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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **July 19, 2021**

CHEMBIO DIAGNOSTICS, INC.

Nevada	**0-30379**	**88-0425691**
(State or Other Jurisdiction of Incorporation or Organization)	*(Commission File Number)*	*(I.R.S. Employer Identification No.)*

555 Wireless Blvd., Hauppauge, NY 11788
(Address of principal executive offices) (Zip code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol	Name of each exchange on which registered
Common Stock, $0.01 par value	CEMI	The NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

DPP, STAT-PAK and SURE CHECK are our registered trademarks, and the Chembio logo is our trademark. For convenience, these trademarks appear in this release without ® or ™ symbols, but that practice does not mean that we will not assert, to the fullest extent under applicable law, our rights to the trademarks. This Current Report on Form 8-K also includes trademarks, trade names and service marks owned by other organizations.

Item 1.01. Entry into a Material Definitive Agreement.

On July 19, 2021, we entered into an At the Market Offering Agreement, or the ATM Agreement, with Craig-Hallum Capital Group LLC, or Craig-Hallum, pursuant to which we may sell from time to time, at our option, up to an aggregate of $60,000,000 of shares of common stock, or the Shares, through Craig-Hallum, as sales agent. Any sales of Shares made pursuant to the ATM Agreement will be made pursuant to our shelf registration statement on Form S-3 (File No. 333-254261) and the related prospectus previously declared effective by the Securities and Exchange Commission, or the SEC, on May 5, 2021, as supplemented by a prospectus supplement dated July 19, 2021 that we are filing with the SEC, pursuant to Rule 424(b)(5) under the Securities Act of 1933, or the Securities Act, on the filing date of this Current Report on Form 8-K.

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

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

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

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

We currently anticipate that the net proceeds from any sale of Shares under the ATM Agreement will be used for general corporate purposes, which may include, but are not limited to, working capital and capital expenditures. We cannot provide any assurances that we will issue any Shares pursuant to the ATM Agreement.

The foregoing description of the ATM Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the ATM Agreement, which is filed as Exhibit 10.1 to this Current Report on Form 8-K and is incorporated into this Item 1.01 by reference.

This Current Report on Form 8-K shall not constitute an offer to sell or the solicitation of an offer to buy any Shares, nor shall there be any offer, solicitation, or sale of the Shares in any state or country in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or country.

Item 2.02 Results of Operations and Financial Condition.

We set forth below our preliminary estimates of certain operating results for the second quarter of 2021, including our cash and cash-equivalents position at June 30, 2021, together with information relating to our limited cash position.

Our estimated operating results for the three months ended, and as of, June 30, 2021 are preliminary because we need to complete our financial closing procedures for the three-month period, our independent registered public accounting firm will need to review our operating results for the period in accordance with Public Company Accounting Oversight Board Auditing Standard (AS) 4105, *Reviews of Interim Financial Information*, and other developments may arise by the time the financial results for the period are completed. The preliminary results set forth below are not meant to be a comprehensive statement of our unaudited financial results for the three months ended June 30, 2021. We expect to release our operating results for the three months ended, and as of, June 30, 2021 during the first week of August 2021. Until that time, the preliminary results described in this press release are subject to revisions that could cause our final results to differ materially. We undertake no responsibility to update our preliminary estimates in the interim prior to our release of operating results in August 2021.

As discussed under "Estimated Cash Position and Related Actions" below, factors and considerations with respect to our liquidity raise substantial doubt as to our ability to continue as a going concern through one year after the filing date of this Current Report on Form 8-K. We are providing the preliminary estimates set forth below on a going concern basis, which assumes that we will be able to meet our commitments, realize our assets and discharge our liabilities in the normal course of business. Those preliminary estimates do not include any adjustment to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

Estimated Revenue Results

We estimate that our total revenues for the three months ended June 30, 2021 were $6.4 million and that those total revenues will be comprised as set forth in the following table, which also includes comparable information for the corresponding prior-year period (three months ended June 30, 2020) and the most recent prior quarter (three months ended March 31, 2021):

