As filed with the Securities and Exchange Commission on September 7, 2022

Registration No. 333-

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

FORM S-1
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

CHEMBIO DIAGNOSTICS, INC.

(Exact name of registrant as specified in its charter)

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

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	**Robert F. Charron**
K&L Gates LLP	**Ellenoff Grossman & Schole LLP**
300 South Tryon St, Suite 1000	**1345 Avenue of the Americas**
Charlotte, NC 28202	**New York, NY 10105**
(704) 331-7406	**(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	☐	Accelerated filer	☑
Non-accelerated filer	☐	Smaller reporting company	☑
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 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 September 7, 2022

PRELIMINARY PROSPECTUS

CHEMBIO DIAGNOSTICS, INC.

Shares of Common Stock
Warrants to Purchase up to Shares of Common Stock
and Pre-Funded Warrants to Purchase up to Shares of Common Stock

We are offering shares of common stock, par value $0.01 per share, together with warrants to purchase 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 warrant to purchase one share of common stock. 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 warrant is $, which is the last reported sale price of our common stock on The Nasdaq Capital Market on , 2022.

The warrants will be exercisable at any time after we receive approval from our stockholders (the "Stockholder Approval") to increase the number of shares of common stock we are authorized to issue and/or to effect a reverse stock split of our outstanding shares of common stock, each in an amount to be determined by the board of directors (an increase in authorized shares or a reverse stock split, each a "Capital Event"). Each warrant will be exercisable on the date of the Capital Event for a term of five years from the date of the Capital Event, and has an exercise price of $ per share.

We are also offering pre-funded warrants to purchase up to 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 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 warrant described above that is being issued with each share of common stock. The assumed public offering price for each such pre-funded warrant and accompanying warrant is $, which is equal to the assumed public offering price for a share of common stock and accompanying warrant 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 the accompanying warrant 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.

Our common stock is listed on The Nasdaq Capital Market under the symbol "CEMI." On , 2022, the last reported sale price of our common stock on The Nasdaq Capital Market was $ per share. 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 Warrant(1)	Per Pre-Funded Warrant and Warrant(1)	Total
Public offering price	$	$	$
Underwriting discounts and commissions(2)	$	$	$
Proceeds, before expenses, to us(3)	$	$	$

(1) The public offering price corresponds to (a) a public offering price per share of $ and a public offering price per warrant of $ and (b) a public offering price per pre-funded warrant of $ and a public offering price per warrant of $.

(2) See "Underwriting" beginning on page 60 for additional information regarding underwriting compensation.

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

We have granted the underwriter an option for a period of 30 days from the date of this prospectus to purchase up to additional shares of common stock and/or warrants to purchase additional shares of common stock in any combination thereof, at the public offering price per share or warrant, less the underwriting discounts and commissions.

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.

TABLE OF CONTENTS

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 8 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 8 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 Middle East, and Africa (the"EMEA"), 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 September 6, 2022, we have sold 14,372,538 shares of common stock, for gross proceeds of $44.7 million and net proceeds, after giving effect to commissions and other transaction costs, of $42.6 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 $3.9 million and net proceeds of $3.8 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 of 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 of settlement, or that the court will approve the terms of a stipulation of settlement.

Liquidity Issues

We may experience significant liquidity issues in the future, and, as of August 31, 2022, we had approximately $22.3 million in cash and cash equivalents. On September 30, 2022, we are required to begin 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. For the next four quarters, 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 shares of common stock and warrants to purchase up to shares of common stock, or pre-funded warrants to purchase shares of common stock and warrants to purchase shares of common stock. 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 exercise price of $ per share of common stock. The warrants will not be exercisable until we effect a Capital Event in an amount sufficient to permit exercise in full of the warrants. The warrants will be exercisable on the date of the Capital Event, 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 Capital Event. See "Description of Securities". We are also registering 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 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 warrant is $, which is the assumed public offering price of one share of common stock and accompanying warrant less $0.01, and the exercise price of the pre-funded warrant is $0.01. For each pre-funded warrant and accompanying warrant 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.
Common stock outstanding before this offering	shares of common stock.
Common stock outstanding after this offering	shares of common stock (assuming all of the pre-funded warrants and none of the warrants issued in this offering are exercised).

