split and/or the Authorization Increase.

“Closing” means the closing of the purchase and sale of the Closing Securities pursuant to Section 2.1.

“Closing Common Warrants” shall have the meaning ascribed to such term in Section 2.1(a)(ii).

“Closing Date” means the hour and the date on the Trading Day on which all conditions precedent to (i) the Underwriters’ obligations to pay the Closing Purchase Price and (ii) the Company’s obligations to deliver the Closing Securities, in each case, have been satisfied or waived, but in no event later than 10:00 a.m. (New York City time) on the second (2nd) Trading Day following the date hereof or at such earlier time as shall be agreed upon by the Representative and the Company.

“Closing Purchase Price” shall have the meaning ascribed to such term in Section 2.1(b), which aggregate purchase price shall be net of the underwriting discounts and commissions.

“Closing Pre-Funded Warrants” shall have the meaning ascribed to such term in Section 2.1(a)(iii).

“Closing Securities” shall have the meaning ascribed to such term in Section 2.1(a)(iii).

“Closing Shares” shall have the meaning ascribed to such term in Section 2.1(a)(i).

“Commission” means the United States Securities and Exchange Commission.

“Common Stock” means the common stock of the Company, par value \$0.01 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

“Common Stock Equivalents” means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

“Common Warrant Shares” means the shares of Common Stock issuable upon exercise of the Common Warrants.

“Common Warrants” means collectively, the Common Stock purchase warrants delivered to the Underwriters in accordance with Section 2.1(a)(ii) which Common Warrants shall be exercisable on the Common Warrants Initial Exercise Date and have a term of exercise equal to five (5) years from the Common Warrants Initial Exercise Date and each Common Warrant shall be exercisable for one Common Warrant Share, in the form of Exhibit A-1 attached hereto.

“Common Warrants Initial Exercise Date” means the first date on which both Stockholder Approval and Nasdaq Stockholder Approval have been obtained and Authorization Increase and/or Reverse Stock Split are deemed effective in accordance with the laws of the State of Nevada.

“Company Auditor” means Ernst & Young LLP, with offices located at One Jericho Plaza, Suite 105, Jericho, New York 11753.

“Company Counsel” means K&L Gates LLP, with offices located at 300 South Tryon Street, Suite 1000, Charlotte, North Carolina 28202.

“Company Nevada Counsel” means Ballard Spahr LLP, with offices located at One Summerlin, 1980 Festival Plaza Drive, Suite 900, Las Vegas, Nevada 89135-2958.

“Effective Date” shall have the meaning ascribed to such term in Section 3.1(f).

“EGS” means Ellenoff Grossman & Schole LLP, with offices located at 1345 Avenue of the Americas, New York, New York 10105.

“Exchange Act” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

“Execution Date” shall mean the date on which the parties execute and enter into this Agreement.

“Exempt Issuance” means the issuance of (a) shares of Common Stock or options or other equity awards to employees, officers, consultants or directors of the Company (i) pursuant to any stock or option plan or other equity incentive plan duly adopted for such purpose by a majority of the non-employee members of the Board of Directors or a majority of the members of a committee of non-employee directors established for such purpose for services rendered to the Company or (ii) made as a material inducement to a grantee’s entry into employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4) (or any successor to such rule), (b) securities upon the exercise or exchange of or conversion of any Securities issued hereunder and/or other securities exercisable or exchangeable for or convertible into shares of Common Stock issued and outstanding on the date of this Agreement, provided that such securities have not been amended since the date of this Agreement to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities or to extend the term of such securities, and (c) securities issued pursuant to acquisitions or strategic transactions approved by a majority of the disinterested directors of the Company, provided that such securities are issued as “restricted securities” (as defined in Rule 144) and carry no registration rights that require or permit the filing of any registration statement in connection therewith until the earlier of (a) the date that is the six (6) month anniversary of the Closing Date and (b) the Common Warrants Initial Exercise Date, and provided that any such issuance shall only be to a Person (or to the equity holders of a Person) which is, itself or through its subsidiaries, an operating company or an owner of an asset in a business synergistic with the business of the Company and shall provide to the Company additional benefits in addition to the investment of funds, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities.

“FCPA” means the Foreign Corrupt Practices Act of 1977, as amended.

“FINRA” means the Financial Industry Regulatory Authority.

“GAAP” shall have the meaning ascribed to such term in Section 3.1(i).

“Indebtedness” means (a) any liabilities for borrowed money or amounts owed in excess of \$50,000 (other than trade accounts payable incurred in the ordinary course of business), (b) all guaranties, endorsements and other contingent obligations in respect of indebtedness of others, whether or not the same are or should be reflected in the Company’s consolidated balance sheet (or the notes thereto), except guaranties by endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business; and (c) the present value of any lease payments in excess of \$50,000 due under leases required to be capitalized in accordance with GAAP.

“Liens” means a lien, charge, pledge, security interest, encumbrance, right of first refusal, preemptive right or other restriction.

“Lock-Up Agreements” means the lock-up agreements that are delivered on the date hereof by each of the Company’s officers and directors, in the form of Exhibit D attached hereto.

“Material Adverse Effect” means (i) a material adverse effect on the legality, validity or enforceability of any Transaction Document, (ii) a material adverse effect on the results of operations, assets, business, prospects or condition (financial or otherwise) of the Company and the Subsidiaries, taken as a whole or (iii) a material adverse effect on the Company’s ability to perform in any material respect on a timely basis its obligations under any Transaction Document; provided that a change in the market price or trading volume of the Common Stock alone shall not be deemed, in and of itself, to constitute a Material Adverse Effect and adverse effects resulting solely from or relating solely to the following shall not be taken into account in determining whether there has been a Material Adverse Effect, except, in each case of the clauses below, to the extent the impact of the event described therein has an adverse effect on the Company taken as a whole that is materially disproportionate to the Company taken as a whole compared to other companies operating in the same industry: (a) general economic conditions, or conditions in financial, banking or securities markets; (b) general conditions in the industry or any industry sector in which the Company operates or participates; (c) any natural disaster or any national or international political or social conditions or any act of terrorism, sabotage, military action or war or any escalation or worsening thereof; or (d) any changes in applicable laws or governmental regulations or the interpretation thereof.

“Nasdaq Stockholder Approval” means such approval as may be required by the applicable rules and regulations of the Nasdaq Stock Market (or any successor entity) from the stockholders of the Company with respect to the issuance of the Common Warrants and the Common Warrant Shares upon exercise thereof.

“Offering” shall have the meaning ascribed to such term in Section 2.1(c).

“Person” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“Pre-Funded Warrants” means the pre-funded Common Stock purchase warrants delivered to the Underwriters in accordance with Section 2.1(a) hereof, which Pre-Funded Warrants shall be exercisable immediately and shall be exercisable until exercised in full, in the form of Exhibit A-2 hereto.

“Pre-Funded Warrant Shares” means the shares of Common Stock issuable upon exercise of the Pre-Funded Warrants.

“Pricing Disclosure Package” means, as of the Applicable Time, the most recent Preliminary Prospectus, together with the information included in Schedule II hereto, and each Issuer Free Writing Prospectus filed or used by the Company at or before the Applicable Time.

“Pricing Prospectus” means the Preliminary Prospectus that was included in the Registration Statement immediately prior to the time of execution of this Agreement.

“Proceeding” means an action, claim, suit, investigation or proceeding (including, without limitation, an informal investigation or partial proceeding, such as a deposition), whether commenced or, to the Company’s knowledge, threatened.

“Prospectus” means the final prospectus filed for the Registration Statement.

“Prospectus Supplement” means, if any, any supplement to the Prospectus complying with Rule 424(b) of the Securities Act that is filed with the Commission.

“Registration Statement” means, collectively, the various parts of the registration statement prepared by the Company on Form S-1 (File No. 333-267320) with respect to the Securities, each as amended as of the date hereof, including the Preliminary Prospectus, the Prospectus and any Prospectus Supplement, if any, and all exhibits filed with or incorporated by reference into such registration statement, and includes any Rule 462(b) Registration Statement.

“Required Approvals” shall have the meaning ascribed to such term in Section 3.1(e).

“Reverse Stock Split” means, subject to Stockholder Approval, a reverse stock split of the outstanding shares of Common Stock that is effected by the Company’s filing of the Certificate of Amendment with the Secretary of State of the State of Nevada and the acceptance thereof, which reverse stock split shall have a ratio as determined by the Board of Directors and such ratio shall be sufficient for the issuance in full of the Common Warrant Shares.

“Rule 424” means Rule 424 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.

“Rule 462(b) Registration Statement” means any registration statement prepared by the Company registering additional Closing Securities, which was filed with the Commission on or prior to the date hereof and became automatically effective pursuant to Rule 462(b) promulgated by the Commission pursuant to the Securities Act.

“SEC Reports” shall have the meaning ascribed to such term in Section 3.1(i).

“Securities” means the Closing Securities and the Warrant Shares.

“Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“Shares” means the shares of Common Stock delivered to the Underwriters in accordance with Section 2.1(a)(i).

“Stockholder Approval” means such approval as may be required by the laws of the State of Nevada from the stockholders of the Company with respect to the Authorization Increase and/or the Reverse Stock Split, and such approval is deemed effective in accordance with the laws of the State of Nevada.

“Subsidiary” means any subsidiary of the Company and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

“Trading Day” means a day on which the principal Trading Market is open for trading.

“Trading Market” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange (or any successors to any of the foregoing).

“Transaction Documents” means this Agreement, the Warrants, the Warrant Agency Agreement, the Lock-Up Agreements, and any other documents or agreements executed in connection with the transactions contemplated hereunder.

“Transfer Agent” means Action Stock Transfer Corp., the current transfer agent of the Company, and any successor transfer agent of the Company.

“Variable Rate Transaction” shall have the meaning ascribed to such term in Section 4.19.

“Warrant Agency Agreement” means the warrant agency agreement dated on or about the date hereof, among the Company and Action Stock Transfer Corp. as warrant agent related to the Common Warrants, in the form of Exhibit E attached hereto.

“Warrant Shares” means the Common Warrant Shares and the Pre-Funded Warrant Shares.

“Warrants” means, collectively, the Common Warrants and the Pre-Funded Warrants.

ARTICLE II. PURCHASE AND SALE

2.1 Closing.

(a) Upon the terms and subject to the conditions set forth herein, the Company agrees to sell (i) in the aggregate _____ shares of Common Stock, (ii) Pre-Funded Warrants exercisable for an aggregate of _____ shares of Common Stock and (iii) Common Warrants exercisable for an aggregate of _____ shares of Common Stock, and each Underwriter agrees to purchase, severally and not jointly, at the Closing, the following securities of the Company:

(i) the number of shares of Common Stock (the “Closing Shares”) set forth opposite the name of such Underwriter on Schedule I hereof; and

(ii) Common Warrants to purchase up to the number of shares of Common Stock set forth opposite the name of such Underwriter on Schedule I hereto, which shall have an exercise price equal to \$_____ per Common Warrant Share (subject to adjustment therein) (the “Closing Common Warrants”); and

(iii) Pre-Funded Warrants to purchase up to the number of shares of Common Stock set forth opposite the name of such Underwriter on Schedule I hereto, which shall have an exercise price equal to \$0.01 (subject to adjustment therein) (the “Closing Pre-Funded Warrants” and collectively with the Closing Shares and the Closing Common Warrants, the “Closing Securities”).

(b) The aggregate purchase price for the Closing Securities shall equal the amount set forth opposite the name of such Underwriter on Schedule I hereof (the “Closing Purchase Price”). The combined purchase price for one Share and one and one-quarter (1.25) Common Warrants shall be \$_____. The combined purchase price for one Pre-Funded Warrant to purchase one Pre-Funded Warrant Share and one and one-quarter (1.25) Common Warrants shall be \$_____.

(c) On the Closing Date, each Underwriter shall deliver or cause to be delivered to the Company, via wire transfer, immediately available funds equal to such Underwriter's Closing Purchase Price and the Company shall deliver to, or as directed by, such Underwriter its respective Closing Securities and the Company shall deliver the other items required pursuant to Section 2.3 deliverable at the Closing. Upon satisfaction of the covenants and conditions set forth in Sections 2.3 and 2.4, the Closing shall occur at the offices of EGS or such other location as the Company and Representative shall mutually agree. The Closing Securities are to be offered initially to the public at the offering price set forth on the cover page of the Prospectus (the "Offering").

(d) The Company acknowledges and agrees that, with respect to any Notice(s) of Exercise (as defined in the Pre-Funded Warrants) delivered by a Holder (as defined in the Pre-Funded Warrants) on or prior to 9:00 a.m. (New York City time) on the Closing Date, which Notice(s) of Exercise may be delivered at any time after the time of execution of this Agreement, the Company shall deliver the Pre-Funded Warrant Shares subject to such notice(s) to the Holder by 4:00 p.m. (New York City time) on the Closing Date and the Closing Date shall be the Warrant Share Delivery Date (as defined in the Pre-Funded Warrants). The Company acknowledges and agrees that the Holders are third-party beneficiaries of this covenant of the Company.

2.2 [RESERVED]

2.3 Deliveries. The Company shall deliver or cause to be delivered to each Underwriter (if applicable) the following:

(i) At the Closing Date, the Closing Shares, which shares shall be delivered via The Depository Trust Company Deposit or Withdrawal at Custodian system for the accounts of the several Underwriters;

(ii) At the Closing Date, the Closing Common Warrants, which shall be delivered via The Depository Trust Company Deposit or Withdrawal at Custodian system for the accounts of the several Underwriters;

(iii) At the Closing Date, the Closing Pre-Funded Warrants in certificated form registered in the name or names and in such authorized denominations as the applicable Underwriter may request in writing at least one Business Day prior to the Closing Date;

(iv) At the Closing Date, the Warrant Agency Agreement duly executed by the parties thereto;

(v) At the Closing Date, a legal opinion of Company Counsel addressed to the Underwriters, including, without limitation, a negative assurance letter, and a legal opinion of Company Nevada Counsel, substantially in the form of Exhibit F-1 and Exhibit F-2 respectively attached hereto;

(vi) Contemporaneously herewith, a cold comfort letter, addressed to the Underwriters and in form and substance satisfactory in all respects to the Representative from the Company Auditor dated, as of the date of this Agreement and a bring-down letter dated as of the Closing Date satisfactory in all respects to the Representative;

(vii) On the Closing Date, the duly executed and delivered Officer's Certificate, substantially in the form attached hereto as Exhibit B;

(viii) On the Closing Date, the duly executed and delivered Secretary's Certificate, substantially in the form attached hereto as Exhibit C; and

(ix) Contemporaneously herewith, the duly executed and delivered Lock-Up Agreements.

2.4 Closing Conditions. The respective obligations of each Underwriter hereunder in connection with the Closing are subject to the following conditions being met:

(i) the accuracy in all material respects when made and on the date in question (other than representations and warranties of the Company already qualified by materiality, which shall be true and correct in all respects) of the representations and warranties of the Company contained herein (unless as of a specific date therein);

(ii) all obligations, covenants and agreements of the Company required to be performed at or prior to the date in question shall have been performed;

(iii) the delivery by the Company of the items set forth in Section 2.3 of this Agreement;

(iv) the Registration Statement shall be effective on the date of this Agreement and at the Closing Date no stop order suspending the effectiveness of the Registration Statement shall have been issued and no proceedings for that purpose shall have been instituted or shall, to the Company's knowledge, be pending or contemplated by the Commission and any request on the part of the Commission for additional information shall have been complied with to the reasonable satisfaction of the Representative;

(v) by the Execution Date, if required by FINRA, the Underwriters shall have received clearance from FINRA as to the amount of compensation allowable or payable to the Underwriters as described in the Registration Statement;

(vi) the Closing Shares and the Warrant Shares have been approved for listing on the Nasdaq Capital Market; and

(vii) prior to and on the Closing Date: (i) there shall have been no material adverse change or development involving a prospective material adverse change in the condition or prospects or the business activities, financial or otherwise, of the Company from the latest dates as of which such condition is set forth in the Registration Statement and Prospectus; (ii) no action suit or proceeding, at law or in equity, shall have been pending or, to the Company's knowledge, threatened against the Company or any Affiliate of the Company before or by any court or federal or state commission, board or other administrative agency wherein an unfavorable decision, ruling or finding would be reasonably likely to materially adversely affect the business, operations, prospects or financial condition or income of the Company, except as set forth in the Registration Statement and Prospectus; (iii) no stop order shall have been issued under the Securities Act and no proceedings therefor shall have been initiated or threatened by the Commission; and (iv) the Registration Statement and the Prospectus and any amendments or supplements thereto shall contain all material statements which are required to be stated therein in accordance with the Securities Act and the rules and regulations thereunder and shall conform in all material respects to the requirements of the Securities Act and the rules and regulations thereunder, and neither the Registration Statement nor the Prospectus nor any amendment or supplement thereto shall contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

ARTICLE III. REPRESENTATIONS AND WARRANTIES

3.1 Representations and Warranties of the Company. Except as disclosed in the Registration Statement, the Preliminary Prospectus and the Prospectus (including the information incorporated by reference therein from the SEC Reports), the Company represents and warrants to the Underwriters as of the Execution Date, as of the Closing Date as follows:

(a) Subsidiaries. All of the direct and indirect Subsidiaries of the Company are set forth in the SEC Reports. Except as disclosed in the Registration Statement, the Preliminary Prospectus and the Prospectus the Company owns, directly or indirectly, all of the capital stock or other equity interests of each Subsidiary which ownership is free and clear of any Liens, and all of the issued and outstanding shares of capital stock of each Subsidiary are validly issued and are fully paid, non-assessable and free of preemptive and similar rights to subscribe for or purchase securities. If the Company has no Subsidiaries, all other references to the Subsidiaries or any of them in the Transaction Documents shall be disregarded.