	Three Months Ended			Increase (Decrease) vs. June 30, 2021 (estimated)	
	June 30, 2021 (estimated)	March 31, 2021	June 30, 2020	March 31, 2021	June 30, 2020
	(in millions; unaudited)				
Product revenue	$ 3.9	$ 4.0	$ 3.8	$ (0.1)	$ 0.1
R&D revenue	—	1.1	1.2	(1.1)	(1.2)
Government grant income	2.3	3.4	—	(1.1)	2.3
License and royalty revenue	0.2	0.2	0.1	—	0.1
Total revenues	$ 6.4	$ 8.7	$ 5.1	$ (2.3)	$ 1.3

Our revenues during the three months ended June 30, 2021 did not meet our expectations, and the shortfall in our revenues has been a principal cause of our current limited cash and cash-equivalents position, as described under "—Estimated Cash Position and Related Actions" below. For a discussion of certain business and regulatory factors and developments that have limited the growth of our product revenue and our operations generally during 2021, please see "Business Update" under "Item 8.01. Other Matters" below.

We expect, based on the above preliminary estimates, that our total revenues for the three months ended June 30, 2021 will satisfy the minimum total revenues covenant set forth in the Credit Agreement and Guaranty dated September 3, 2019, or the Credit Agreement, that we and certain of our subsidiaries, as guarantors, entered into with Perceptive Credit Holdings II, LP, or Perceptive, with respect to a $20,000,000 senior secured term loan credit facility.

Estimated Non-Cash Write-Downs

Based on internal reviews being conducted as part of our financial closing procedures for the three months ended June 30, 2021, we expect that we will record two non-cash write-downs that will affect our reported operating results for the period.

We expect to record an impairment loss of an estimated $1.3 million for the three months ended June 30, 2021 as the result of our write-off of the intangible assets, net, leasehold improvements, net and right-of-use assets for leases, net associated with our Malaysian operations that underwent a retrenchment during the second quarter of 2020. During the three months ended June 30, 2021, we were informed that the World Health Organization had prioritized its review of prequalification of the manufacture of our HIV 1/2 STAT-PAK Assay on our U.S. automated manufacturing processes, which would reduce our reliance on manual labor that otherwise could have been performed at our Malaysian facilities had we re-started operations there. The products produced on our automated and manual production lines at any time depend on, among other things, the timing of customer orders and the mix of products being produced.

We estimate that we will incur a loss of $0.5 million to $1.0 million for the three months ended June 30, 2021 on the recognition of overhead related to excess capacity and the write-down of inventory for products that are not salable, including as the result of obsolete packaging and changes in accounting estimates based on our periodic review of the current status and future benefits of inventory.

Estimated Cash Position and Related Actions

We estimate that our cash and cash equivalents totaled $5.8 million at June 30, 2021, a decrease of $8.6 million from $14.4 million at March 31, 2021. Cash and cash equivalents at March 31, 2021 represented a decrease of $8.7 million from $23.1 million at December 31, 2020. Our decrease in cash and cash-equivalents over the first two quarters of 2021 reflected market, clinical trial and regulatory complications we faced in seeking to develop and commercialize a portfolio of COVID-19 test systems during the continuing, but evolving, uncertainty of the COVID-19 pandemic. The decrease also resulted in part from significant continuing expenses incurred in connection with pending legal matters (see “Legal Matters” under “Item 8.01. Other Matters” below), lower product revenue and delayed invoicing associated with government grant income (see “Business Update” under “Item 8.01. Other Matters” below), our investments in inventory as described below, and our continuing automation of U.S. manufacturing.