Use of proceeds	We estimate the net proceeds from this offering will be approximately $ 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. We intend to use the net proceeds from this offering to repay amounts owed to the Lender under the Credit Agreement. Remaining net proceeds, if any, will be used for working capital and general corporate purposes. See "Use of Proceeds" on page 43 of this prospectus.
Risk factors	See "Risk Factors" beginning on page 8 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.
Nasdaq Symbol	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.
Transfer Agent	Action Stock Transfer Corp.

The number of shares of our common stock to be outstanding after this offering is based on 33,986,729 shares of our common stock outstanding as of August 31, 2022, and excludes:

- 3,692,739 shares issuable upon the exercise of options with a weighted-average exercise price of $2.20 per share;
- 1,740,012 shares underlying restricted and performance stock units;
- 129,627 shares reserved for future issuance under our 2019 Omnibus Incentive Plan; and
- 538,577 shares reserved for future issuance pursuant to inducement grants made outside of our equity incentive plans.

Unless otherwise indicated, all information contained in this prospectus assumes:

- 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 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;

- 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 Capital Event, 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 may not have any value.

The warrants offered by this prospectus have an exercise price of $ per share and will be exercisable for five years from the date of effectiveness of the Capital Event. 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 with any additional net proceeds being used for working capital and general corporate purposes. 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 $0.45 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 a deficiency letter from the Listing Qualifications Department of The Nasdaq Stock Market notifying us that, because the bid price for shares of our common stock had closed below the $1.00 per share minimum Bid Price Requirement for thirty consecutive business days, our common stock may be subject to delisting by as early as October 3, 2022 if we are unable to regain compliance with the Bid Price Requirements or to qualify for an additional period to regain compliance by such date, all as described in more detail in the Current Report on Form 8-K filed with the SEC on April 7, 2022. The closing price of our common stock was $ on , 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.

We do not have enough authorized shares of common stock to issue shares upon the exercise of all of the warrants offered hereunder, and we require approval from our stockholders, or the Stockholder Approval, to increase the number of shares of common stock we are authorized to issue or to effect a reverse stock split to reduce the number of shares of common stock outstanding, which we refer to (in either case) as a Capital Event, and the subsequent filing of a certificate of amendment to our articles of incorporation with the Secretary of State of the State of Nevada to effect such Capital Event in order to have a sufficient number of shares of common stock available for issuance upon exercise of all of the warrants offered hereunder. There is no assurance that the Stockholder Approval will be obtained, in which case the warrants would be non-exercisable, which would materially and adversely impact the rights of the warrant holders.

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. As a result, the warrants will not be exercisable until we obtain Stockholder Approval to effect a Capital Event in an amount sufficient to permit full exercise of the warrants. We currently have 100,000,000 shares of common stock authorized under our articles of incorporation, and, as of August 31, 2022, a total of 33,986,729 shares were outstanding and shares will be outstanding after giving effect to this offering (assuming no exercise of the underwriter's over-allotment option and exercise in full of the pre-funded warrants issued in this offering). We do not have sufficient authorized shares, however, for the warrants to be immediately exercised. Accordingly, the warrants may not be exercised until we receive Stockholder Approval for a Capital Event and we effect such Capital Event by filing a certificate of amendment to our articles of incorporation with the Secretary of State of the State of Nevada. If our shareholders do not approve a Capital Event, we will be obligated to continue to hold meetings of our shareholders to solicit approval until the Capital Event is approved. The Company has agreed to use reasonable best efforts to call a special meeting to obtain Stockholder Approval for a Capital Event, and engage a proxy solicitation firm to solicit proxies in connection with obtaining such Stockholder Approval. There is no assurance we will be able to obtain Stockholder Approval in which case the warrant holders would not be able to exercise their warrants and the warrants would have little or no value.

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

We currently have 100,000,000 shares of common stock authorized under our articles of incorporation, and, as of August 31, 2022, a total of 33,986,729 shares were outstanding and shares will be outstanding after giving effect to this offering (assuming no exercise of the underwriter's over-allotment option but exercise in full of the pre-funded warrants). As a result, after giving effect to this offering, we will have issued 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 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 Steenvorden.