(b) Organization and Qualification. The Company and each of the Subsidiaries is an entity duly incorporated or otherwise organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization, with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted. Neither the Company nor any Subsidiary is in violation nor default of any of the provisions of its respective certificate or articles of incorporation, bylaws or other organizational or charter documents. Each of the Company and the Subsidiaries is duly qualified to conduct business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, could not reasonably be expected to result in a Material Adverse Effect and no Proceeding has been instituted in any such jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification.

(c) Authorization; Enforcement. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement and each of the other Transaction Documents to which the Company is a party and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of this Agreement and each of the other Transaction Documents by the Company and the consummation by it of the transactions contemplated hereby and thereby have been duly authorized by all necessary action on the part of the Company and no further action is required by the Company, the Board of Directors or the Company's stockholders in connection herewith or therewith other than in connection with the Required Approvals. This Agreement and each other Transaction Document to which the Company is a party has been (or upon delivery will have been) duly executed by the Company and constitutes, or, when delivered in accordance with the terms thereof and hereof, will constitute the valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(d) No Conflicts. The execution, delivery and performance by the Company of this Agreement and the other Transaction Documents to which it is a party, the issuance and sale of the Securities and the consummation by it of the transactions contemplated hereby and thereby do not and will not (i) conflict with or violate any provision of the Company's or any Subsidiary's certificate or articles of incorporation, bylaws or other organizational or charter documents, or (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any Lien upon any of the properties or assets of the Company or any Subsidiary, or give to others any rights of termination, amendment, anti-dilution or similar adjustments, acceleration or cancellation (with or without notice, lapse of time or both) of, any agreement, credit facility, debt or other instrument (evidencing a Company or Subsidiary debt or otherwise) or other understanding to which the Company or any Subsidiary is a party or by which any property or asset of the Company or any Subsidiary is bound or affected, or (iii) subject to the Required Approvals, conflict with or result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority to which the Company or a Subsidiary is subject (including federal and state securities laws and regulations), or by which any property or asset of the Company or a Subsidiary is bound or affected; except in the case of each of clauses (ii) and (iii), such as could not reasonably be expected to result in a Material Adverse Effect.

(e) Filings, Consents and Approvals. The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any court or other federal, state, local or other governmental authority or other Person in connection with the execution, delivery and performance by the Company of the Transaction Documents, other than: (i) the filing with the Commission of the Prospectus, (ii) applications to each applicable Trading Market for the listing of the Shares and the Warrant Shares for trading thereon in the time and manner required thereby and (iii) such filings as are required to be made under applicable state securities laws (collectively, the “Required Approvals”).

(f) Registration Statement. The Company has filed with the Commission the Registration Statement, including any related Preliminary Prospectus or Prospectus, for the registration of the Securities under the Securities Act, which Registration Statement has been prepared by the Company in all material respects in conformity with the requirements of the Securities Act and the rules and regulations of the Commission under the Securities Act. The Registration Statement has been declared effective by the Commission on _____, 2022 (the “Effective Date”). The Company has advised the Representative of all further information (financial and other) with respect to the Company required to be set forth therein in the Registration Statement, the Preliminary Prospectus, the Pricing Disclosure Package and the Prospectus. Any reference in this Agreement to the Registration Statement, the Preliminary Prospectus, the Pricing Disclosure Package, the Prospectus or any Prospectus Supplement shall be deemed to refer to and include the documents incorporated by reference therein; and any reference in this Agreement to the terms “amend,” “amendment” or “supplement” with respect to the Registration Statement, the Preliminary Prospectus, the Pricing Disclosure Package, the Prospectus or any Prospectus Supplement shall be deemed to refer to and include the filing of any document under the Exchange Act after the date of this Agreement, or the issue date of the Preliminary Prospectus, the Pricing Disclosure Package, the Prospectus or any Prospectus Supplement, as the case may be, deemed to be incorporated therein by reference. All references in this Agreement to financial statements and schedules and other information which is “contained,” “included,” “described,” “referenced,” “set forth” or “stated” in the Registration Statement, the Preliminary Prospectus, the Pricing Disclosure Package, the Prospectus or any Prospectus Supplement (and all other references of like import) shall be deemed to mean and include all such financial statements and schedules and other information which is or is deemed to be incorporated by reference in the Registration Statement, the Preliminary Prospectus, the Pricing Disclosure Package, the Prospectus or any Prospectus Supplement, as the case may be. No stop order suspending the effectiveness of the Registration Statement or the use of the Preliminary Prospectus, the Pricing Disclosure Package or the Prospectus or any Prospectus Supplement has been issued, and no proceeding for any such purpose is pending or has been initiated or, to the Company’s knowledge, is threatened by the Commission. For purposes of this Agreement, “free writing prospectus” has the meaning set forth in Rule 405 under the Securities Act. The Company will not, without the prior consent of the Representative, prepare, use or refer to, any free writing prospectus.

(g) Issuance of Securities. The Securities are duly authorized and, when issued and paid for in accordance with the applicable Transaction Documents, will be duly and validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company. The Warrant Shares, when issued in accordance with the terms of the Warrants, will be validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company. The Company has reserved from its duly authorized capital stock the maximum number of shares of Common Stock issuable pursuant to this Agreement and the Warrants. The holder of the Securities will not be subject to personal liability by reason of being such holders. The Securities are not and will not be subject to the preemptive rights of any holders of any security of the Company or similar contractual rights granted by the Company. All corporate action required to be taken for the authorization, issuance and sale of the Securities has been duly and validly taken. The Securities conform in all material respects to all statements with respect thereto contained in the Registration Statement.

(h) Capitalization. The capitalization of the Company is as set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus. The Company has not issued any capital stock since its most recently filed periodic report under the Exchange Act, other than pursuant to the exercise of employee stock options or other equity grants under the Company's equity incentive plan or inducement grants made outside of the Company's equity incentive plans, pursuant to the conversion and/or exercise of securities exercisable, exchangeable or convertible into Common Stock ("Common Stock Equivalents"), pursuant to the 2019 Brazil Consulting Agreement entered into as of November 25, 2019 among the Company, Orangelife Comercio e Industria Ltda. and the consultant named therein (the "Brazil Consulting Agreement") or pursuant to the Amended and Restated Agency & Commission Agreement entered into as of November 25, 2019 between Chembio Diagnostic Systems, Inc., a wholly owned subsidiary of the Company, and Marco Collovati, as amended (the "Agency & Commission Agreement"). No Person has any right of first refusal, preemptive right, right of participation, or any similar right to participate in the transactions contemplated by the Transaction Documents. Except as set forth in the Registration Statement, the Pricing Disclosure Package or the Prospectus and as a result of the purchase and sale of the Securities, there are no outstanding options, warrants, scrip rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire, any shares of Common Stock or the capital stock of any Subsidiary, or contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to issue additional shares of Common Stock or Common Stock Equivalents or capital stock of any Subsidiary. The issuance and sale of the Securities will not obligate the Company or any Subsidiary to issue shares of Common Stock or other securities to any Person. Except as set forth in the Registration Statement, the Pricing Disclosure Package or the Prospectus, there are no outstanding securities or instruments of the Company or any Subsidiary with any provision that adjusts the exercise, conversion, exchange or reset price of such security or instrument upon an issuance of securities by the Company or any Subsidiary. There are no outstanding securities or instruments of the Company or any Subsidiary that contain any redemption or similar provisions, and there are no contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to redeem a security of the Company or such Subsidiary. The Company does not have any stock appreciation rights or "phantom stock" plans or agreements or any similar plan or agreement. All of the outstanding shares of capital stock of the Company are duly authorized, validly issued, fully paid and nonassessable, have been issued in compliance with all federal and state securities laws, and none of such outstanding shares was issued in violation of any preemptive rights or similar rights to subscribe for or purchase securities. The authorized shares of the Company conform in all material respects to all statements relating thereto contained in the Registration Statement, the Pricing Disclosure Package, and the Prospectus. The offers and sales of the Company's securities were at all relevant times either registered under the Securities Act and the applicable state securities or Blue Sky laws or, based in part on the representations and warranties of the purchasers, exempt from such registration requirements. No further approval or authorization of any stockholder, the Board of Directors or others is required for the issuance and sale of the Securities. Except for the Lock-Up Agreements and except as set forth in the Registration Statement, the Pricing Disclosure Package or the Prospectus, there are no stockholders agreements, voting agreements or other similar agreements with respect to the Company's capital stock to which the Company is a party or, to the knowledge of the Company, between or among any of the Company's stockholders.

(i) SEC Reports; Financial Statements. The Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the two years preceding the date hereof (or such shorter period as the Company was required by law or regulation to file such material) (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, together with the Pricing Disclosure Package, the Prospectus and any Prospectus Supplement, being collectively referred to herein as the “SEC Reports”) on a timely basis or has received a valid extension of such time of filing and has filed any such SEC Reports prior to the expiration of any such extension. As of their respective dates, the SEC Reports complied in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable, and none of the SEC Reports, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved (“GAAP”), except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company and its consolidated Subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments. The agreements and documents described in the Registration Statement, the Pricing Disclosure Package, the Prospectus, the Prospectus Supplement and the SEC Reports conform to the descriptions thereof contained therein and there are no agreements or other documents required by the Securities Act and the rules and regulations thereunder to be described in the Registration Statement, the Pricing Disclosure Package, the Prospectus, the Prospectus Supplement or the SEC Reports or to be filed with the Commission as exhibits to the Registration Statement, that have not been so described or filed. Each agreement or other instrument (however characterized or described) to which the Company is a party or by which it is or may be bound or affected and (i) that is referred to in the Registration Statement, the Pricing Disclosure Package, the Prospectus, the Prospectus Supplement or the SEC Reports, or (ii) is material to the Company’s business, has been duly authorized and validly executed by the Company, is in full force and effect in all material respects and is enforceable against the Company and, to the Company’s knowledge, the other parties thereto, in accordance with its terms, except (x) as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting creditors’ rights generally, (y) as enforceability of any indemnification or contribution provision may be limited under the federal and state securities laws, and (z) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefore may be brought. None of such agreements or instruments has been assigned by the Company, and neither the Company nor, to the best of the Company’s knowledge, any other party is in default thereunder and, to the best of the Company’s knowledge, no event has occurred that, with the lapse of time or the giving of notice, or both, would constitute a default thereunder. To the best of the Company’s knowledge, performance by the Company of the material provisions of such agreements or instruments will not result in a violation of any existing applicable law, rule, regulation, judgment, order or decree of any governmental agency or court, domestic or foreign, having jurisdiction over the Company or any of its assets or businesses, including, without limitation, those relating to environmental laws and regulations.

(j) Material Changes; Undisclosed Events, Liabilities or Developments. Since the date of the latest audited financial statements included within the SEC Reports, except as specifically disclosed in Registration Statement, the Pricing Disclosure Package or the Prospectus, (i) there has been no event, occurrence or development that has had or that could reasonably be expected to result in a Material Adverse Effect, (ii) the Company has not incurred any material liabilities (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company's financial statements pursuant to GAAP or disclosed in filings made with the Commission, (iii) the Company has not altered its method of accounting, (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock, (v) the Company has not issued any equity securities to any officer, director or Affiliate, except pursuant to existing Company stock incentive plans and (vi) no officer or director of the Company has resigned from any position with the Company. The Company does not have pending before the Commission any request for confidential treatment of information. Except for the issuance of the Securities contemplated by this Agreement, no event, liability, fact, circumstance, occurrence or development has occurred or exists or is reasonably expected to occur or exist with respect to the Company or its Subsidiaries or their respective businesses, properties, operations, assets or financial condition that would be required to be disclosed by the Company under applicable securities laws at the time this representation is made or deemed made that has not been publicly disclosed at least 1 Trading Day prior to the date that this representation is made. Unless otherwise disclosed in the Registration Statement, the Pricing Disclosure Package or the Prospectus, the Company has not: (i) issued any securities or incurred any liability or obligation, direct or contingent, for borrowed money; or (ii) declared or paid any dividend or made any other distribution on or in respect to its capital stock, each since the date of the latest audited financial statements included in the Registration Statement.

(k) Litigation. Except as set forth in the Registration Statement, the Pricing Disclosure Package or the Prospectus, there is no material action, suit, inquiry, notice of violation, Proceeding or investigation pending or, to the knowledge of the Company, threatened against or affecting the Company, any Subsidiary or any of their respective properties before or by any court, arbitrator, governmental or administrative agency or regulatory authority (federal, state, county, local or foreign) (collectively, an "Action") which (i) adversely affects or challenges the legality, validity or enforceability of this Agreement or the Securities or (ii) could, if there were an unfavorable decision, reasonably be expected to result in a Material Adverse Effect. Except as set forth in the Registration Statement, the Pricing Disclosure Package or the Prospectus, neither the Company nor any Subsidiary, nor, to the Company's knowledge, any current director or officer thereof, is or has been the subject of any Action involving a claim of violation of or liability under federal or state securities laws or a claim of breach of fiduciary duty. There has not been, and to the Company's knowledge, there is not pending or contemplated, any investigation by the Commission involving the Company or any current or former director or officer of the Company. The Commission has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company or any Subsidiary under the Exchange Act or the Securities Act.

(l) Labor Relations. No material labor dispute exists or, to the knowledge of the Company, is imminent with respect to any of the employees of the Company, which could reasonably be expected to result in a Material Adverse Effect. None of the Company's or its Subsidiaries' employees is a member of a union that relates to such employee's relationship with the Company or such Subsidiary, and neither the Company nor any of its Subsidiaries is a party to a collective bargaining agreement. To the knowledge of the Company, no executive officer of the Company or any Subsidiary, is, or is now expected to be, in violation of any material term of any employment contract, confidentiality, disclosure or proprietary information agreement or non-competition agreement, or any other contract or agreement or any restrictive covenant in favor of any third party, and the continued employment of each such executive officer does not subject the Company or any of its Subsidiaries to any liability with respect to any of the foregoing matters. The Company and its Subsidiaries are in compliance with all U.S. federal, state, local and foreign laws and regulations relating to employment and employment practices, terms and conditions of employment and wages and hours, except where the failure to be in compliance could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(m) Compliance. Neither the Company nor any Subsidiary: (i) is in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by the Company or any Subsidiary under), nor has the Company or any Subsidiary received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived), (ii) is in violation of any judgment, decree or order of any court, arbitrator or other governmental authority or (iii) is or has been in violation of any statute, rule, ordinance or regulation of any governmental authority, including without limitation all foreign, federal, state and local laws relating to taxes, environmental protection, occupational health and safety, product quality and safety and employment and labor matters, except in each case as could not reasonably be expected to result in a Material Adverse Effect.