We continually evaluate, and seek to manage, our liquidity requirements based on our operating results and needs and planned growth initiatives. As reported in our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2021, for example, on January 14, 2021 the board of directors approved a restructuring plan pursuant to which we terminated employees, primarily in our manufacturing department, to better align our cost structure with the skills and resources required to more effectively pursue opportunities in the marketplace and execute our long-term growth strategy. In addition, on March 12, 2021 we filed a shelf registration statement on Form S-3 with the U.S. Securities and Exchange Commission, or the SEC, for the offering from time to time of securities with an aggregate offering price of up to $100,000,000, which registration statement was declared effective by the SEC on May 5, 2021. We believe investments we made earlier this year in inventory for the DPP SARS-CoV-2 Antigen System position us to take advantage of sales opportunities outside the United States that, for a variety of reasons, were repeatedly deferred in the first half of 2021 (see “Business—COVID-19 Antigen Test System—Commercialization” under “Item 8.01. Other Matters” below). In addition, we believe that, beginning in the three months ending September 30, 2021, our cash requirements for legal services performed in connection with the matters described in “¾SEC Investigation” and “¾Legal Proceedings¾Stockholder Litigation” under “Item 8.01. Other Matters¾“Legal Matters” below will likely decrease as the result of our total related legal fees exceeding the self-insured retention under our applicable insurance policy.

As described in “Business Update” under “Item 8.01. Other Matters” below, we are continuing to pursue (a) an emergency use authorization, or EUA, from the U.S. Food and Drug Administration, or FDA, as well as 510(k) clearance from the FDA, for the DPP SARS-CoV-2 Antigen test system, (b) an EUA from the FDA for the DPP Respiratory Panel, and (c) a Clinical Laboratory Improvement Amendment, or CLIA, waiver from the FDA for the DPP HIV-Syphilis test system.

In light of the uncertainty of the timing and any receipt of those regulatory approvals, the timing of progress on and results of clinical trial programs, and the timing and any receipt of product orders from the commercialization of the COVID-19 Diagnostic Test Systems and other diagnostic test systems both within and outside the United States, in mid-May 2021 we engaged the services of an independent financial advisory firm, which we refer to as the Financial Advisor. The Financial Advisor spent four weeks working with management to develop a forecast model to assess the amount and timing of our liquidity needs, assuming various business cases. The Financial Advisor's work and resulting liquidity forecast model considered, among numerous other factors, the minimum liquidity covenant under the Credit Agreement, which requires that we maintain aggregate unrestricted cash of not less than $3,000,000 at all times, as well as the following developments during the four-week period when the liquidity forecast model was being prepared:

- delays, due to factors outside our control, in obtaining certain potentially significant customer orders that were, and continue to be, under discussion and negotiation; and
- our inability, due to the COVID-19 vaccination rollout and related positivity rates at clinical trials, to achieve clinical plan enrollment levels, and the impact of the resulting delays in our clinical trials on:
    - the timing of our achievement of revenue- and cash-generating milestones under a $12.7 million award granted pursuant to our previously announced contract dated December 2, 2020 with the Biomedical Advanced Research and Development Authority (part of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response), or BARDA, supporting (a) our development and pursuit of an EUA for the DPP Respiratory Antigen Panel system and (b) our conduct of clinical trials, and preparation of a submission, in pursuit of FDA 510(k) clearance for the DPP SARS-CoV-2 Antigen test system, and
    - the timing and uncertainty of our receipt of the related regulatory approvals from the FDA, and the impact of any such approvals on the timing of commercialization of our COVID-19 test systems in the United States.

Please see "Business" under "Item 8.01. Other Matters" below for further information about the factors described above.

Both before and after the Financial Advisor completed its liquidity forecast model, we worked with the Financial Advisor to investigate alternative approaches to enhancing our liquidity position. Among other actions, we held discussions with Perceptive with respect to the Credit Agreement and identified, and prepared materials for presentation to, other potential lenders that might be approached to refinance some or all of the Credit Agreement and/or provide additional debt funding. In late June 2021, however, we determined, in consultation with the Financial Advisor, that, particularly in light of the continuing delays and uncertainty in our receipt of significant customer orders and continuing delays in invoicing associated with BARDA grant awards, our projected liquidity needs would not allow us sufficient time to pursue negotiations with other potential lenders or to undertake other corporate or restructuring transactions intended to address our near-term liquidity needs.

Based on the liquidity forecast model and other advice from the Financial Advisor, the market, clinical trial and regulatory information we gained in June 2021, and our discussions with Perceptive with respect to the Credit Agreement, on July 1, 2021 we retained investment banking firm Craig-Hallum to provide certain investment banking services on an exclusive basis, including serving as agent or underwriter in connection with certain securities offerings. The board subsequently determined that it was in our best interests to proceed promptly with an "at-the-market" offering of common stock as described under "Item 1.01. Entry into a Material Definitive Agreement" above.