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.

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 a deficiency letter from the Listing Qualifications Department of The Nasdaq Stock Market notifying us that, because the bid price for shares of our common stock had closed below the $1.00 per share minimum Bid Price Requirement for thirty consecutive business days, our common stock may be subject to delisting by as early as October 3, 2022 if we have been unable to regain compliance with the Bid Price Requirements or to qualify for an additional period to regain compliance by such date, all as described in more detail in the Current Report on Form 8-K we filed with the SEC on April 7, 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.

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. For the next four quarters, 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;

- 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.

As appropriate, we intend to file patent applications and obtain patent protection for our proprietary technology. These patent applications and patents will cover, as applicable, compositions of matter for our products, methods of making those products, methods of using those products and apparatuses relating to the use or manufacture of those products.

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

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

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

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

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

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

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

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

the protection of our patents or to liability in the form of past royalty payments, penalties, reimbursement of litigation costs and legal fees, special and punitive damages, or future royalty payments, any of which could significantly affect our future earnings.

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

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

Risks Related to Our Reliance on Third Parties

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

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

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

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

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

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

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

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

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

Our U.S. government contracts require compliance with numerous laws and increase our risk and liability.

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

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

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

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

Risks Related to Regulations

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

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

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

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

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

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

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

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

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

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

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

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

Regulations of the FDA and other federal, state and foreign regulatory agencies have significant effects on many aspects of our operations and the operations of our suppliers and distributors, including packaging, labeling, manufacturing, adverse event reporting, recalls, distribution, storage, advertising, promotion and record keeping. We are subject to routine inspection by the FDA and other agencies to determine compliance with FDA regulatory requirements, including Quality System Regulations ("QSRs"), in the United States and other applicable regulations worldwide, including International Organization for Standardization ("ISO") standards. We believe that our facilities and procedures are in material compliance with the FDA requirements and ISO standards, but the regulations may be unclear and are subject to change, and we cannot be sure that the FDA or other regulators will agree with our compliance with these requirements. The FDA and foreign regulatory agencies may require post-marketing testing and surveillance to monitor the performance of approved or cleared products or impose conditions on any product clearances or approvals that could restrict the distribution or commercial applications of those products. Regulatory agencies may impose restrictions on our or our

distributors' advertising and promotional activities or preclude these activities altogether if a noncompliance is believed to exist. In addition, the subsequent discovery of previously unknown problems with a product may result in restrictions on the product or additional regulatory actions, including withdrawal of the product from the market.

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

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

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

We believe that our existing products and procedures are in material compliance with all applicable FDA regulations, ISO requirements, and other applicable regulatory requirements, but the regulations regarding the manufacture and sale of our products and QSR, ISO and other requirements may be unclear and are subject to change. Newly promulgated regulations could require changes to our products, necessitate additional clinical trials or procedures, or make it impractical or impossible for us to market our products for certain uses, in certain markets, or at all. The FDA and other regulatory authorities also have the ability to change the requirements for obtaining product approval and/or impose new or additional requirements as part of the approval process. These changes or new or additional requirements may occur after the completion of substantial clinical work and other costly development activities. The implementation of such changes or new or additional requirements may result in additional clinical trials and substantial additional costs and could delay or make it more difficult or complicated to obtain approvals and sell our products. In addition, the FDA may revoke an EUA under which our products are sold, where it is determined that the underlying health emergency no longer exists or warrants such authorization. Such revocation would preclude the sale of our affected products unless and until a further regulatory approval or authorization is obtained. For example, on June 16, 2020, the FDA revoked the EUA it had granted for the DPP COVID-19 IgM/IgG System based in part on performance criteria identified after the EUA was granted on April 14, 2020, and since that time we expended resources to design the new COVID-19 Diagnostic Test Systems, including the DPP Respiratory Antigen Panel. We do not currently have an EUA from the FDA for any of the COVID-19 Diagnostic Test Systems. We cannot anticipate or predict the effect, if any, that these types of changes might have on our business, financial condition or results of operations.