(n) Regulatory Permits. The Company and the Subsidiaries possess all certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct their respective businesses as described in the SEC Reports, except where the failure to possess such permits could not reasonably be expected to result in a Material Adverse Effect (each, a "Material Permit"), and neither the Company nor any Subsidiary has received any notice of proceedings relating to the revocation or modification of any Material Permit. The disclosures in the Registration Statement concerning the effects of Federal, State, local and all foreign regulation on the Company's business as currently contemplated are correct in all material respects.

(o) Title to Assets. The Company and the Subsidiaries have good and marketable title to, or have valid rights to lease or otherwise use, all real and personal property that is material to the business of the Company, which leases are valid, subsisting and enforceable and with which the Company and the Subsidiaries are in compliance, in each case free and clear of all Liens, except for (i) Liens as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and the Subsidiaries and (ii) Liens for the payment of federal, state or other taxes, for which appropriate reserves have been made therefor in accordance with GAAP and, the payment of which is neither delinquent nor subject to penalties. Any real property and facilities held under lease by the Company and the Subsidiaries are held by them under valid, subsisting and enforceable leases with which the Company and the Subsidiaries are in material compliance, except where the failure to be in compliance could not reasonably be expected to have a Material Adverse Effect.

(p) Intellectual Property. The Company and the Subsidiaries have, or have rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other similar intellectual property rights necessary or material for use in connection with their respective businesses as described in the SEC Reports and which the failure to so have could reasonably be expected to have a Material Adverse Effect (collectively, the “Intellectual Property Rights”). None of, and neither the Company nor any Subsidiary has received a written notice that any of, the Intellectual Property Rights has expired, terminated or been abandoned, or is expected to expire or terminate or be abandoned, within two (2) years from the date of this Agreement. Neither the Company nor any Subsidiary has received, since the date of the latest audited financial statements included within the SEC Reports, a written notice of a claim or otherwise has any knowledge that the Intellectual Property Rights violate or infringe upon the rights of any Person, except as could not reasonably be expected to have a Material Adverse Effect. To the knowledge of the Company, all such Intellectual Property Rights are enforceable and there is no existing infringement by another Person of any of the Intellectual Property Rights. The Company and its Subsidiaries have taken reasonable security measures to protect the secrecy, confidentiality and value of all of their Intellectual Property Rights, except where failure to do so could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(q) Insurance. The Company and the Subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are prudent and customary for companies of similar size as the Company in the businesses in which the Company and the Subsidiaries are engaged, including, but not limited to, directors and officers insurance coverage. To the knowledge of the Company, such insurance contracts and policies are accurate and complete. Neither the Company nor any Subsidiary has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business without a significant increase in cost.

(r) Transactions With Affiliates and Employees. Except as set forth in the SEC Reports, none of the officers or directors of the Company or any Subsidiary and, to the knowledge of the Company, none of the employees of the Company or any Subsidiary is presently a party to any transaction with the Company or any Subsidiary (other than for services as employees, officers and directors), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from, providing for the borrowing of money from or lending of money to or otherwise requiring payments to or from, any officer, director or such employee or, to the knowledge of the Company, any entity in which any officer, director, or any such employee has a substantial interest or is an officer, director, trustee, stockholder, member or partner, in each case in excess of \$120,000 other than for (i) payment of salary or consulting fees for services rendered, (ii) reimbursement for expenses incurred on behalf of the Company and (iii) other employee benefits, including stock option agreements under any equity incentive plan of the Company.

(s) Sarbanes-Oxley; Internal Accounting Controls. The Company and the Subsidiaries are in material compliance with all applicable requirements of the Sarbanes-Oxley Act of 2002 that are effective as of the date hereof, and any and all applicable rules and regulations promulgated by the Commission thereunder that are effective as of the date hereof and as of the Closing Date. Except as set forth in the Registration Statement, the Pricing Disclosure Package or the Prospectus, the Company and the Subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization, and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company and the Subsidiaries have established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and the Subsidiaries and designed such disclosure controls and procedures to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. The Company's certifying officers have evaluated the effectiveness of the disclosure controls and procedures of the Company and the Subsidiaries as of the end of the period covered by the most recently filed periodic report under the Exchange Act (such date, the "Evaluation Date"). The Company presented in its most recently filed periodic report under the Exchange Act the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no changes in the internal control over financial reporting (as such term is defined in the Exchange Act) of the Company and its Subsidiaries that have materially affected, or is reasonably likely to materially affect, the internal control over financial reporting of the Company and its Subsidiaries.

(t) Certain Fees. Except as set forth in the Pricing Disclosure Package or Prospectus, no brokerage or finder's fees or commissions are or will be payable by the Company, any Subsidiary or Affiliate of the Company to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by the Transaction Documents. To the Company's knowledge, there are no other arrangements, agreements or understandings of the Company or, to the Company's knowledge, any of its stockholders that may affect the Underwriters' compensation, as determined by FINRA. The Company has not made any direct or indirect payments (in cash, securities or otherwise) to: (i) any person, as a finder's fee, consulting fee or otherwise, in consideration of such person raising capital for the Company or introducing to the Company persons who raised or provided capital to the Company; (ii) any FINRA member; or (iii) any person or entity that has any direct or indirect affiliation or association with any FINRA member, within the twelve months prior to the Execution Date. Except as set forth in the Pricing Disclosure Package or Prospectus, none of the net proceeds of the Offering will be paid by the Company to any participating FINRA member or its affiliates.

(u) Investment Company. The Company is not, and is not an Affiliate of, and immediately after receipt of payment for the Securities will not be or be an Affiliate of, an "investment company" within the meaning of the Investment Company Act of 1940, as amended. The Company shall conduct its business in a manner so that it will not become an "investment company" subject to registration under the Investment Company Act of 1940, as amended.

(v) Registration Rights. No Person has any right to cause the Company or any Subsidiary to effect the registration under the Securities Act of any securities of the Company or any Subsidiary.

(w) Listing and Maintenance Requirements. The Common Stock is registered pursuant to Section 12(b) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the Commission is contemplating terminating such registration. Except as set forth in the Registration Statement, the Pricing Disclosure Package or the Prospectus, the Company has not, in the 12 months preceding the date hereof, received notice from any Trading Market on which the Common Stock is or has been listed or quoted to the effect that the Company is not in compliance with the listing or maintenance requirements of such Trading Market. Except as set forth in the Registration Statement, the Pricing Disclosure Package or the Prospectus, the Company is in material compliance with all such listing and maintenance requirements. The Common Stock is currently eligible for electronic transfer through the Depository Trust Company or another established clearing corporation and the Company is current in payment of the fees of the Depository Trust Company (or such other established clearing corporation) in connection with such electronic transfer.

(x) Application of Takeover Protections. The Company and the Board of Directors have taken all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Company's certificate of incorporation (or similar charter documents) or the laws of its state of incorporation that is or could become applicable as a result of the Underwriters and the Company fulfilling their obligations or exercising their rights under the Transaction Documents.

(y) Disclosure; 10b-5. The Registration Statement contains all exhibits and schedules as required by the Securities Act. Each of the Registration Statement and any post-effective amendment thereto, if any, at the time it became effective, complied in all material respects with the Securities Act and the Exchange Act and the applicable rules and regulations under the Securities Act and did not and, as amended or supplemented, if applicable, will not, contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. The Preliminary Prospectus, the Pricing Disclosure Package, Prospectus and the Prospectus Supplement, each as of its respective date, comply in all material respects with the Securities Act and the Exchange Act and the applicable rules and regulations. Each of the Preliminary Prospectus, the Pricing Disclosure Package, the Prospectus and the Prospectus Supplement, as amended or supplemented, did not and will not contain as of the date thereof any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The SEC Reports, when they were filed with the Commission, conformed in all material respects to the requirements of the Exchange Act and the applicable rules and regulations, and none of such documents, when they were filed with the Commission, contained any untrue statement of a material fact or omitted to state a material fact necessary to make the statements therein (with respect to the SEC Reports incorporated by reference in the Preliminary Prospectus, Pricing Disclosure Package, Prospectus or Prospectus Supplement), in light of the circumstances under which they were made not misleading; and any further documents so filed and incorporated by reference in the Preliminary Prospectus, Prospectus or Prospectus Supplement, when such documents are filed with the Commission, will conform in all material respects to the requirements of the Exchange Act and the applicable rules and regulations, as applicable, and will not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made not misleading. No post-effective amendment to the Registration Statement reflecting any facts or events arising after the date thereof which represent, individually or in the aggregate, a fundamental change in the information set forth therein is required to be filed with the Commission. Notwithstanding the foregoing, the Company makes no representation or warranty with respect to any Underwriter Information (as such term is hereinafter defined) in the Registration Statement, the Preliminary Prospectus, the Pricing Disclosure Package or the Prospectus. There are no documents required to be filed with the Commission in connection with the transaction contemplated hereby that (x) have not been filed as required pursuant to the Securities Act or (y) will not be filed within the requisite time period. There are no contracts or other documents required to be described in the Preliminary Prospectus, Pricing Disclosure Package, Prospectus or Prospectus Supplement, or to be filed as exhibits or schedules to the Registration Statement, which have not been described or filed as required. The press releases disseminated by the Company during the twelve months preceding the date of this Agreement taken as a whole do not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made and when made, not misleading.

(z) No Integrated Offering. Neither the Company, nor any of its Affiliates, nor any Person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause this offering of the Securities to be integrated with prior offerings by the Company for purposes of any applicable shareholder approval provisions of any Trading Market on which any of the securities of the Company are listed or designated.

(aa) Solvency. Except as set forth in the Registration Statement, the Pricing Disclosure Package or the Prospectus, based on the consolidated financial condition of the Company as of the Closing Date, after giving effect to the receipt by the Company of the proceeds from the sale of the Securities hereunder, (i) the fair saleable value of the Company's assets exceeds the amount that will be required to be paid on or in respect of the Company's existing debts and other liabilities (including known contingent liabilities) as they mature, (ii) the Company's assets do not constitute unreasonably small capital to carry on its business as now conducted and as proposed to be conducted including its capital needs taking into account the particular capital requirements of the business conducted by the Company, consolidated and projected capital requirements and capital availability thereof, and (iii) the current cash flow of the Company, together with the proceeds the Company would receive, were it to liquidate all of its assets, after taking into account all anticipated uses of the cash, would be sufficient to pay all amounts on or in respect of its liabilities when such amounts are required to be paid. The Company does not intend to incur debts beyond its ability to pay such debts as they mature (taking into account the timing and amounts of cash to be payable on or in respect of its debt). Except as set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company has no knowledge of any facts or circumstances which lead it to believe that it will file for reorganization or liquidation under the bankruptcy or reorganization laws of any jurisdiction within one year from the Closing Date. The Registration Statement, the Pricing Disclosure Package and the Prospectus set forth as of the date hereof all outstanding secured and unsecured Indebtedness of the Company or any Subsidiary, or for which the Company or any Subsidiary has commitments. Neither the Company nor any Subsidiary is in default with respect to any Indebtedness.

(bb) Tax Status. Except for matters that would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect, the Company and its Subsidiaries each (i) has made or filed all United States federal, state and local income and all foreign income and franchise tax returns, reports and declarations required by any jurisdiction to which it is subject, (ii) has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations and (iii) has set aside on its books provision reasonably adequate for the payment of all material taxes for periods subsequent to the periods to which such returns, reports or declarations apply. There are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction, and the officers of the Company or of any Subsidiary know of no basis for any such claim. The provisions for taxes payable, if any, shown on the financial statements filed with or as part of the Registration Statement are sufficient for all accrued and unpaid taxes, whether or not disputed, and for all periods to and including the dates of such consolidated financial statements. The term "taxes" mean all federal, state, local, foreign, and other net income, gross income, gross receipts, sales, use, ad valorem, transfer, franchise, profits, license, lease, service, service use, withholding, payroll, employment, excise, severance, stamp, occupation, premium, property, windfall profits, customs, duties or other taxes, fees, assessments, or charges of any kind whatsoever, together with any interest and any penalties, additions to tax, or additional amounts with respect thereto. The term "returns" means all returns, declarations, reports, statements, and other documents required to be filed in respect to taxes.

(cc) Foreign Corrupt Practices. Neither the Company nor any Subsidiary, nor to the knowledge of the Company or any Subsidiary, any agent or other person acting on behalf of the Company or any Subsidiary, has (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company or any Subsidiary (or made by any person acting on its behalf of which the Company is aware) which is in violation of law, or (iv) violated in any material respect any provision of FCPA. The Company has taken reasonable steps to ensure that its accounting controls and procedures are sufficient to cause the Company to comply in all material respects with the FCPA.

(dd) Accountants. To the knowledge and belief of the Company, the Company Auditor (i) is an independent registered public accounting firm as required by the Exchange Act and (ii) to the Company's knowledge, shall express its opinion with respect to the financial statements to be included in the Company's Annual Report for the fiscal year ending December 31, 2022. The Company Auditor has not, during the periods covered by the financial statements included in the Prospectus, provided to the Company any non-audit services, as such term is used in Section 10A(g) of the Exchange Act.

(ee) FDA. As to each product subject to the jurisdiction of the U.S. Food and Drug Administration ("FDA") under the Federal Food, Drug and Cosmetic Act, as amended, and the regulations thereunder ("FDCA") that is manufactured, packaged, labeled, tested, distributed, sold, and/or marketed by the Company or any of its Subsidiaries (each such product, a "Diagnostic Product"), such Diagnostic Product is being manufactured, packaged, labeled, tested, distributed, sold and/or marketed by the Company in compliance with all applicable requirements under FDCA and similar laws, rules and regulations relating to registration, investigational use, premarket clearance, licensure, or application approval, good manufacturing practices, good laboratory practices, good clinical practices, product listing, quotas, labeling, advertising, record keeping and filing of reports, except where the failure to be in compliance would not have a Material Adverse Effect. There is no pending, completed or, to the Company's knowledge, threatened, action (including any lawsuit, arbitration, or legal or administrative or regulatory proceeding, charge, complaint, or investigation) against the Company or any of its Subsidiaries, and none of the Company or any of its Subsidiaries has received any notice, warning letter or other communication from the FDA or any other governmental entity, which (i) contests the premarket clearance, licensure, registration, or approval of, the uses of, the distribution of, the manufacturing or packaging of, the testing of, the sale of, or the labeling and promotion of any Diagnostic Product, (ii) withdraws its approval of, requests the recall, suspension, or seizure of, or withdraws or orders the withdrawal of advertising or sales promotional materials relating to, any Diagnostic Product, (iii) imposes a clinical hold on any clinical investigation by the Company or any of its Subsidiaries, (iv) enjoins production at any facility of the Company or any of its Subsidiaries, (v) enters or proposes to enter into a consent decree of permanent injunction with the Company or any of its Subsidiaries, or (vi) otherwise alleges any violation of any laws, rules or regulations by the Company or any of its Subsidiaries, and which, either individually or in the aggregate, would have a Material Adverse Effect. The properties, business and operations of the Company have been and are being conducted in all material respects in accordance with all applicable laws, rules and regulations of the FDA. The Company has not been informed by the FDA that the FDA will prohibit the marketing, sale, license or use in the United States of any product proposed to be developed, produced or marketed by the Company nor has the FDA expressed any concern as to approving or clearing for marketing any product being developed or proposed to be developed by the Company.

(ff) Equity Incentive Plans. Each stock option granted by the Company under the Company's equity incentive plan was granted (i) in accordance with the terms of the Company's equity incentive plan and (ii) with an exercise price at least equal to the fair market value of the Common Stock on the date such stock option would be considered granted under GAAP and applicable law. No stock option granted under the Company's stock option plan has been backdated. The Company has not knowingly granted, and there is no and has been no Company policy or practice to knowingly grant, stock options prior to, or otherwise knowingly coordinate the grant of stock options with, the release or other public announcement of material information regarding the Company or its Subsidiaries or their financial results or prospects.

(gg) Office of Foreign Assets Control. Neither the Company nor any Subsidiary nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company or any Subsidiary is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department.

(hh) Money Laundering. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance in all material respects with applicable financial record-keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, applicable money laundering statutes and applicable rules and regulations thereunder (collectively, the "Money Laundering Laws"), and no Action or Proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any Subsidiary with respect to the Money Laundering Laws is pending or, to the knowledge of the Company or any Subsidiary, threatened.