The factors and considerations discussed above with respect to our liquidity raise substantial doubt as to our ability to continue as a going concern through one year after the filing date of this Current Report on Form 8-K. We believe we will need to raise capital in the near future in order to have sufficient resources to fund our operations and meet the obligations specified in the Credit Agreement for the next twelve months. 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, or that we will be successful in any of our other endeavors to become financially viable and continue as a going concern. Our inability to raise additional capital on acceptable terms in the near future would have a material adverse effect on our business, prospects, results of operations, liquidity and financial condition. Furthermore, any decline in the market price of our common stock could make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate.

Item 8.01 Other Matters.

Business

The following discussion updates, and should be read in conjunction with, the description of our business and other information set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, as amended, and our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2021, each as filed with the SEC.

COVID-19 Antigen Test System

EUA Applications

In July 2020 we received from BARDA a $628,071 grant, which we refer to as the Initial Grant, to assist us in developing, submitting and obtaining an EUA application for a COVID-19 point-of-care antigen system using DPP technology. Since that time, we have taken a number of actions in pursuant of an EUA for a COVID-19 Antigen test system:

- In October 2020, following BARDA's review and approval in accordance with the Initial Grant, we submitted to the FDA an EUA application for the DPP SARS-CoV-2 Antigen System, which consists of a DPP SARS-CoV-2 Antigen test cartridge, a DPP Micro Reader optical analyzer and a minimally invasive nasal swab.

- In January 2021 the FDA notified us that it was declining to review the DPP SARS-CoV-2 Antigen System based on its updated prioritization guidance, under which review of the test system was not a priority. The FDA supplementally advised us of the type and nature of information it would need to receive in a subsequent EUA application in order for the DPP SARS-CoV-2 Antigen System to be prioritized for review.

- In May 2021, following BARDA's review and approval in accordance with the Initial Grant, we submitted to the FDA a new EUA application for the DPP SARS-CoV-2 Antigen System that was intended to reflect the information necessary for the test system to be prioritized by the FDA for review.

- In June 2021 the FDA notified us that it was again declining to review the DPP SARS-CoV-2 Antigen System based on the FDA's then-effective prioritization guidance, under which review of the test system was not a priority because of the anticipated resources needed by the FDA to continue review of our EUA request, the volume of EUA requests the FDA had received, and a variety of other factors, such as the public health need for the test system, the extent to which the test system would serve a significant unmet medical need, and the availability and adequacy of the information concerning the likelihood that the test system would be safe and effective in diagnosing the disease. Our clinical trials and the related timeline and achievement of related milestones under the Initial Grant had been delayed by factors including (a) the evolving U.S. populations with low COVID-19 positivity rates triggered by vaccination rollouts, (b) the impact of those evolving populations on the rate of enrolling subjects, and (c) the absence of guidance from the FDA regarding how to treat low positivity rates within a clinical study. The effects of the changing population were reflected in our clinical results and created complexities in the data set submitted for the FDA review in connection with the EUA application for the DPP SARS-CoV-2 Antigen System.

In June 2021 BARDA extended the Initial Grant's contract period of performance at no additional cost to BARDA, in order to provide us the opportunity to submit a new EUA to the FDA to address the FDA's additional priorities and incorporate additional data collected from international populations with higher positivity rates. Subsequent to our EUA submission in May 2021, the FDA issued guidance permitting the inclusion in clinical data of foreign-sourced samples from regions with high COVID-19 positivity rates. We are in the process of collecting such samples in order to address the complexities in our data set that we believe resulted in the FDA's decision to deprioritize our second EUA application. We then intend to incorporate the collected samples in our clinical data for a new EUA application for the DPP SARS-CoV-2 Antigen System. There can be no assurance that the FDA will prioritize the review of our new EUA application if made or that, if the FDA does determine to review the new EUA application, the submitted materials will satisfy the performance criteria and other FDA review standards and requirements then being considered and applied by the FDA.