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

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

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

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

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

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

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

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

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

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

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

Healthcare reform initiatives will continue to be proposed, and may reduce healthcare related funding in an effort. It is impossible to predict the ultimate content and timing of any healthcare reform legislation and its resulting impact on us. If significant reforms are made to the healthcare system in the United States, or in other jurisdictions, those reforms may increase our costs or otherwise negatively 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 September 6, 2022, we have sold 14,372,538 shares of common stock, for gross proceeds of $44.7 million and net proceeds, after giving effect to commissions and other transaction costs, of $42.6 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 $3.9 million and net proceeds of $3.8 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.

In order to raise additional capital, we may in the future seek to offer pursuant to the ATM Agreement additional shares of common stock for up to $15.3 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 $ million, assuming a public offering price of $ per share of common stock and accompanying warrant, which was the last reported sale price per share of our common stock on The Nasdaq Capital Market on , 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. Under the Credit Agreement, no principal repayments were due prior to September 30, 2022. 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.

We intend to use any additional net proceeds from this offering for working capital and general corporate purposes.

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 shares of common stock and accompanying warrants to purchase up to shares of common stock in this offering, at an assumed public offering price of $ per share and accompanying warrant, which was the last reported sale price of our common stock on The Nasdaq Capital Market on , 2022, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, and assuming no exercise of the warrants being issued in this offering.

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	$
Current portion of long-term debt	3,000	
Finance lease liabilities	74	
Long-term finance lease liabilities	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 shares issued and outstanding pro forma	303	
Additional paid-in capital	167,041	
Accumulated deficit	(146,747)	
Treasury Stock, 48.057 shares at cost, at June 30, 2022, actual and pro forma	(207)	
Accumulated other comprehensive loss	(486)	
Total stockholders' equity	$ 19,905	$
Total liabilities and stockholders' equity	$ 56,056	$

(1) Each $0.10 increase or decrease in the assumed public offering price per share of common stock and accompanying warrant of $, which was the last reported sale price of our common stock on The Nasdaq Capital Market on , 2022, would increase (decrease) the pro forma amount of each of cash and cash equivalents, current portion of long-term debt, long-term debt, net and stockholders' equity by $ million, 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 1,000,000 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 (decrease) the pro forma amount of each of cash and cash equivalents, current portion of long-term debt, long-term debt, net and stockholders' equity by $ million, 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:

- 3,692,739 shares issuable upon the exercise of options with a weighted-average exercise price of $2.20 per share;
- 1,740,012 shares underlying restricted and performance stock units;
- 129,627 shares reserved for future issuance under our 2019 Omnibus Incentive Plan; and
- 538,577 shares reserved for future issuance pursuant to inducement grants made outside of our equity incentive plans.

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 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 warrant, assuming no value is attributable to the warrant, and the 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 shares of common stock and accompanying warrants at an assumed public offering price per share of common stock and accompanying warrant of $, which was the last reported sale price of common stock on The Nasdaq Capital Market on , 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 $ million, or $ per share. This represents an immediate increase in net tangible book value of $ per share to our existing stockholders and an immediate dilution in as adjusted net tangible book value of $ per share 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	$
Net tangible book value per share as of June 30, 2022	$0.66
Pro Forma increase in net tangible book value per share attributable to investors purchasing in this offering	$
As adjusted net tangible book value per share as of June 30, 2022 after this offering	$
Dilution per share to new investors purchasing in this offering	$

Each $0.10 increase (decrease) in the assumed public offering price of $ per share and accompanying warrant, which is the last reported sale price of our common stock on The Nasdaq Capital Market on , 2022, would increase (decrease) as adjusted net tangible book value per share by $ per share and dilution to new investors by $ per share, 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 1,000,000 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 as adjusted net tangible book value per share by $ per share and decrease dilution to new investors by $ per share and a decrease of 1,000,000 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 as adjusted net tangible book value per share by $ per share and increase dilution to new investors by $ 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 30,104,986 shares of our common stock outstanding as of June 30, 2022 and does not include:

- 3,692,739 shares issuable upon the exercise of options with a weighted-average exercise price of $2.20 per share;
- 1,740,012 shares underlying restricted and performance stock units;
- 129,627 shares reserved for future issuance under our 2019 Omnibus Incentive Plan; and
- 538,577 shares reserved for future issuance pursuant to inducement grants made outside of our equity incentive plans.