(ii) D&O Questionnaires. To the Company's knowledge, all information contained in the questionnaires completed by each of the Company's directors and officers at the most recent date prior to the Offering and in the Lock-Up Agreement provided to the Underwriters is true and correct in all respects and the Company has not become aware of any information which would cause the information disclosed in such questionnaires become inaccurate and incorrect.

(jj) FINRA Affiliation. To the Company's knowledge, no officer, director or any beneficial owner of 5% or more of the Company's unregistered securities has any direct or indirect affiliation or association with any FINRA member (as determined in accordance with the rules and regulations of FINRA) that is participating in the Offering. The Company will advise the Representative and EGS if it learns that any officer, director or owner of 5% or more of the Company's outstanding shares of Common Stock or Common Stock Equivalents is or becomes an affiliate or associated person of a FINRA member firm.

(kk) Officers' Certificate. Any certificate signed by any duly authorized officer of the Company and delivered to the Representative or EGS shall be deemed a representation and warranty by the Company to the Underwriters as to the matters covered thereby.

(ll) Board of Directors. The Board of Directors is comprised of the persons set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus. The qualifications of the persons serving as board members and the overall composition of the Board of Directors comply with the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder applicable to the Company and the rules of the Trading Market. At least one member of the Board of Directors qualifies as a "financial expert" as such term is defined under the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder and the rules of the Trading Market. In addition, at least a majority of the persons serving on the Board of Directors qualify as "independent" as defined under the rules of the Trading Market.

(mm) Cybersecurity. Except as set forth in Registration Statement, the Pricing Disclosure Package and the Prospectus, to the Company's knowledge, there has been no security breach or other compromise of or relating to any of the Company's or any Subsidiary's information technology and computer systems, networks, hardware, software, data (including the data of its respective customers, employees, suppliers, vendors and any third party data maintained by or on behalf of it), equipment or technology (collectively, "IT Systems and Data") and (y) the Company and the Subsidiaries have not been notified of, and has no knowledge of any event or condition that would reasonably be expected to result in, any security breach or other compromise to its IT Systems and Data; (ii) the Company and the Subsidiaries are presently in compliance in all material respects with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Data and to the protection of such IT Systems and Data from unauthorized use, access, misappropriation or modification, except as would not, individually or in the aggregate, have a Material Adverse Effect; (iii) the Company and the Subsidiaries have implemented and maintained commercially reasonable safeguards to maintain and protect its material confidential information and the integrity, continuous operation, redundancy and security of all IT Systems and Data; and (iv) the Company and the Subsidiaries have implemented backup and disaster recovery technology consistent with industry standards and practices.

(nn) Environmental Laws. The Company and its Subsidiaries (i) are in compliance with all federal, state, local and foreign laws relating to pollution or protection of human health or the environment (including ambient air, surface water, groundwater, land surface or subsurface strata), including laws relating to emissions, discharges, releases or threatened releases of chemicals, pollutants, contaminants, or toxic or hazardous substances or wastes (collectively, "Hazardous Materials") into the environment, or otherwise relating to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials, as well as all authorizations, codes, decrees, demands, or demand letters, injunctions, judgments, licenses, notices or notice letters, orders, permits, plans or regulations, issued, entered, promulgated or approved thereunder ("Environmental Laws"); (ii) have received all permits licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses; and (iii) are in compliance with all terms and conditions of any such permit, license or approval where in each clause (i), (ii) and (iii), the failure to so comply could be reasonably expected to have, individually or in the aggregate, a Material Adverse Effect.

ARTICLE IV. OTHER AGREEMENTS OF THE PARTIES

4.1 Amendments to Registration Statement. The Company has delivered, or will as promptly as practicable deliver, to the Underwriters complete conformed copies of the Registration Statement and of each consent and certificate of experts, as applicable, filed as a part thereof, and conformed copies of the Registration Statement (without exhibits), the Pricing Disclosure Package, the Preliminary Prospectus, the Prospectus and any Prospectus Supplement, as amended or supplemented, in such quantities and at such places as an Underwriter reasonably requests. Neither the Company nor any of its directors and officers has distributed and none of them will distribute, prior to the Closing Date, any offering material in connection with the offering and sale of the Securities other than the Registration Statement, Pricing Disclosure Package, the Preliminary Prospectus, the Prospectus, any Permitted Free Writing Prospectus and copies of the documents incorporated by reference therein. The Company shall not file any such amendment or supplement to which the Representative shall reasonably object in writing.

4.2 Federal Securities Laws.

(a) Compliance. During the time when a Prospectus is required to be delivered under the Securities Act, the Company will use its reasonable best efforts to comply with all requirements imposed upon it by the Securities Act and the rules and regulations thereunder and the Exchange Act and the rules and regulations thereunder, as from time to time in force, so far as necessary to permit the continuance of sales of or dealings in the Securities in accordance with the provisions hereof and the Prospectus. If at any time when a Prospectus relating to the Securities is required to be delivered under the Securities Act, any event shall have occurred as a result of which, in the opinion of counsel for the Company or counsel for the Underwriters, the Prospectus, as then amended or supplemented, includes an untrue statement of a material fact or omits to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, or if it is necessary at any time to amend the Prospectus to comply with the Securities Act, the Company will notify the Underwriters promptly and prepare and file with the Commission, subject to Section 4.1 hereof, an appropriate amendment or supplement in accordance with Section 10 of the Securities Act.

(b) Filing of Final Prospectus. The Company will file the Prospectus (in form and substance reasonably satisfactory to the Representative) with the Commission pursuant to the requirements of Rule 424.

(c) Exchange Act Registration. For a period of three years from the Execution Date, the Company will use its reasonable best efforts to maintain the registration of the Common Stock under the Exchange Act. The Company will not deregister the Common Stock under the Exchange Act without the prior written consent of the Representative.

(d) Free Writing Prospectuses. The Company represents and agrees that it has not made and will not make any offer relating to the Securities that would constitute an issuer free writing prospectus, as defined in Rule 433 of the rules and regulations under the Securities Act, without the prior written consent of the Representative. Any such free writing prospectus consented to by the Representative is herein referred to as a “Permitted Free Writing Prospectus.” The Company represents that it will treat each Permitted Free Writing Prospectus as an “issuer free writing prospectus” as defined in rule and regulations under the Securities Act, and has complied and will comply with the applicable requirements of Rule 433 of the Securities Act, including timely Commission filing where required, legending and record keeping.

4.3 Delivery to the Underwriters of Prospectuses. The Company will deliver to the Underwriters, without charge, from time to time during the period when the Prospectus is required to be delivered under the Securities Act or the Exchange Act such number of copies of each Prospectus as the Underwriters may reasonably request and, as soon as the Registration Statement or any amendment or supplement thereto becomes effective, upon the Representative’s written request, deliver to you two original executed Registration Statements, including exhibits, and all post-effective amendments thereto and copies of all exhibits filed therewith or incorporated therein by reference and all original executed consents of certified experts.

4.4 Effectiveness and Events Requiring Notice to the Underwriters. The Company will use its reasonable best efforts to cause the Registration Statement to remain effective with a current prospectus until the later of nine (9) months from the Execution Date and the date on which the Warrants are no longer outstanding, and will notify the Underwriters and holders of the Warrants promptly and confirm the notice in writing: (i) of the effectiveness of the Registration Statement and any amendment thereto; (ii) of the issuance by the Commission of any stop order or of the initiation, or the threatening, of any proceeding for that purpose; (iii) of the issuance by any state securities commission of any proceedings for the suspension of the qualification of the Securities for offering or sale in any jurisdiction or of the initiation, or the threatening, of any proceeding for that purpose; (iv) of the mailing and delivery to the Commission for filing of any amendment or supplement to the Registration Statement or Prospectus; (v) of the receipt of any comments or request for any additional information from the Commission; and (vi) of the happening of any event during the period described in this Section 4.4 that, in the judgment of the Company, makes any statement of a material fact made in the Registration Statement or the Prospectus untrue or that requires the making of any changes in the Registration Statement or the Prospectus in order to make the statements therein, in light of the circumstances under which they were made, not misleading. If the Commission or any state securities commission shall enter a stop order or suspend such qualification at any time, the Company will make every reasonable effort to obtain promptly the lifting of such order.

4.5 Expenses of the Offering.

(a) General Expenses Related to the Offering. The Company hereby agrees to pay on the Closing Date all expenses incident to the performance of the obligations of the Company under this Agreement, including, but not limited to: (a) all filing fees and communication expenses relating to the registration of the Securities to be sold in the Offering with the Commission; (b) all FINRA Public Offering Filing System fees associated with the review of the Offering by FINRA; all fees and expenses relating to the listing of such Closing Shares and Warrant Shares on the Trading Market; (c) all fees, expenses and disbursements relating to the registration or qualification of such Securities under the “blue sky” securities laws of such states and other foreign jurisdictions as the Representative may reasonably designate; (d) the costs of all mailing and printing of the underwriting documents (including, without limitation, the Underwriting Agreement, any Blue Sky Surveys and, if appropriate, any Agreement Among Underwriters, Selected Dealers’ Agreement, Underwriters’ Questionnaire and Power of Attorney), Registration Statements, Prospectuses and all amendments, supplements and exhibits thereto and as many preliminary and final Prospectuses as the Representative may reasonably deem necessary; (e) the costs and expenses of the Company’s public relations firm, if any; (f) the costs of preparing, printing and delivering the Securities; (g) fees and expenses of the Transfer Agent for the Securities (including, without limitation, any fees required for same-day processing of any instruction letter delivered by the Company and the fees and expenses pursuant to the Warrant Agency Agreement); (h) stock transfer and/or stamp taxes, if any, payable upon the transfer of securities from the Company to the Underwriters; (i) the fees and expenses of the Company’s accountants; (j) the fees and expenses of the Company’s legal counsel and other agents and representatives; (k) expenses of the Underwriters’ use of i-Deal’s book-building, prospectus tracking and compliance software (or other similar software) for the Offering; and (l) the Underwriters’ actual “road show” expenses for the Offering. The Underwriters may also deduct from the net proceeds of the Offering payable to the Company on the Closing Date the expenses set forth herein to be paid by the Company to the Underwriters.

(b) Expenses of the Representative. The Company further agrees that, in addition to the expenses payable pursuant to Section 4.5(a), on the Closing Date, the Company shall reimburse the Representative for its out-of-pocket expenses, including, without limitation, the fees and expenses of counsel to the Representative, up to \$100,000 (which shall include any expenses under clauses (k) and (l) in Section 4.5(a) herein), which shall be paid by deduction from the proceeds of the Offering contemplated herein.

4.6 Application of Net Proceeds. The Company will apply the net proceeds from the Offering received by it in a manner consistent with the application described under the caption “Use of Proceeds” in the Prospectus.

4.7 Delivery of Earnings Statements to Security Holders. The Company will make generally available to its security holders as soon as practicable, but not later than the first day of the fifteenth full calendar month following the Execution Date, an earnings statement (which need not be certified by independent public or independent certified public accountants unless required by the Securities Act or the Rules and Regulations under the Securities Act, but which shall satisfy the provisions of Rule 158(a) under Section 11(a) of the Securities Act) covering a period of at least twelve consecutive months beginning after the Execution Date, provided that any reports, schedules, forms, statements or other documents that are filed or furnished by the Company with the Commission after the Execution Date shall be deemed to constitute delivery.

4.8 Stabilization. Neither the Company, nor, to its knowledge, any of its employees, directors or shareholders (without the consent of the Representative) has taken or will take, directly or indirectly, any action designed to or that has constituted or that might reasonably be expected to cause or result in, under the Exchange Act, or otherwise, stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities.

4.9 Internal Controls. The Company will maintain a system of internal accounting controls sufficient to provide reasonable assurances that: (i) transactions are executed in accordance with management’s general or specific authorization; (ii) transactions are recorded as necessary in order to permit preparation of financial statements in accordance with GAAP and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management’s general or specific authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

4.10 Accountants. The Company shall continue to retain a nationally recognized independent certified public accounting firm for a period of at least three years after the Execution Date. The Underwriters acknowledge that the Company Auditor is acceptable to the Underwriters.

4.11 FINRA. The Company shall advise the Underwriters (who shall make an appropriate filing with FINRA) if it is aware that any 5% or greater shareholder of the Company becomes an affiliate or associated person of an Underwriter.

4.12 No Fiduciary Duties. The Company acknowledges and agrees that the Underwriters’ responsibility to the Company is solely contractual and commercial in nature, based on arms-length negotiations and that neither the Underwriters nor their Affiliates or any selected dealer shall be deemed to be acting in a fiduciary capacity, or otherwise owes any fiduciary duty to the Company or any of its Affiliates in connection with the Offering and the other transactions contemplated by this Agreement. Notwithstanding anything in this Agreement to the contrary, the Company acknowledges that the Underwriters may have financial interests in the success of the Offering that are not limited to the difference between the price to the public and the purchase price paid to the Company by the Underwriters for the securities and the Underwriters have no obligation to disclose, or account to the Company for, any of such additional financial interests. The Company hereby waives and releases, to the fullest extent permitted by law, any claims that the Company may have against the Underwriters with respect to any breach or alleged breach of fiduciary duty.

4.13 Warrant Shares. If all or any portion of a Warrant is exercised at a time when there is an effective registration statement to cover the issuance of the Warrant Shares or if the Warrant is exercised via cashless exercise, the Warrant Shares issued pursuant to any such exercise shall be issued free of all restrictive legends. If at any time following the date hereof the Registration Statement (or any subsequent registration statement registering the sale or resale of the Warrant Shares) is not effective or is not otherwise available for the sale of the Warrant Shares, the Company shall promptly notify the holders of the Warrants in writing that such registration statement is not then effective and thereafter shall promptly notify such holders when the registration statement is effective again and available for the sale of the Warrant Shares (it being understood and agreed that the foregoing shall not limit the ability of the Company to issue, or any holder thereof to sell, any of the Warrant Shares in compliance with applicable federal and state securities laws).

4.14 Board Composition and Board Designations. The Company shall ensure that: (i) the qualifications of the persons serving as board members and the overall composition of the Board of Directors comply with the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder and with the listing requirements of the Trading Market and (ii) if applicable, at least one member of the Board of Directors qualifies as a “financial expert” as such term is defined under the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder.

4.15 Securities Laws Disclosure; Publicity. At the request of the Representative, by ___ a.m./p.m. (New York City time) on the date hereof, the Company shall issue a press release disclosing the material terms of the Offering. The Company and the Representative shall consult with each other in issuing any other press releases with respect to the Offering, and neither the Company nor any Underwriter shall issue any such press release nor otherwise make any such public statement without the prior consent of the Company, with respect to any press release of such Underwriter, or without the prior consent of such Underwriter, with respect to any press release of the Company, which consent shall not unreasonably be withheld or delayed, except if such disclosure is required by law, in which case the disclosing party shall promptly provide the other party with prior notice of such public statement or communication. The Company will not issue press releases or engage in any other publicity, without the Representative’s prior written consent, for a period ending at 5:00 p.m. (New York City time) on the first business day following the 30th day following the Closing Date, other than normal and customary releases issued in the ordinary course of the Company’s business.

4.16 Shareholder Rights Plan. No claim will be made or enforced by the Company or, with the consent of the Company, any other Person, that any Underwriter of the Securities is an “Acquiring Person” under any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or similar anti-takeover plan or arrangement in effect or hereafter adopted by the Company, or that any Underwriter of Securities could be deemed to trigger the provisions of any such plan or arrangement, by virtue of receiving Securities.

4.17 Reservation of Common Stock. As of the date hereof, the Company has reserved and the Company shall continue to reserve and keep available at all times, free of preemptive rights, a sufficient number of shares of Common Stock for the purpose of enabling the Company to issue the Pre-Funded Warrant Shares pursuant to any exercise of the Pre-Funded Warrants. As of the date on which Stockholder Approval is obtained, the Company shall reserve and the Company shall continue to reserve and keep available at all times, free of preemptive rights, a sufficient number of shares of Common Stock for the purpose of enabling the Company to issue the Common Warrant Shares pursuant to any exercise of the Common Warrants.