510(k) Submission

In December 2020 we received from BARDA a $12.7 million grant, which we refer to as the Second Grant, to, among other things, support preparation, submission and approval of FDA 510(k) clearance for the DPP SARS-CoV-2 Antigen System.

Throughout 2021, with BARDA's support in accordance with the Second Grant, we have proceeded with clinical trials to support submissions for 510(k) clearance from the FDA with respect to the DPP SARS-CoV-2 Antigen System. These clinical trials are ongoing, although the timeline for the clinical trials and our achievement of related milestones and recognition of associated revenue and invoicing under the Second Grant, including the rate of enrolling eligible subjects, have been delayed by factors including (a) the evolving U.S. populations with low COVID-19 positivity rates triggered by vaccination rollouts, (b) the impact of those evolving populations on the rate of enrolling subjects, (c) the absence of guidance from the FDA regarding how to treat low positivity rates within a clinical study and (d) the FDA's as-yet unissued 510(k) guidance regarding COVID-19 Antigen tests.

On July 14, 2021, BARDA amended the Second Grant in order to subdivide, effective retrospectively, certain previously specified milestones with respect to the clinical trials for the DPP SARS-CoV-2 Antigen System in order to reflect the effects of the delays we experienced in the clinical trials, which were outside our control. We had achieved certain of the newly defined milestones prior to July 14, 2021, and as a result of the amendment, we have initiated the process of invoicing BARDA for payment in connection with those milestones.

We have begun to incorporate in the 510(k) clinical trials foreign-sourced samples similar to the planned EUA resubmission for the DPP SARS-CoV-2 Antigen System (see "—EUA Applications" above) with the objective of mitigating the impact of low COVID-19 positivity rates resulting from the vaccination rollout in the United States.

Commercialization

Delays in the clinical trials and regulatory submissions for the DPP SARS-CoV-2 Antigen System, which are described above, have constrained, and continue to constrain, our ability to achieve milestones and submit invoices under the Initial Grant and the Second Grant, to recognize government grant income, and to realize cash flows to fund ongoing development and clinical trial work. In addition, these delays have hindered our ability to commercialize the test system, which in turn has inhibited our ability to realize recurring revenue and cash flows from sales of the test systems.

Throughout 2021 we have been actively pursuing sales opportunities for the DPP SARS-CoV-2 Antigen System with governmental agencies, non-governmental organizations and distributors in countries where the test system is approved and registered. Historically, a significant majority of our product revenue has been generated outside the United States. We believe that there continue to be opportunities for business awards in countries where the DPP SARS-CoV-2 Antigen System is approved and registered, and in 2021 we have invested in finished goods and work-in-progress inventory in order to be prepared to meet the timing requirements of those awards. Those business awards, including the issuance of purchase orders, have been repeatedly delayed for various reasons, including the impact of periodic COVID-19 lockdowns affecting product registrations and purchasing organization processes, and we remain subject to continuing delays and uncertainty in our receipt of any such purchase orders. In addition, we are seeing evidence of overcapacity among suppliers of competing tests in a growing number of regions, which could adversely affect the pricing of the DPP SARS-CoV-2 Antigen System.

COVID-19 and Influenza Respiratory Antigen Panel Test System

Under the terms of the Second Grant, BARDA is also supporting our development, submission and receipt of an EUA for a rapid, multiplex respiratory antigen panel point-of-care test system using DPP technology.

We have developed the DPP Respiratory Antigen Panel, a test system designed, when used in combination with the DPP Micro Reader optical analyzer, to provide simultaneous, discrete and differential detection of SARS-CoV-2, Influenza A and Influenza B antigens from a single patient respiratory specimen, such as a nasal swab, in approximately 20 minutes. The test system is intended to enable appropriate clinical management of patients with suspected respiratory infections and to assist in the containment of COVID-19 cases during the flu season. We completed development of the DPP Respiratory Antigen Panel on time relative to the plans in the Second Grant.