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 shares of common stock, together with warrants to purchase up to shares of common stock. Each warrant has an exercise price of $ per 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 Approval to effect a Capital Event in an amount sufficient to permit exercise in full of the warrants. In the event we never obtain Stockholder Approval, 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 warrant 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 , 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 August 31, 2022, there were outstanding (a) 33,986,729 shares of common stock held by approximately stockholders of record, (b) options exercisable, upon vesting, to acquire 3,692,739 shares of common stock and (c) 1,740,012 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.

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.

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 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, at our 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.

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 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 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, at our 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. A pre-funded warrant may be transferred by a holder, upon surrender of the pre-funded warrant, properly endorsed (by the holder executing an assignment in the form attached to the pre-funded warrant). 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 Approval to effect a Capital Event in an amount sufficient to permit exercise in full of the warrants. 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. 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

Each warrant represents the right to purchase one share of common stock at an exercise price equal to $, subject to adjustment and limitations as described below. The warrants will not be exercisable until we obtain Stockholder Approval to effect a Capital Event in an amount sufficient to permit exercise in full of the warrants. After a Capital Event takes effect, each warrant may be exercised through and including the close of business on the fifth anniversary of the date of effectiveness of the Capital Event. Each warrant will have a cashless exercise right in the event that the shares of common stock underlying such warrants are not covered by an effective registration statement at the time of such exercise.

Exercisability

After a Capital Event takes effect, the 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). No fractional shares of common stock will be issued in connection with the exercise of a warrant. In lieu of fractional shares, we will, at our 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. 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 of 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, at our 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. 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

The exercise price and the number of shares underlying the 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 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 each 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 Warrants have been issued in registered form under a warrant agreement between Action Stock Transfer Corp., as warrant agent, and us. The warrant agreement provides that the terms of the warrants may be amended with the consent of the Company and the Holder (as defined therein). You should review a copy of the warrant agreement, which is filed as an exhibit to the registration statement of which this prospectus is a part, for a complete description of the terms and conditions applicable to the warrants.

Following the Capital Event, Warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the warrant agent, with the exercise form on the reverse side of the warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price (or on a cashless basis, if applicable), by certified or official bank check payable to us, for the number of Warrants being exercised. 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. 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 holder of such warrant and us.

Stockholder Approval

We have agreed to hold a stockholders' meeting in order to seek Stockholder Approval to effect a Capital Event. The Company has agreed to use reasonable best efforts to call a special meeting to obtain Stockholder Approval

for a Capital Event, and engage a proxy solicitation firm to solicit proxies in connection with obtaining such Stockholder Approval. In the event that we are unable to obtain such Stockholder Approval to effect a Capital Event, 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 a warrant to acquire one share of our common stock, 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

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 warrant 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 warrant.

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 warrants 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.

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

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 a price less a concession not in excess of $ per share and accompanying warrant or $ per pre-funded warrant and accompanying warrant, based on the combined public offering price per share and accompanying warrant or pre-funded warrant and accompanying warrant. After the shares of common stock and/or pre-funded warrants and accompanying warrants are released for sale to the public, the underwriter may change the offering price, the concession, and other selling terms at various times.

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 Warrant	Per Pre-Funded Warrant and Warrant	No Exercise	Full Exercise
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 $, which includes the fees and expenses for which we have agreed to reimburse the underwriter.

Over-allotment Option

We have granted to the underwriter an option, exercisable not later than 30 days after the date of this prospectus, to purchase up to a number of additional shares of common stock equal to 15% of the sum of the number of shares of common stock and shares of common stock underlying the pre-funded warrants sold in the primary offering and/or up to a number of additional warrants to purchase shares of common stock equal to 15% of the number of warrants sold in the primary offering, in any combination of common stock and warrants. Any shares so purchased will be sold at a price per share equal to the public offering price, less the underwriting discount. Any warrants so purchased will be sold at a price per warrant equal to the public offering price less the underwriting discount. The underwriter may exercise the option solely to cover over-allotments, if any, made in connection with this offering. The over-allotment option may be used to purchase shares of common stock or warrants, or any combination thereof, as determined by the underwriter.