4.18 Listing of Common Stock. The Company hereby agrees to use best efforts to maintain the listing or quotation of the Common Stock on the Trading Market on which it is currently listed, and concurrently with the Closing, the Company shall apply to list or quote all of the Closing Shares and Warrant Shares on such Trading Market and promptly secure the listing of all of the Closing Shares and Warrant Shares on such Trading Market. The Company further agrees, if the Company applies to have the Common Stock traded on any other Trading Market, it will then include in such application all of the Closing Shares and Warrant Shares, and will take such other action as is necessary to cause all of the Closing Shares and Warrant Shares to be listed or quoted on such other Trading Market as promptly as possible. The Company will then take all action reasonably necessary to continue the listing and trading of its Common Stock on a Trading Market and will comply in all respects with the Company's reporting, filing and other obligations under the bylaws or rules of the Trading Market. The Company agrees to maintain the eligibility of the Common Stock for electronic transfer through the Depository Trust Company or another established clearing corporation, including, without limitation, by timely payment of fees to the Depository Trust Company or such other established clearing corporation in connection with such electronic transfer.

4.19 Subsequent Equity Sales.

(a) From the date hereof until the earlier of (a) the date that is the six (6) month anniversary of the Closing Date and (b) the Common Warrants Initial Exercise Date, neither the Company nor any Subsidiary shall issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of Common Stock or Common Stock Equivalents.

(b) From the date hereof until the date that is the twelve (12) month anniversary of the Closing Date, the Company shall be prohibited from effecting or entering into an agreement to effect any issuance by the Company or any of its Subsidiaries of Common Stock or Common Stock Equivalents (or a combination of units thereof) involving a Variable Rate Transaction. "Variable Rate Transaction" means a transaction in which the Company (i) issues or sells any debt or equity securities that are convertible into, exchangeable or exercisable for, or include the right to receive, additional shares of Common Stock either (A) at a conversion price, exercise price or exchange rate or other price that is based upon, and/or varies with, the trading prices of or quotations for the shares of Common Stock at any time after the initial issuance of such debt or equity securities or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such debt or equity security or upon the occurrence of specified or contingent events directly or indirectly related to the business of the Company or the market for the Common Stock or (ii) enters into, or effects a transaction under, any agreement, including, but not limited to, an equity line of credit or an "at-the-market offering", whereby the Company may issue securities at a future determined price regardless of whether shares pursuant to such agreement have actually been issued and regardless of whether such agreement is subsequently canceled; provided, however, that, after the earlier of (a) the date that is the six (6) month anniversary of the Closing Date and (b) the Common Warrants Initial Exercise Date, the issuance of shares of Common Stock in an "at the market" offering with the Representative as sales agent shall not be deemed a Variable Rate Transaction. Any Underwriter shall be entitled to obtain injunctive relief against the Company to preclude any such issuance, which remedy shall be in addition to any right to collect damages.

(c) Notwithstanding the foregoing, this Section 4.19 shall not apply in respect of an Exempt Issuance, except that no Variable Rate Transaction shall be an Exempt Issuance.

4.20 Stockholder Meeting. The Company shall hold a special meeting or meetings of stockholders (which may also be at the annual meeting of stockholders) on or prior to December 20, 2022 for the purpose of obtaining each of Stockholder Approval and Nasdaq Stockholder Approval, with the recommendation of the Company's Board of Directors that such proposals are approved, and the Company shall solicit proxies from its stockholders in connection therewith in the same manner as all other management proposals in such proxy statement and all management-appointed proxyholders shall vote their proxies in favor of such proposal. The Company shall use its best efforts to obtain each of Stockholder Approval and Nasdaq Stockholder Approval, including, without limitation, the Company's hiring of a reputable national proxy solicitation firm to solicit proxies from its stockholders in connection therewith. In connection with an Authorization Increase, the Board of Directors shall determine an amount of increase in the number of authorized shares of Common Stock that shall be sufficient for the issuance of all of the Common Warrant Shares upon exercise in full of the Common Warrants. In connection with a Reverse Stock Split, the Board of Directors shall determine a ratio for such reverse stock split that shall be sufficient for the issuance of all of the Common Warrant Shares upon exercise in full of the Common Warrants. If the Company does not obtain each of Stockholder Approval and Nasdaq Stockholder Approval at the first meeting or meetings, the Company shall call a meeting every seventy-five (75) days thereafter to seek Stockholder Approval and/or Nasdaq Stockholder Approval until the earlier of the date on which Stockholder Approval and Nasdaq Stockholder Approval are obtained or the Common Warrants are no longer outstanding, and shall use its best efforts to obtain Stockholder Approval and/or Nasdaq Stockholder Approval at such meeting, including, without limitation, the Company's hiring of a reputable national proxy solicitation firm to solicit proxies from its stockholders in connection with such meeting. When the Company obtains Stockholder Approval, the Company shall file the Certificate of Amendment with the State of Nevada as soon as practicable, but in no event later than one (1) Business Day following the date of Stockholder Approval, and shall file a Form 8-K disclosing that the Certificate of Amendment has been filed with and accepted by the State of Nevada.

4.21 Research Independence. The Company acknowledges that each Underwriter's research analysts and research departments, if any, are required to be independent from their respective investment banking divisions and are subject to certain regulations and internal policies, and that such Underwriter's research analysts may hold and make statements or investment recommendations and/or publish research reports with respect to the Company and/or the offering that differ from the views of its investment bankers. The Company hereby waives and releases, to the fullest extent permitted by law, any claims that the Company may have against such Underwriter with respect to any conflict of interest that may arise from the fact that the views expressed by their independent research analysts and research departments may be different from or inconsistent with the views or advice communicated to the Company by such Underwriter's investment banking divisions. The Company acknowledges that the Representative is a full service securities firm and as such from time to time, subject to applicable securities laws, may effect transactions for its own account or the account of its customers and hold long or short position in debt or equity securities of the Company.

ARTICLE V.
DEFAULT BY UNDERWRITERS

If on the Closing Date any Underwriter shall fail to purchase and pay for the portion of the Closing Securities which such Underwriter has agreed to purchase and pay for on such date (otherwise than by reason of any default on the part of the Company), the Representative, or if the Representative is the defaulting Underwriter, the non-defaulting Underwriters, shall use their reasonable efforts to procure within 36 hours thereafter one or more of the other Underwriters, or any others, to purchase from the Company such amounts as may be agreed upon and upon the terms set forth herein, the Closing Securities which the defaulting Underwriter or Underwriters failed to purchase. If during such 36 hours the Representative shall not have procured such other Underwriters, or any others, to purchase the Closing Securities agreed to be purchased by the defaulting Underwriter or Underwriters, then (a) if the aggregate number of Closing Securities with respect to which such default shall occur does not exceed 10% of the Closing Securities covered hereby, the other Underwriters shall be obligated, severally, in proportion to the respective numbers of Closing Securities which they are obligated to purchase hereunder, to purchase the Closing Securities which such defaulting Underwriter or Underwriters failed to purchase, or (b) if the aggregate number of Closing Securities with respect to which such default shall occur exceeds 10% of the Closing Securities covered hereby, the Company or the Representative will have the right to terminate this Agreement without liability on the part of the non-defaulting Underwriters or of the Company except to the extent provided in Article VI hereof. In the event of a default by any Underwriter or Underwriters, as set forth in this Article V, the applicable Closing Date may be postponed for such period, not exceeding seven days, as the Representative, or if the Representative is the defaulting Underwriter, the non-defaulting Underwriters, may determine in order that the required changes in the Prospectus or in any other documents or arrangements may be effected. The term "Underwriter" includes any Person substituted for a defaulting Underwriter. Any action taken under this Section shall not relieve any defaulting Underwriter from liability in respect of any default of such Underwriter under this Agreement.

ARTICLE VI. INDEMNIFICATION

6.1 Indemnification of the Underwriters. Subject to the conditions set forth below, the Company agrees to indemnify and hold harmless the Underwriters, and each dealer selected by each Underwriter that participates in the offer and sale of the Securities (each a “Selected Dealer”) and each of their respective directors, officers and employees and each Person, if any, who controls such Underwriter or any Selected Dealer (“Controlling Person”) within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, against any and all loss, liability, claim, damage and expense whatsoever (including but not limited to any and all legal or other expenses reasonably incurred in investigating, preparing or defending against any litigation, commenced or threatened, or any claim whatsoever, whether arising out of any action between such Underwriter and the Company or between such Underwriter and any third party or otherwise) to which they or any of them may become subject under the Securities Act, the Exchange Act or any other statute or at common law or otherwise or under the laws of foreign countries, arising out of or based upon any untrue statement or alleged untrue statement of a material fact contained in (i) the Registration Statement, the Pricing Disclosure Package, any Preliminary Disclosure Package, if any, or the Prospectus (as from time to time each may be amended and supplemented); (ii) any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the offering of the Securities, including any “road show” or investor presentations made to investors by the Company (whether in person or electronically); or (iii) any application or other document or written communication (in this Article VI, collectively called “application”) executed by the Company or based upon written information furnished by the Company in any jurisdiction in order to qualify the Securities under the securities laws thereof or filed with the Commission, any state securities commission or agency, Trading Market or any securities exchange; or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, unless such statement or omission was made in reliance upon and in conformity with written information furnished to the Company with respect to the applicable Underwriter by or on behalf of such Underwriter expressly for use in the Registration Statement, the Pricing Disclosure Package, Preliminary Prospectus, the Prospectus, or any Prospectus Supplement, or any amendment or supplement thereto, or in any application, as the case may be, which shall be limited to the information in the section titled “Underwriting” in the Registration Statement with respect to the selling concession and the information in the subsection of the section titled “Underwriting” with respect to “Stabilization” (such information, the “Underwriter Information”). With respect to any untrue statement or omission or alleged untrue statement or omission made in the Pricing Disclosure Package, if any, the indemnity agreement contained in this Section 6.1 shall not inure to the benefit of an Underwriter to the extent that any loss, liability, claim, damage or expense of such Underwriter results from the fact that a copy of the Prospectus was not given or sent to the Person asserting any such loss, liability, claim or damage at or prior to the written confirmation of sale of the Securities to such Person as required by the Securities Act and the rules and regulations thereunder, and if the untrue statement or omission has been corrected in the Prospectus, unless such failure to deliver the Prospectus was a result of non-compliance by the Company with its obligations under this Agreement. The Company agrees promptly to notify each Underwriter of the commencement of any litigation or proceedings against the Company or any of its officers, directors or Controlling Persons in connection with the issue and sale of the Closing Securities or in connection with the Registration Statement or Prospectus.

6.2 Procedure. If any action is brought against an Underwriter, a Selected Dealer or a Controlling Person in respect of which indemnity may be sought against the Company pursuant to Section 6.1, such Underwriter, such Selected Dealer or Controlling Person, as the case may be, shall promptly notify the Company in writing of the institution of such action and the Company shall assume the defense of such action, including the employment and fees of counsel (subject to the reasonable approval of such Underwriter or such Selected Dealer, as the case may be) and payment of actual expenses. Such Underwriter, such Selected Dealer or Controlling Person shall have the right to employ its or their own counsel in any such case, but the fees and expenses of such counsel shall be at the expense of such Underwriter, such Selected Dealer or Controlling Person unless (i) the employment of such counsel at the expense of the Company shall have been authorized in writing by the Company in connection with the defense of such action, or (ii) the Company shall not have employed counsel to have charge of the defense of such action, or (iii) such indemnified party or parties shall have reasonably concluded that there may be defenses available to it or them which are different from or additional to those available to the Company (in which case the Company shall not have the right to direct the defense of such action on behalf of the indemnified party or parties), in any of which events the reasonable fees and expenses of not more than one additional firm of attorneys selected by such Underwriter (in addition to local counsel), Selected Dealer and/or Controlling Person shall be borne by the Company. Notwithstanding anything to the contrary contained herein, if any Underwriter, Selected Dealer or Controlling Person shall assume the defense of such action as provided above, the Company shall have the right to approve the terms of any settlement of such action which approval shall not be unreasonably withheld.

6.3 Indemnification of the Company. Each Underwriter severally and not jointly agrees to indemnify and hold harmless the Company, its directors, officers and employees and agents who control the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act against any and all loss, liability, claim, damage and expense described in the foregoing indemnity from the Company to such Underwriter, as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions made in any the Registration Statement, the Pricing Disclosure Package, the Preliminary Prospectus, the Prospectus or any Prospectus Supplement or any amendment or supplement thereto or in any application, in reliance upon, and in strict conformity with, written information furnished to the Company with respect to such Underwriter by or on behalf of such Underwriter expressly for use in such Preliminary Prospectus, if any, the Registration Statement or Prospectus or any amendment or supplement thereto or in any such application. In case any action shall be brought against the Company or any other Person so indemnified based on any Preliminary Prospectus, if any, the Registration Statement or Prospectus or any amendment or supplement thereto or any application, and in respect of which indemnity may be sought against such Underwriter, such Underwriter shall have the rights and duties given to the Company, and the Company and each other Person so indemnified shall have the rights and duties given to such Underwriter by the provisions of this Article VI. Notwithstanding the provisions of this Section 6.3, no Underwriter shall be required to indemnify the Company for any amount in excess of the underwriting discounts and commissions applicable to the Securities purchased by such Underwriter. The Underwriters' obligations in this Section 6.3 to indemnify the Company are several in proportion to their respective underwriting obligations and not joint.

6.4 Contribution.

(a) Contribution Rights. In order to provide for just and equitable contribution under the Securities Act in any case in which (i) any Person entitled to indemnification under this Article VI makes a claim for indemnification pursuant hereto but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration of time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case notwithstanding the fact that this Article VI provides for indemnification in such case, or (ii) contribution under the Securities Act, the Exchange Act or otherwise may be required on the part of any such Person in circumstances for which indemnification is provided under this Article VI, then, and in each such case, the Company and each Underwriter, severally and not jointly, shall contribute to the aggregate losses, liabilities, claims, damages and expenses of the nature contemplated by said indemnity agreement incurred by the Company and such Underwriter, as incurred, in such proportions that such Underwriter is responsible for that portion represented by the percentage that the underwriting discount appearing on the cover page of the Prospectus bears to the initial offering price appearing thereon and the Company is responsible for the balance; provided, that, no Person guilty of a fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation. For purposes of this Section, each director, officer and employee of such Underwriter or the Company, as applicable, and each Person, if any, who controls such Underwriter or the Company, as applicable, within the meaning of Section 15 of the Securities Act shall have the same rights to contribution as such Underwriter or the Company, as applicable. Notwithstanding the provisions of this Section 6.4, no Underwriter shall be required to contribute any amount in excess of the underwriting discounts and commissions applicable to the Securities purchased by such Underwriter. The Underwriters' obligations in this Section 6.4 to contribute are several in proportion to their respective underwriting obligations and not joint.

(b) Contribution Procedure. Within fifteen days after receipt by any party to this Agreement (or its representative) of notice of the commencement of any action, suit or proceeding, such party will, if a claim for contribution in respect thereof is to be made against another party ("contributing party"), notify the contributing party of the commencement thereof, but the failure to so notify the contributing party will not relieve it from any liability which it may have to any other party other than for contribution hereunder. In case any such action, suit or proceeding is brought against any party, and such party notifies a contributing party or its representative of the commencement thereof within the aforesaid fifteen days, the contributing party will be entitled to participate therein with the notifying party and any other contributing party similarly notified. Any such contributing party shall not be liable to any party seeking contribution on account of any settlement of any claim, action or proceeding affected by such party seeking contribution without the written consent of such contributing party. The contribution provisions contained in this Section 6.4 are intended to supersede, to the extent permitted by law, any right to contribution under the Securities Act, the Exchange Act or otherwise available.

**ARTICLE VII.
MISCELLANEOUS**

7.1 Termination.

(a) Termination Right. The Representative shall have the right to terminate this Agreement at any time prior to the Closing Date, (i) if any domestic or international event or act or occurrence has materially disrupted, or in its opinion will in the immediate future materially disrupt, general securities markets in the United States; or (ii) if trading on any Trading Market shall have been suspended or materially limited, or minimum or maximum prices for trading shall have been fixed, or maximum ranges for prices for securities shall have been required by FINRA or by order of the Commission or any other government authority having jurisdiction, or (iii) if the United States shall have become involved in a new war or an increase in major hostilities, or (iv) if a banking moratorium has been declared by a New York State or federal authority, or (v) if a moratorium on foreign exchange trading has been declared which materially adversely impacts the United States securities markets, or (vi) if the Company shall have sustained a material loss by fire, flood, accident, hurricane, earthquake, theft, sabotage or other calamity or malicious act which, whether or not such loss shall have been insured, will, in the Representative's opinion, make it inadvisable to proceed with the delivery of the Securities, or (vii) if the Company is in material breach of any of its representations, warranties or covenants hereunder, or (viii) if the Representative shall have become aware after the date hereof of such a material adverse change in the conditions or prospects of the Company, or such adverse material change in general market conditions as in the Representative's judgment would make it impracticable to proceed with the offering, sale and/or delivery of the Securities or to enforce contracts made by the Underwriters for the sale of the Securities.

(b) Expenses. In the event this Agreement shall be terminated pursuant to Section 7.1(a), within the time specified herein or any extensions thereof pursuant to the terms herein, the Company shall be obligated to pay to the Representative its actual and accountable reasonable out of pocket expenses related to the transactions contemplated herein then due and payable, including the Representative's legal fees and disbursements of EGS up to \$100,000 in the aggregate (provided, however, that such expense cap in no way limits or impairs the indemnification and contribution provisions of this Agreement).

(c) Indemnification. Notwithstanding any contrary provision contained in this Agreement, any election hereunder or any termination of this Agreement, and whether or not this Agreement is otherwise carried out, the provisions of Article VI shall not be in any way effected by such election or termination or failure to carry out the terms of this Agreement or any part hereof.

7.2 Entire Agreement. The Transaction Documents, together with the exhibits and schedules thereto, the Pricing Disclosure Package, any Preliminary Prospectus, the Prospectus and the Prospectus Supplement, contain the entire understanding of the parties with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, oral or written, with respect to such matters, which the parties acknowledge have been merged into such documents, exhibits and schedules. Notwithstanding anything herein to the contrary, the Engagement Agreement, dated July 1, 2021, as amended on April 22, 2022 and September 6, 2022 ("Engagement Agreement"), by and between the Company and the Representative, shall continue to be effective and the terms therein, shall continue to survive and be enforceable by the Representative in accordance with its terms, provided that, in the event of a conflict between the terms of the Engagement Agreement and this Agreement, the terms of this Agreement shall prevail.

7.3 Notices. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be in writing and shall be deemed given and effective on the earliest of: (a) the time of transmission, if such notice or communication is delivered via e-mail attachment at the email address set forth on the signature pages attached hereto at or prior to 5:30 p.m. (New York City time) on a Trading Day, (b) the next Trading Day after the time of transmission, if such notice or communication is delivered via e-mail attachment at the e-mail address as set forth on the signature pages attached hereto on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (c) the second (2nd) Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service or (d) upon actual receipt by the party to whom such notice is required to be given. The address for such notices and communications shall be as set forth on the signature pages attached hereto.

7.4 Amendments; Waivers. No provision of this Agreement may be waived, modified, supplemented or amended except in a written instrument signed, in the case of an amendment, by the Company and the Representative. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right.

7.5 Headings. The headings herein are for convenience only, do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof.

7.6 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties and their successors and permitted assigns.

7.7 Governing Law. All questions concerning the construction, validity, enforcement and interpretation of the Transaction Documents shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal Proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement and any other Transaction Documents (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any Action or Proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such Action or Proceeding is improper or is an inconvenient venue for such Proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such Action or Proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an Action or Proceeding to enforce any provisions of the Transaction Documents, then, in addition to the obligations of the Company under Article VI, the prevailing party in such Action or Proceeding shall be reimbursed by the other party for its reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such Action or Proceeding.

7.8 Survival. The representations and warranties contained herein shall survive the Closing and the delivery of the Securities.

7.9 Execution. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to each other party, it being understood that the parties need not sign the same counterpart. In the event that any signature is delivered by e-mail delivery of a “.pdf” format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such “.pdf” signature page were an original thereof.

7.10 Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their commercially reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

7.11 Remedies. In addition to being entitled to exercise all rights provided herein or granted by law, including recovery of damages, the Underwriters and the Company will be entitled to specific performance under the Transaction Documents. The parties agree that monetary damages may not be adequate compensation for any loss incurred by reason of any breach of obligations contained in the Transaction Documents and hereby agree to waive and not to assert in any Action for specific performance of any such obligation the defense that a remedy at law would be adequate.

7.12 Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.

7.13 Construction. The parties agree that each of them and/or their respective counsel have reviewed and had an opportunity to revise the Transaction Documents and, therefore, the normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of the Transaction Documents or any amendments thereto. In addition, each and every reference to share prices and shares of Common Stock in any Transaction Document shall be subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement.

7.14 **WAIVER OF JURY TRIAL.** IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY ANY PARTY AGAINST ANY OTHER PARTY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY, THE PARTIES EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVE FOREVER ANY RIGHT TO TRIAL BY JURY.

(Signature Pages Follow)

If the foregoing correctly sets forth the understanding between the Underwriters and the Company, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement among the Company and the several Underwriters in accordance with its terms.

Very truly yours,

CHEMBIO DIAGNOSTICS, INC.

By: _____

Name:

Title:

Address for Notice:

555 Wireless Blvd.

Hauppauge, New York 11788

Attention: Larry Steenvoorden, Chief Financial Officer

Email: lsteenvoorden@chembio.com

Copy to:

K&L Gates LLP

300 South Tryon Street, Suite 1000

Charlotte, North Carolina 28202

Attention: Sean M. Jones

Email: sean.jones@klgates.com

Accepted on the date first above written.

CRAIG-HALLUM CAPITAL GROUP, LLC

As the Representative of the several

Underwriters listed on Schedule I

By: _____

Name:

Title:

Address for Notice:

222 South Ninth Street, Suite 350

Minneapolis, Minnesota 55402

Attention: Rick Hartfiel

Email: rick.hartfiel@craig-hallum.com

Copy to:

Ellenoff Grossman & Schole LLP

1345 Avenue of the Americas

New York, New York 10105

Attention: Robert F. Charron

Email: capmks@egsllp.com

SCHEDULE I

SCHEDULE OF UNDERWRITERS

<u>Underwriters</u>	<u>Closing Shares</u>	<u>Closing Pre-Funded Warrants</u>	<u>Closing Common Warrants</u>	<u>Closing Purchase Price</u>
Craig-Hallum Capital Group LLC				\$
Total				\$

SCHEDULE II

Orally Conveyed Pricing Information

1. Public Offering Price per Share and Accompanying Warrants:
2. Public Offering Price per Pre-Funded Warrant and Accompanying Warrants:
3. Exercise Price per Pre-Funded Warrant:
4. Number of Closing Shares Offered:
5. Number of Closing Pre-Funded Warrants Offered:
6. Number of Closing Warrants Offered:

COMMON STOCK PURCHASE WARRANT

CHEMBIO DIAGNOSTICS, INC.

Warrant Shares: _____

Issue Date: _____, 2022

THIS COMMON STOCK PURCHASE WARRANT (the “Warrant”) certifies that, for value received, _____ or its assigns (the “Holder”) is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the Common Warrants Initial Exercise Date (the “Initial Exercise Date”) and on or prior to 5:00 p.m. (New York City time) on the five (5) year anniversary of the Common Warrants Initial Exercise Date (the “Termination Date”) but not thereafter, to subscribe for and purchase from Chembio Diagnostics, Inc., a Nevada corporation (the “Company”), up to _____ shares (as subject to adjustment hereunder, the “Warrant Shares”) of Common Stock. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b). This Warrant shall initially be issued and maintained in the form of a security held in book-entry form and the Depository Trust Company or its nominee (“DTC”) shall initially be the sole registered holder of this Warrant, subject to a Holder’s right to elect to receive a Warrant in certificated form pursuant to the terms of the Warrant Agency Agreement, in which case this sentence shall not apply.

Section 1. Definitions. In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated in this Section 1:

“Affiliate” means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

“Authorization Increase” means, subject to Stockholder Approval, an increase in the number of authorized shares of Common Stock of the Company by the Company’s filing of the Certificate of Amendment with the Secretary of State of the State of Nevada and the acceptance thereof, provided that the amount of such increase shall be determined by the Board of Directors and shall be sufficient for the issuance of all of the Common Warrant Shares (as defined in the Underwriting Agreement) upon exercise in full of the Common Warrants (as defined in the Underwriting Agreement).

“Bid Price” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the bid price of the Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on the Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

“Board of Directors” means the board of directors of the Company.

“Business Day” means any day other than Saturday, Sunday or other day on which commercial banks in The City of New York are authorized or required by law to remain closed; provided, however, for clarification, commercial banks shall not be deemed to be authorized or required by law to remain closed due to “stay at home”, “shelter-in-place”, “non-essential employee” or any other similar orders or restrictions or the closure of any physical branch locations at the direction of any governmental authority so long as the electronic funds transfer systems (including for wire transfers) of commercial banks in The City of New York generally are open for use by customers on such day.

“Certificate of Amendment” means the amendment to the Company’s Articles of Incorporation that effects the Reverse Stock Split and/or the Authorization Increase.

“Commission” means the United States Securities and Exchange Commission.

“Common Stock” means the common stock of the Company, par value \$0.01 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

“Common Stock Equivalents” means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

“Common Warrants Initial Exercise Date” means the first date on which both Stockholder Approval and Nasdaq Stockholder Approval have been obtained and Authorization Increase and/or Reverse Stock Split are deemed effective in accordance with the laws of the State of Nevada.

“Exchange Act” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

“Exempt Issuance” means the issuance of (a) shares of Common Stock or options or other equity awards to employees, officers, consultants or directors of the Company (i) pursuant to any stock or option plan or other equity incentive plan duly adopted for such purpose by a majority of the non-employee members of the Board of Directors or a majority of the members of a committee of non-employee directors established for such purpose for services rendered to the Company or (ii) made as a material inducement to a grantee’s entry into employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4) (or any successor to such rule), (b) securities upon the exercise or exchange of or conversion of any securities issued pursuant to the Underwriting Agreement and/or other securities exercisable or exchangeable for or convertible into shares of Common Stock issued and outstanding on the issuance date of this Warrant, provided that such securities have not been amended since the issuance date of this Warrant to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities or to extend the term of such securities, and (c) securities issued pursuant to acquisitions or strategic transactions approved by a majority of the disinterested directors of the Company, provided that such securities are issued as “restricted securities” (as defined in Rule 144) and carry no registration rights that require or permit the filing of any registration statement in connection therewith until the earlier of (a) the date that is the six (6) month anniversary of the issuance date of this Warrant and (b) the Common Warrants Initial Exercise Date, and provided that any such issuance shall only be to a Person (or to the equity holders of a Person) which is, itself or through its subsidiaries, an operating company or an owner of an asset in a business synergistic with the business of the Company and shall provide to the Company additional benefits in addition to the investment of funds, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities.

“Nasdaq Stockholder Approval” means such approval as may be required by the applicable rules and regulations of the Nasdaq Stock Market (or any successor entity) from the stockholders of the Company with respect to the issuance of the Common Warrants (as defined in the Underwriting Agreement) and the Common Warrant Shares (as defined in the Underwriting Agreement) upon exercise thereof.

“Person” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“Registration Statement” means the Company’s registration statement on Form S-1 (File No. 333-267320).

“Reverse Stock Split Date” means the first date on which a Reverse Stock Split is deemed effective in accordance with the laws of the State of Nevada (it being understood that, if the Company effects a second reverse stock split of the Common Stock subsequent to the Reverse Stock Split Date, such second reverse stock split would not be a Reverse Stock Split Date for purposes of this Warrant).

“Reverse Stock Split” means, subject to Stockholder Approval, a reverse stock split of the outstanding shares of Common Stock that is effected by the Company’s filing of the Certificate of Amendment with the Secretary of State of the State of Nevada and the acceptance thereof, which reverse stock split shall have a ratio as determined by the Board of Directors and shall be sufficient for the issuance in full of the Common Warrant Shares (as defined in the Underwriting Agreement) upon exercise in full of the Common Warrants (as defined in the Underwriting Agreement).

“Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“Stockholder Approval” means such approval as may be required by the laws of the State of Nevada from the stockholders of the Company with respect to the Authorization Increase and/or the Reverse Stock Split, and such approval is deemed effective in accordance with the laws of the State of Nevada.

“Subsidiary” means any subsidiary of the Company and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

“Trading Day” means a day on which the Common Stock is traded on a Trading Market.

“Trading Market” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange (or any successors to any of the foregoing).

“Transfer Agent” means Action Stock Transfer Corp., the current transfer agent of the Company, with a mailing address of 2469 E. Fort Union Blvd., Suite 214, Salt Lake City, UT 84121, and any successor transfer agent of the Company.

“Trigger Date” means the sixth (6th) Trading Day immediately following the Reverse Stock Split Date.

“Underwriting Agreement” means the underwriting agreement, dated as of _____, 2022, among the Company and Craig-Hallum Capital Group LLC as representative of the underwriters named therein, as amended, modified or supplemented from time to time in accordance with its terms.

“VWAP” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on the Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

“Warrant Agency Agreement” means that certain warrant agency agreement, dated on or about the Initial Exercise Date, between the Company and the Warrant Agent.

“Warrant Agent” means the Transfer Agent and any successor warrant agent of the Company.

“Warrants” means this Warrant and other Common Stock purchase warrants issued by the Company pursuant to the Registration Statement.

Section 2. Exercise.

a) Exercise of Warrant. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company of a duly executed PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form annexed hereto (the “Notice of Exercise”). Within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the shares specified in the applicable Notice of Exercise by wire transfer or cashier’s check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date on which the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Business Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

The Holder and any such assignee, by acceptance of this Warrant, further acknowledge and agree that (i) an Authorization Increase or Reverse Stock Split may never occur, (ii) Nasdaq Stockholder Approval may never occur, (iii) as a result, the Common Warrants Initial Exercise Date may never occur and this Warrant may never become exercisable, and (iii) the Company shall have no liability or other obligation to the Holder or such assignee as a result thereof.

Notwithstanding the foregoing in this Section 2(a), a holder whose interest in this Warrant is a beneficial interest in certificate(s) representing this Warrant held in book-entry form through DTC (or another established clearing corporation performing similar functions), shall effect exercises made pursuant to this Section 2(a) by delivering to DTC (or such other clearing corporation, as applicable) the appropriate instruction form for exercise, complying with the procedures to effect exercise that are required by DTC (or such other clearing corporation, as applicable), subject to a Holder’s right to elect to receive a Warrant in certificated form pursuant to the terms of the Warrant Agency Agreement, in which case this sentence shall not apply.

b) Exercise Price. The exercise price per share of Common Stock under this Warrant shall be \$_____, subject to adjustment hereunder (the “Exercise Price”). In addition, on the Trigger Date, the Exercise Price shall be reduced, and only reduced, to the lesser of (i) the then Exercise Price and (ii) the lowest VWAP on any Trading Day during the five (5) Trading Day period immediately prior to the Trigger Date (the “Reset Exercise Price”, which shall thereafter be the new Exercise Price, subject to further adjustment hereunder, and such five (5) Trading Day period shall be referred to herein as the “Measurement Period”). The Company shall notify each Holder of the applicable adjustment to the Exercise Price as of such date and include the applicable adjusted number of Warrant Shares as of such date (each notice, a “Trigger Date Adjustment Notice”). For purposes of clarification, whether or not the Company provides a Trigger Date Adjustment Notice pursuant to this Section 2(b), each Holder shall only be required to pay the Reset Exercise Price with respect to such exercise, regardless of whether a Holder accurately refers to such price in any Notice of Exercise. If the aggregate Exercise Price paid by the Holder exceeds the amount that should have been paid based on the Reset Exercise Price, the Company shall promptly return any excess aggregate Exercise Price to the Holder. Any adjustment to the Exercise Price pursuant to this Section shall be effective retroactively to the first Trading Day during such Measurement Period.

c) Cashless Exercise. If at the time of exercise hereof there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of the Warrant Shares to the Holder, then this Warrant may also be exercised, in whole or in part, at such time by means of a “cashless exercise” in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing $[(A-B)(X)]$ by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of “regular trading hours” (as defined in Rule 600(b) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) the Bid Price of the Common Stock on the principal Trading Market as reported by Bloomberg L.P. as of the time of the Holder’s execution of the applicable Notice of Exercise if such Notice of Exercise is executed during “regular trading hours” on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of “regular trading hours” on a Trading Day) pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of “regular trading hours” on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised. The Company agrees not to take any position contrary to this Section 2(c).