Determination of Offering Price

Our common stock is currently traded on The Nasdaq Capital Market under the symbol "CEMI." On , 2022, the closing price of our common stock was $ 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.

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 of a Capital Event 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 of a Capital Event 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.

Price Stabilization, Short Positions and Penalty Bids

In connection with this offering, the underwriter may engage in stabilizing transactions, overallotment transactions, syndicate covering transactions and penalty bids in connection with our common stock.

Stabilizing transactions permit bids to purchase shares of common stock so long as the stabilizing bids do not exceed a specified maximum.

Overallotment transactions involve sales by the underwriter of shares of common stock in excess of the number of shares the underwriter is obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriter is not greater than the number of shares that it may purchase in the overallotment option. In a naked short position, the number of shares involved is greater than the number of shares in the overallotment option. The underwriter may close out any short position by exercising its overallotment option and/or purchasing shares in the open market.

Syndicate covering transactions involve purchases of common stock in the open market after the distribution has been completed in order to cover syndicate short positions. Such a naked short position would be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriter is concerned that there could be downward pressure on the price of the securities in the open market after pricing that could adversely affect investors who purchase in the offering.

Penalty bids permit the underwriter to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction

to cover syndicate short positions. These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriter makes any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on the Nasdaq, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

In connection with this offering, the underwriter also may engage in passive market making transactions in our common stock in accordance with Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of the distribution. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for that security. However, if all independent bids are lowered below the passive market maker's bid that bid must then be lowered when specific purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

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, warrant agent and registrar for our common stock 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 underwriters 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 and May 26, 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	
FINRA filing fee	
Accounting fees and expenses	
Legal fees and expenses	
Printing expenses	
Transfer agent fees and expenses	
Miscellaneous	
Total	

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 of 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 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

EXHIBIT NO.	DESCRIPTION
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.

+ Indicated to be filed by amendment.

(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.

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 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 registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Hauppauge, State of New York, on September 7, 2022.

CHEMBIO DIAGNOSTICS, INC.

By: /s/ Richard L. Eberly

Richard L. Eberly

Chief Executive Officer and President

POWER OF ATTORNEY AND SIGNATURES

KNOW ALL PERSONS BY THESE PRESENTS that each person whose signature appears below constitutes and appoints Richard L. Eberly and Lawrence J. Steenvoorden, and each or either of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her, and in his or her name in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, and any registration statement for the same offering that is to be effective under Rule 462(b) of the Securities Act, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the SEC, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them, or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

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

Exhibit 23.1

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 the Registration Statement on Form S-1 and related Prospectus of Chembio Diagnostics, Inc. dated September 7, 2022.

/s/ Ernst & Young LLP

Jericho, New York
September 7, 2022

Exhibit 107

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) (2)	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 (3)	457(o)	—	—		0.0000927					
	Equity	Warrants (3) (4)	457(g)	—	—		0.0000927					
	Equity	Pre-Funded Warrants (3) (4)	457(g)	—	—		0.0000927					
	Equity	Shares of Common Stock, par value $0.01 per share, issuable upon exercise of Warrants	457(o)	—	—		0.0000927					
	Equity	Shares of Common Stock, par value $0.01 per share, issuable upon exercise of Pre-Funded Warrants	457(o)	—	—	(3)	0.0000927					
						$23,000,000	0.0000927	$2,132.10				
Fees Previously Paid	—	—	—	—		—		—				
Carry Forward Securities												
Carry Forward Securities	—	—	—	—		—			—	—	—	—
	Total Offering Amounts					$23,000,000		$2,132.10				
	Total Fees Previously Paid							—				
	Total Fee Offsets							—				
	Net Fees Due							$2,132.10				

(1) Estimated solely for the purpose of calculating the registration fee pursuant Rule 457(o) under the Securities Act of 1933, as amended (the "Securities Act"). Includes shares of common stock and warrants issuable upon exercise of the underwriter's over-allotment option.

(2) Pursuant to Rule 416(a) under 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.

(3) 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 $23,000,000.

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