Notwithstanding anything herein to the contrary, on the Termination Date, this Warrant shall be automatically exercised via cashless exercise pursuant to this Section 2(c).

d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder’s or its designee’s balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system (“DWAC”) if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by Holder or (B) this Warrant is being exercised via cashless exercise, and otherwise by physical delivery of a certificate, registered in the Company’s share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earliest of (i) two (2) Trading Days after the delivery to the Company of the Notice of Exercise, (ii) one (1) Trading Day after delivery of the aggregate Exercise Price to the Company and (iii) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company of the Notice of Exercise (such date, the “Warrant Share Delivery Date”). Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period following delivery of the Notice of Exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, “Standard Settlement Period” means the standard settlement period, expressed in a number of Trading Days, on the Company’s primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Exercise.

- ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.
- iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.
- iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of \$11,000 to cover a Buy-In with respect to an attempted exercise of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of \$10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder \$1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.
- v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.
- vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that, in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.
- vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within one Trading Day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% (or, upon election by a Holder prior to the issuance of any Warrants, 9.99%) of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) Adjustment Upon Issuance of Shares of Common Stock. If and whenever on or after the issue date of this Warrant (the “Issuance Date”), the Company issues or sells (or enters into any agreement to grant, issue or sell), or in accordance with this Section 3(b) is deemed to have issued or sold, any shares of Common Stock and/or Common Stock Equivalents (including the issuance or sale of shares of Common Stock owned or held by or for the account of the Company, but excluding any Exempt Issuance issued or sold or deemed to have been issued or sold) for a consideration per share (the “New Issuance Price”) less than a price equal to the Exercise Price in effect immediately prior to such issuance or sale or deemed issuance or sale (such Exercise Price then in effect is referred to herein as the “Applicable Price”) (the foregoing a “Dilutive Issuance”), then simultaneously with the consummation (or, if earlier, the announcement) of each such Dilutive Issuance, the Exercise Price then in effect shall be reduced to an amount equal to the New Issuance Price. For all purposes of the foregoing (including, without limitation, determining the adjusted Exercise Price and the New Issuance Price under this Section 3(b)), the following shall be applicable:

(i) Issuance of Options. If the Company in any manner grants or sells any rights, warrants or options to subscribe for or purchase shares of preferred stock and/or Common Stock or Common Stock Equivalents (“Options”) and the lowest price per share for which one share of Common Stock is at any time issuable upon the exercise of any such Option or upon conversion, exercise or exchange of any Common Stock Equivalents issuable upon exercise of any such Option or otherwise pursuant to the terms thereof is less than the Applicable Price, then such share of Common Stock shall be deemed to be outstanding and to have been issued and sold by the Company at the time of the granting or sale of such Option for such price per share. For purposes of this Section 3(b)(i), the “lowest price per share for which one share of Common Stock is issuable upon the exercise of any such Options or upon conversion, exercise or exchange of any Common Stock Equivalents issuable upon exercise of any such Option or otherwise pursuant to the terms thereof” shall be equal to the lower of (x) the sum of the lowest amounts of consideration (if any) received or receivable by the Company with respect to any one share of Common Stock upon the granting or sale of such Option, upon exercise of such Option and upon conversion, exercise or exchange of any Common Stock Equivalents issuable upon exercise of such Option or otherwise pursuant to the terms thereof and (y) the lowest exercise price set forth in such Option for which one share of Common Stock is issuable upon the exercise of any such Options or upon conversion, exercise or exchange of any Common Stock Equivalents issuable upon exercise of any such Option or otherwise pursuant to the terms thereof. Except as contemplated below, no further adjustment of the Exercise Price shall be made upon the actual issuance of such shares of Common Stock or of such Common Stock Equivalents upon the exercise of such Options or otherwise pursuant to the terms of or upon the actual issuance of such shares of Common Stock upon conversion, exercise or exchange of such Common Stock Equivalents. This Section 3(b)(i) shall not apply to any Exempt Issuance.

(ii) Issuance of Common Stock Equivalents. If the Company in any manner issues or sells any Common Stock Equivalents and the lowest price per share for which one share of Common Stock is at any time issuable upon the conversion, exercise or exchange thereof or otherwise pursuant to the terms thereof is less than the Exercise Price, then such share of Common Stock shall be deemed to be outstanding and to have been issued and sold by the Company at the time of the issuance or sale of such Common Stock Equivalents for such price per share. For the purposes of this Section 3(b)(ii), the “lowest price per share for which one share of Common Stock is issuable upon the conversion, exercise or exchange thereof or otherwise pursuant to the terms thereof” shall be equal to (1) the lower of (x) the sum of the lowest amounts of consideration (if any) received or receivable by the Company with respect to one share of Common Stock upon the issuance or sale of the Common Stock Equivalent and upon conversion, exercise or exchange of such Common Stock Equivalent or otherwise pursuant to the terms thereof and (y) the lowest conversion price set forth in such Common Stock Equivalent for which one share of Common Stock is issuable upon conversion, exercise or exchange thereof or otherwise pursuant to the terms thereof minus (2) the sum of all amounts paid or payable to the holder of such Common Stock Equivalent (or any other Person) upon the issuance or sale of such Common Stock Equivalent plus the value of any other consideration received or receivable by, or benefit conferred on, the holder of such Common Stock Equivalent (or any other Person). Except as contemplated below, no further adjustment of the Exercise Price shall be made upon the actual issuance of such shares of Common Stock upon conversion, exercise or exchange of such Common Stock Equivalents or otherwise pursuant to the terms thereof, and if any such issuance or sale of such Common Stock Equivalents is made upon exercise of any Options for which adjustment of the Warrant has been or is to be made pursuant to other provisions of this Section 3(b), except as contemplated below, no further adjustment of the Exercise Price shall be made by reason of such issuance or sale.

(iii) Change in Option Price or Rate of Conversion. If the purchase or exercise price provided for in any Options, the additional consideration, if any, payable upon the issue, conversion, exercise or exchange of any Common Stock Equivalents, or the rate at which any Common Stock Equivalents are convertible into or exercisable or exchangeable for shares of Common Stock increases or decreases at any time (other than proportional changes in conversion or exercise prices, as applicable, in connection with an event referred to in Section 3(a)), the Exercise Price in effect at the time of such increase or decrease shall be adjusted to the Exercise Price which would have been in effect at such time had such Options or Common Stock Equivalents provided for such increased or decreased purchase price, additional consideration or increased or decreased conversion rate, as the case may be, at the time initially granted, issued or sold. For purposes of this Section 3(b)(iii), if the terms of any Option or Common Stock Equivalents that was outstanding as of the Issuance Date are increased or decreased in the manner described in the immediately preceding sentence, then such Option or Common Stock Equivalents and the shares of Common Stock deemed issuable upon exercise, conversion or exchange thereof shall be deemed to have been issued as of the date of such increase or decrease. No adjustment pursuant to this Section 3(b) shall be made if such adjustment would result in an increase of the Exercise Price then in effect

(iv) Calculation of Consideration Received. If any Option and/or Common Stock Equivalents and/or Adjustment Right (as defined below) is issued in connection with the issuance or sale or deemed issuance or sale of any other securities of the Company (as determined by the Holder, the “Primary Security”, and such Option and/or Common Stock Equivalents and/or Adjustment Right, the “Secondary Securities” and together with the Primary Security, each a “Unit”), together comprising one integrated transaction, the aggregate consideration per share of Common Stock with respect to such Primary Security shall be deemed to be the lowest of (x) the purchase price of such Unit, (y) if such Primary Security is an Option and/or Common Stock Equivalent, the lowest price per share for which one share of Common Stock is at any time issuable upon the exercise or conversion of the Primary Security in accordance with Section 3(b)(i) or 3(b)(ii) above and (z) the lowest VWAP on any Trading Day during the five (5) Trading Day period (the “Adjustment Period”) immediately following the public announcement of such Dilutive Issuance (for the avoidance of doubt, (i) if such public announcement is released prior to the opening of the applicable Trading Market on a Trading Day, such Trading Day shall be the first Trading Day in such five Trading Day period and (ii) if this Warrant is exercised on any given Trading Day during any such Adjustment Period, solely with respect to such portion of this Warrant exercised on such applicable Trading Day, such applicable Adjustment Period shall be deemed to have ended on, and included, the Trading Day immediately prior to such Trading Day on which such exercise occurred). If any shares of Common Stock, Options or Common Stock Equivalents are issued or sold or deemed to have been issued or sold for cash, the consideration received therefor will be deemed to be the net amount of consideration received by the Company therefor. If any shares of Common Stock, Options or Common Stock Equivalents are issued or sold for a consideration other than cash, the amount of such consideration received by the Company will be the fair value of such consideration, except where such consideration consists of publicly traded securities, in which case the amount of consideration received by the Company for such securities will be the arithmetic average of the VWAPs of such security for each of the five (5) Trading Days immediately preceding the date of receipt. If any shares of Common Stock, Options or Common Stock Equivalents are issued to the owners of the non-surviving entity in connection with any merger in which the Company is the surviving entity, the amount of consideration therefor will be deemed to be the fair value of such portion of the net assets and business of the non-surviving entity as is attributable to such shares of Common Stock, Options or Common Stock Equivalents (as the case may be). The fair value of any consideration other than cash or publicly traded securities will be determined jointly by the Company and the Holder. If such parties are unable to reach agreement within ten (10) days after the occurrence of an event requiring valuation (the “Valuation Event”), the fair value of such consideration will be determined within five (5) Trading Days after the tenth (10th) day following such Valuation Event by an independent, reputable appraiser jointly selected by the Company and the Holder. The determination of such appraiser shall be final and binding upon all parties absent manifest error and the fees and expenses of such appraiser shall be borne by the Company. For purposes of hereof, “Adjustment Right” means any right granted with respect to any securities issued in connection with, or with respect to, any issuance or sale (or deemed issuance or sale in accordance with this Section 3(b)) of shares of Common Stock (other than rights of the type described in Section 3(c) and Section 3(d) hereof) that could result in a decrease in the net consideration received by the Company in connection with, or with respect to, such securities (including, without limitation, any cash settlement rights, cash adjustment or other similar rights).

(v) Record Date. If the Company takes a record of the holders of shares of Common Stock for the purpose of entitling them (A) to receive a dividend or other distribution payable in shares of Common Stock, Options or in Common Stock Equivalents or (B) to subscribe for or purchase shares of Common Stock, Options or Common Stock Equivalents, then such record date will be deemed to be the date of the issuance or sale of the shares of Common Stock deemed to have been issued or sold upon the declaration of such dividend or the making of such other distribution or the date of the granting of such right of subscription or purchase (as the case may be).

c) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the “Purchase Rights”), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, that, to the extent that the Holder’s right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

d) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a “Distribution”), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, that, to the extent that the Holder’s right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

e) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company or any Subsidiary, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50.01% or more of the outstanding Common Stock or 50.01% or more of the voting power of the common equity of the Company, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, merger or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires 50.01% or more of the outstanding shares of Common Stock or 50.01% or more of the voting power of the common equity of the Company (each a “Fundamental Transaction”), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration in the form of cash, securities, property or otherwise (the “Alternate Consideration”) receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. Notwithstanding anything to the contrary, in the event of a Fundamental Transaction, the Company or any Successor Entity (as defined below) shall, at the Holder’s option, exercisable at any time concurrently with, or within 30 days after, the consummation of the Fundamental Transaction (or, if later, the date of the public announcement of the applicable Fundamental Transaction), purchase this Warrant from the Holder by paying to the Holder an amount of cash equal to the Black Scholes Value (as defined below) of the remaining unexercised portion of this Warrant on the date of the consummation of such Fundamental Transaction; provided, however, that, if the Fundamental Transaction is not within the Company’s control, including not approved by the Company’s Board of Directors, Holder shall only be entitled to receive from the Company or any Successor Entity the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of this Warrant, that is being offered and paid to the holders of Common Stock of the Company in connection with the Fundamental Transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of Common Stock are given the choice to receive from among alternative forms of consideration in connection with the Fundamental Transaction; provided, further, that if holders of Common Stock of the Company are not offered or paid any consideration in such Fundamental Transaction, such holders of Common Stock will be deemed to have received common stock of the Successor Entity (which Entity may be the Company following such Fundamental Transaction) in such Fundamental Transaction. “Black Scholes Value” means the value of this Warrant based on the Black-Scholes Option Pricing Model obtained from the “OV” function on Bloomberg, L.P. (“Bloomberg”) determined as of the day of consummation of the applicable contemplated Fundamental Transaction for pricing purposes and reflecting (A) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Termination Date, (B) an expected volatility equal to the 100 day volatility obtained from the HVT function on Bloomberg (determined utilizing a 365 day annualization factor) as of the Trading Day immediately following the public announcement of the applicable contemplated Fundamental Transaction, (C) the underlying price per share used in such calculation shall be the highest VWAP during the period beginning on the Trading Day immediately preceding the public announcement of the applicable contemplated Fundamental Transaction (or the consummation of the applicable Fundamental Transaction, if earlier) and ending on the Trading Day of the Holder’s request pursuant to this Section 3(e), (D) a remaining option time equal to the time between the date of the public announcement of the applicable contemplated Fundamental Transaction and the Termination Date and (E) a zero cost of borrow. The payment of the Black Scholes Value will be made by wire transfer of immediately available funds (or such other consideration) within five Business Days of the Holder’s election (or, if later, on the date of consummation of the Fundamental Transaction). The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the “Successor Entity”) to assume in writing all of the obligations of the Company under this Warrant in accordance with the provisions of this Section 3(e) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall be added to the term “Company” under this Warrant (so that from and after the occurrence or consummation of such Fundamental Transaction, each and every provision of this Warrant referring to the “Company” shall refer instead to each of the Company and the Successor Entity or Successor Entities, jointly and severally), and the Successor Entity or Successor Entities, jointly and severally with the Company, may exercise every right and power of the Company prior thereto and the Successor Entity or Successor Entities shall assume all of the obligations of the Company prior thereto under this Warrant with the same effect as if the Company and such Successor Entity or Successor Entities, jointly and severally, had been named as the Company herein. For the avoidance of doubt, the Holder shall be entitled to the benefits of the provisions of this Section 3(e) regardless of (i) whether the Company has sufficient authorized shares of Common Stock for the issuance of Warrant Shares and/or (ii) whether a Fundamental Transaction occurs prior to the Initial Exercise Date.

f) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

g) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company (or any of its Subsidiaries) is a party, any sale or transfer of all or substantially all of its assets, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by email to the Holder at its last email address as it shall appear upon the Warrant Register of the Company, at least twenty (20) calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

h) Number of Warrant Shares. Simultaneous with any adjustment to the Exercise Price pursuant to Section 2(b) or Section 3(b) herein, the number of Warrant Shares that may be purchased upon exercise of this Warrant shall be increased proportionately, so that after such adjustment the aggregate Exercise Price payable hereunder for the adjusted number of Warrant Shares shall be the same as the aggregate Exercise Price in effect immediately prior to such adjustment (without regard to any limitations on exercise contained herein).

i) Voluntary Adjustment By Company. Subject to the rules and regulations of the Trading Market, the Company may, at any time while this Warrant is outstanding, reduce the then current Exercise Price to any amount and for any period of time deemed appropriate by the board of directors of the Company.

Section 4. Transfer of Warrant.

a) Transferability. Subject to compliance with applicable securities laws, this Warrant and all rights hereunder are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers an assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued. Notwithstanding anything herein to the contrary, the Company has no obligation to cause the Warrants to be listed on a national securities exchange or other trading market.

b) New Warrants. If this Warrant is not held in global form through DTC (or any successor depository), this Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Warrant Agent shall register this Warrant, upon records to be maintained by the Warrant Agent for that purpose (the “Warrant Register”), in the name of the record Holder hereof from time to time. The Company and the Warrant Agent may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 5. Miscellaneous.

a) No Rights as Stockholder Until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting any rights of a Holder to receive Warrant Shares on a “cashless exercise” pursuant to Section 2(c) or to receive cash payments pursuant to Section 2(d)(i) and Section 2(d)(iv) herein, in no event shall the Company be required to net cash settle an exercise of this Warrant.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.

d) Authorized Shares.

The Company covenants that, during the period the Warrant is exercisable, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Warrant (whether brought against a party hereto or their respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Warrant and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action, suit or proceeding to enforce any provisions of this Warrant, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for their reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. Without limiting any other provision of this Warrant, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) Notices. Any and all notices or other communications or deliveries to be provided by the Holders hereunder including, without limitation, any Notice of Exercise, shall be in writing and delivered personally, by e-mail, or sent by a nationally recognized overnight courier service, addressed to the Company, at 555 Wireless Blvd., Hauppauge, New York 11788, Attention: Larry Steenvoorden, Chief Financial Officer, email address: lsteenvoorden@chembio.com, or such other email address or address as the Company may specify for such purposes by notice to the Holders. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by e-mail, or sent by a nationally recognized overnight courier service addressed to each Holder at the e-mail address or address of such Holder appearing on the books of the Company. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the time of transmission, if such notice or communication is delivered via e-mail at the e-mail address set forth in this Section prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the time of transmission, if such notice or communication is delivered via e-mail at the e-mail address set forth in this Section on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company, on the one hand, and Holders or the beneficial owners of Warrants representing more than 50% of the Warrant Shares issuable under the Warrants then outstanding as of the date such consent is sought. Notwithstanding the foregoing, only if this Warrant is issued in certificated form pursuant to a Warrant Exchange (as defined in the Warrant Agency Agreement), this Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company, on the one hand, and the Holder of this Warrant, on the other hand.

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

o) Warrant Agency Agreement. If this Warrant is held in global form through DTC (or any successor depository), this Warrant is issued subject to the Warrant Agency Agreement. To the extent any provision of this Warrant conflicts with the express provisions of the Warrant Agency Agreement, the provisions of this Warrant shall govern and be controlling.

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

CHEMBIO DIAGNOSTICS, INC.

By: _____
Name:
Title:

NOTICE OF EXERCISE

TO: CHEMBIO DIAGNOSTICS, INC.

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

☐ in lawful money of the United States; or

☐ if permitted, the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

The Warrant Shares shall be delivered to the following DWAC Account Number:

[SIGNATURE OF HOLDER]

Name of
Investing
Entity:

Signature of Authorized
Signatory of Investing
Entity:

Name of
Authorized
Signatory:

Title of
Authorized
Signatory:

Date:

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name: _____
(Please Print)

Address: _____
(Please Print)

Phone Number:

Email Address: _____

Dated: _____, _____

Holder's
Signature: _____

Holder's
Address: _____



One Summerlin
1980 Festival Plaza Drive, Suite 900
Las Vegas, NV 89135-2958
TEL 702.471.7000
FAX 702.471.7070
www.ballardspahr.com

October 7, 2022

Chembio Diagnostics, Inc.
555 Wireless Blvd.
Hauppauge, New York 11788

**Re: Chembio Diagnostics, Inc.
Registration Statement on Form S-1**

Ladies and Gentlemen:

We have acted as counsel to Chembio Diagnostics, Inc., a Nevada corporation (the "Company"), in connection with the offer and sale of: (1) 40,476,190 shares (the "Shares") of the Company's common stock, \$0.01 par value per share ("Common Stock"); (2) warrants to purchase 50,595,238 shares of Common Stock (the "Warrants"); (3) pre-funded warrants to purchase 40,476,190 shares of Common Stock (the "Pre-Funded Warrants"); and (4) 91,071,429 shares of Common Stock issuable upon exercise of the Warrants and the Pre-Funded Warrants (the "Warrant Shares" and, together with the Shares, the Warrants and the Pre-Funded Warrants, the "Securities"), registered under the Company's Registration Statement on Form S-1 (Registration No. 333-267320), as filed with the United States Securities and Exchange Commission (the "Commission") on September 7, 2022 (the "Original Registration Statement"), under the Securities Act of 1933, as amended (the "Securities Act"), as amended by the Pre-Effective Amendment No. 1 to the Original Registration Statement, as filed with the Commission on September 28, 2022 (the "First Amendment") and the Pre-Effective Amendment No. 2 to the Original Registration Statement, as filed with the Commission on the date first referenced above (together with the Original Registration Statement and First Amendment, the "Registration Statement").

We have examined executed original or counterparts of the following documents: (a) the Articles of Incorporation of the Company (formerly Trading Solutions.Com, Inc.) filed with the Nevada Secretary of State on May 14, 1999, as amended (the "Articles"); (b) the Amended and Restated Bylaws of the Company; (c) the resolutions adopted by the Company's board of directors approving the Registration Statement and authorizing the offer and sale of the Securities, amongst other items (the "Directors' Resolutions"); (d) the Registration Statement; (e) the Underwriting Agreement to be entered into by the Company and Craig-Hallum Capital Group LLC, as representative of the several underwriters to be named therein (the "Underwriting Agreement"); (f) the Warrant Agency Agreement to be entered into by the Company and Action Stock Transfer Corp., as warrant agent; (g) the form of Warrant; and (h) the form of Pre-Funded Warrant. We have also examined such corporate records and other agreements, documents and instruments, and such certificates or comparable documents of public officials and officers and representatives of the Company and have made such inquiries of such officers and representatives and have considered such matters of law as we have deemed appropriate as the basis for the opinion hereinafter set forth.

In delivering this opinion, we have assumed the genuineness of all signatures, the legal capacity of natural persons, the authenticity of all documents submitted to us as originals, the conformity to originals of all documents submitted to us as certified, photostatic or conformed copies, the authenticity of originals of all such latter documents, and the accuracy and completeness of all records, information and statements submitted to us by officers and representatives of the Company. In making our examination of documents executed by parties other than the Company, we have assumed that such parties had the power, corporate or other, to enter into and perform all obligations thereunder and have also assumed the due authorization of all requisite action, corporate or other, and execution and delivery by such parties of such documents and the validity and binding effect thereof with respect to such parties.

The opinion expressed below is based on the assumption that: (a) the Registration Statement and any amendments or supplements thereto (including any post-effective amendments) have been, or will be, filed by the Company with the Commission and will be effective at the time that any of the Securities are issued, and that persons acquiring the Securities will receive a prospectus containing all of the information required by Part I of the Registration Statement before acquiring such Securities; (b) the Securities will continue to be duly and validly authorized on the dates that the Securities are issued, and, upon the issuance of any of the Securities, the total number of shares of Common Stock of the Company issued and outstanding, after giving effect to such issuance of such Securities, will not exceed the total number of shares of Common Stock that the Company is then authorized to issue under the Articles, as may be further amended; and (c) the Securities will issued and sold in compliance with the Securities Act and the securities or “Blue Sky” laws of various states.

On the basis of the foregoing, and subject to the qualifications, assumptions, and limitations set forth herein, we are of the opinion that:

1. With respect to the offer and sale of the Shares and the Warrant Shares by the Company pursuant to the Registration Statement (the “Offered Shares”), (a) the issuance and sale of the Offered Shares has been duly authorized and (b) when, as and if (i) certificates representing the Offered Shares have been manually signed by an authorized officer of the transfer agent and registrar for the Common Stock and registered by such transfer agent and registrar, and delivered to the purchasers thereof, and (ii) the Company receives consideration per share of the Offered Shares in such amount as contemplated by the Underwriting Agreement and, with respect to the Warrant Shares, the Warrant and the Pre-Funded Warrant, the Offered Shares will be validly issued, fully paid and non-assessable; and

2. With respect to the offer and sale of the Warrants and the Pre-Funded Warrants by the Company pursuant to the Registration Statement (the “Offered Warrants”), (a) the issuance and sale of the Offered Warrants has been duly authorized and (b) when, as and if, (i) the Offered Warrants have been duly executed and countersigned in accordance with the Underwriting Agreement and the Warrant Agency Agreement and issued and sold as contemplated by the Registration Statement, and (ii) the Company has received consideration for the Offered Warrants provided for in the Underwriting Agreement, then such Offered Warrants will be validly issued.

This opinion is limited to the present laws of the State of Nevada. We express no opinion as to the laws of any other jurisdiction, of the United States of America, or to any state “Blue Sky” laws and regulations, and no opinion regarding the statutes, administrative decisions, rules and regulations or requirements of any county, municipality or subdivision or other local authority of any jurisdiction.

We do not undertake to advise you or anyone else of any changes in the opinions expressed herein resulting from changes in law, changes in fact or any other matters that hereafter might occur or be brought to our attention.

We hereby consent to the filing of this opinion letter as an exhibit to the Company’s Registration Statement and to the reference to us under the heading “Legal Matters” in the prospectus forming part of the Registration Statement. In giving such consent, we do not admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations promulgated thereunder.

Very truly yours,

Ballard Spahr LLP

The logo for K&L GATES, featuring the text "K&L GATES" in a white, sans-serif font on a dark blue rectangular background.

October 7, 2022

CHEMBIO DIAGNOSTICS, INC.
555 Wireless Boulevard
Hauppauge, New York 11788

Re: Chembio Diagnostics, Inc.
Registration Statement on Form S-1

Ladies and Gentlemen:

We have acted as counsel to Chembio Diagnostics, Inc., a Nevada corporation (the “Company”), in connection with the Registration Statement on Form S-1 (the “Registration Statement”) filed with the U.S. Securities and Exchange Commission (the “Commission”) under the Securities Act of 1933, as amended (the “Securities Act”), for the registration of up to (i) 40,476,190 shares of common stock, par value \$0.01 per share (“Common Stock”), of the Company, (ii) 50,595,238 warrants to purchase shares of Common Stock (the “Warrants”), (iii) 40,476,190 pre-funded warrants to purchase shares of Common Stock (the “Pre-Funded Warrants”), and (iv) shares of Common Stock issuable from time to time upon exercise of the Warrants and the Pre-Funded Warrants, pursuant to an Underwriting Agreement to be entered into by the Company and Craig-Hallum Capital Group LLC (the “Underwriting Agreement”).

This opinion letter is rendered in accordance with the requirements of Item 601(b)(5) of Regulation S–K under the 1933 Act, and no opinion is expressed herein as to any matter.

This opinion letter has been prepared and should be understood in accordance with the Statement of Opinion Practices, 74 Bus. Law. 807 (2019).

In connection with rendering the opinions set forth below, we have examined

- a.) the Registration Statement;
- b.) the form of Underwriting Agreement;
- c.) the form of Warrant Agency Agreement;
- d.) the form of Warrant; and
- e.) the form of Pre-Funded Warrant.

We have made such investigation of law as we have deemed appropriate. We have examined and relied upon certificates of public officials and such other documents and instruments as we have deemed necessary or advisable for the purpose of rendering our opinion.

K&L GATES LLP
300 S. TRYON STREET CHARLOTTE NC 28202
T +1 704 331 7400 F +1 704 353 3106 kl gates.com

For the purposes of this opinion letter, we have made assumptions that are customary in opinion letters of this kind, including the assumptions that each document submitted to us is accurate and complete, that each such document that is an original is authentic, that each such document that is a copy conforms to an authentic original, and that all signatures on each such document are genuine. We have further assumed the legal capacity of natural persons. Additionally, for purposes of this opinion letter, we have assumed that: (i) the Company is an entity duly organized and validly existing under the laws of the jurisdiction of its organization, (ii) the Company has power and authority to execute, deliver and perform, and has duly authorized, and will execute and deliver, each of the Underwriting Agreement, the Warrant Agency Agreement, all Warrant Certificates and all Pre-Funded Warrant Certificates, (iii) the execution, delivery and performance by the Company of the Underwriting Agreement, the Warrant Agency Agreement, each Warrant Certificate and each Pre-Funded Warrant Certificate do not and will not contravene the Company's articles of incorporation or bylaws and (iv) the Company will have sufficient authorized and unissued shares of its Common Stock upon any issuance of Common Stock upon the exercise of the Warrants and Pre-Funded Warrants. We have not verified any of the foregoing assumptions.

Our opinion set forth below is limited to the laws of the State of New York. We note that Ballard Spahr LLP, special Nevada counsel to the Company, has furnished its opinion, dated the date hereof and filed as an exhibit to the Registration Statement, with respect to certain matters of Nevada law.

Based on the foregoing, and subject to the foregoing and to the additional qualifications and other matters set forth below, it is our opinion that when the Registration Statement becomes effective under the Securities Act and when the Warrants and Pre-Funded Warrants are issued, delivered and paid for as contemplated by the Underwriting Agreement, the Warrant Agency Agreement and the Registration Statement, the Warrants and the Pre-Funded Warrants will constitute the valid and legally binding obligations of the Company, enforceable against the Company in accordance with their respective terms.

Our opinion is subject to and limited by (i) the effect of bankruptcy, insolvency, fraudulent conveyance, reorganization, receivership, moratorium or other similar laws relating to or affecting the rights and remedies of creditors or secured parties generally, (ii) the application of general principles of equity (regardless of whether considered in a proceeding in equity or at law), including, without limitation, the possible unavailability of specific performance, injunctive relief or another equitable remedy, (iii) concepts of materiality, reasonableness, good faith and fair dealing, and (iv) the public policy against indemnifications for violations of securities law.

We hereby consent to the filing of this opinion letter with the Commission as Exhibit 5.1 to the Registration Statement and to the reference to this firm under the heading “Legal Matters” in the prospectus forming a part thereof. In giving this consent, we do not thereby admit that we are experts with respect to any part of the Registration Statement or prospectus within the meaning of the term “expert” as used in Section 11 of the 1933 Act or the rules and regulations promulgated thereunder by the Commission, nor do we admit that we are within the category of persons whose consent is required under Section 7 of the 1933 Act or the rules and regulations of the Commission promulgated thereunder.

Yours truly,

/s/ K&L Gates LLP

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the reference to our firm under the caption "Experts" and to the use of our report dated March 3, 2022, in Amendment Number 2 to the Registration Statement (Form S-1 No. 333-267320) and related Prospectus of Chembio Diagnostics, Inc. dated October 7, 2022.

/s/ Ernst & Young LLP

Jericho, New York
October 7, 2022

Calculation of Filing Fee Tables

.....Form S-1.....
(Form Type)

.....Chembio Diagnostics Inc.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered and Carry Forward Securities

	Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price (1)	Fee Rate	Amount of Registration Fee	Carry Forward Form Type	Carry Forward File Number	Carry Forward Initial effective date	Filing Fee Previously Paid In Connection with Unsold Securities to be Carried Forward
Newly Registered Securities												
Fees to Be Paid	Equity	Common Stock, par value \$0.01 per share and accompanying Warrants (2)	457(o)	—	—	\$17,000,000	0.0001102	\$1,873.40				
	Equity	Shares of Common Stock, par value \$0.01 per share (2)	457(o)	—	—	—	—	—				
	Equity	Pre-Funded Warrants and accompanying Warrants (2) (3)	457(g)	—	—	—	—	—				
	Equity	Pre-Funded Warrants	457(g)	—	—	—	—	—				
	Equity	Warrants (3)	457(g)	—	—	—	—	—				
	Equity	Shares of Common Stock issuable upon exercise of Warrants	457(o)	—	—	\$21,250,000	0.0001102	\$2,341.75				
	Equity	Shares of Common Stock issuable upon exercise of Pre-Funded Warrants (2) (3)	457(o)	—	—	—	—	—				
						\$38,250,000	0.0001102	\$4,215.15				
Fees Previously Paid	—	—	—	—		—		\$4,144.80				
Carry Forward Securities												
Carry Forward Securities	—	—	—	—		—			—	—	—	—
	Total Offering Amounts					\$38,250,000		\$4,215.15				
	Total Fees Previously Paid							\$4,144.80				
	Total Fee Offsets							—				
	Net Fees Due							\$70.35				

(1) Pursuant to Rule 416(a) under the Securities Act of 1933, as amended (the “Securities Act”), this registration statement shall also cover an indeterminate number of shares that may be issued and resold resulting from stock splits, stock dividends or similar transactions.

(2) The proposed maximum aggregate offering price of the common stock will be reduced on a dollar-for-dollar basis based on the offering price of any

pre-funded warrants issued in the offering, and the proposed maximum aggregate offering price of the pre-funded warrants to be issued in the offering will be reduced on a dollar-for-dollar basis based on the offering price of any common stock issued in the offering. Accordingly, the proposed maximum aggregate offering price of the common stock, warrants and pre-funded warrants (including the common stock issuable upon exercise of the pre-funded warrants), if any, is \$17,000,000.

- (3) No fee pursuant to Rule 457(g) of the Securities Act.
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