We have completed the clinical trials for the DPP Respiratory Antigen Panel, which were initiated in April 2021. During those clinical trials, we encountered delays, principally from the near absence of influenza in the United States and also from rapidly declining positivity rates for COVID-19 throughout the United States, including in areas surrounding our clinical trial sites, due to the impact of vaccination programs. Delays in the clinical trials for the DPP Respiratory Antigen Panel constrained our ability to achieve milestones and submit invoices under the Second Grant, to recognize government grant income, and to realize cash flows to fund ongoing development and clinical trial work. We are, following review and approval by BARDA, incorporating in our clinical data for the DPP Respiratory Antigen Panel foreign-sourced influenza-positive samples, which we expect will mitigate the impact of the extremely low incidence of influenza in the United States.

We are working to finalize EUA submission materials for the DPP Respiratory Antigen Panel internally and with BARDA. The FDA has a pathway for manufacturers, such as our company, that do not have a prior 510(k)-approved influenza test. We are not, however, aware of the FDA having awarded to any such manufacturer an EUA for an influenza test, and the FDA may not consider the review of our EUA application for the DPP Respiratory Antigen Panel as a priority and therefore may decline to review EUA application.

COVID-19 Antibody Test System

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

In September 2020 we submitted to the FDA an EUA application for the DPP SARS-CoV-2 IgM/IgG System, a new rapid antibody test system that detected COVID-19 antibodies using a new methodology designed to be consistent with updated FDA guidance. In December 2020 the FDA notified us that it was declining to review the EUA application based on the FDA's then-effective prioritization guidance, under which review of the test system was not a priority because, for example, the FDA determined that authorization of the test system would have a relatively limited impact on testing accessibility or testing capacity.

The global proliferation of COVID-19 vaccination programs may create opportunities for the DPP COVID-19 IgM/IgG System. We continue to pursue those opportunities in regions where the test system has been approved. However, policies of individual countries related to the monitoring of viral loads and other use cases are at an early stage, and we are seeing evidence of overcapacity among suppliers of competing tests. These regulatory and market conditions could adversely affect the demand for, and pricing of, our COVID-19 Antibody test systems outside the United States.

HIV-Syphilis Test System

In October 2020 we received a Premarket Approval, or PMA, from the FDA for the DPP HIV-Syphilis System, which is a multiplex, single-use, 15-minute test designed, when used in combination with the DPP Micro Reader optical analyzer, to simultaneously detect antibodies to HIV types 1 and 2 and Treponema pallidum, the bacteria that causes syphilis. The test uses a 10-microliter sample of fingerstick whole blood, venous whole blood or plasma. The test system is highly sensitive and specific, has a built-in procedural control, may be stored at room temperature, and has a 24-month shelf life.

We submitted an application for a CLIA waiver from the FDA for the DPP HIV-Syphilis System in January 2021. We are in active discussions with the FDA in connection with the FDA's review of our submission, but there can be no assurance that a CLIA waiver will be granted with respect to the DPP HIV-Syphilis System.

Legal Matters

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

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

Legal Proceedings

Stockholder Litigation

Putative Stockholder Securities Class Action Litigation

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

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

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

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

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

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

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

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

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

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

Putative Stockholder Derivative Litigation

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

The Wong complaint requests a declaration that the individual defendants have breached or aided and abetted the breach of their fiduciary duties to us, an award of damages to us, restitution, and an award of the plaintiff's costs and disbursements in the action, including reasonable attorneys' and experts' fees, costs and expenses, and improvements to our corporate governance and internal procedures regarding compliance with laws. Pursuant to a stipulation by which the individual defendants named in the Wong complaint agreed to waive service of process, the Court ordered that the time for defendants to answer or otherwise respond to the complaint be extended to November 19, 2020. The parties subsequently entered into a stipulation for a stay of proceedings in the action relating to the Wong complaint pending final disposition of motions to dismiss the pending putative class action litigation, subject to certain conditions. The Court entered an order granting the requested stay on November 3, 2020.

Commercial Litigation

Our wholly owned subsidiary Chembio Diagnostic Systems Inc., or Systems, and BioSure (UK) Ltd, or BioSure, entered into the BioSure Sure Check HIV 1/2 Assay OTC Agreement dated April 2, 2014 and as subsequently amended, which, as so amended, we refer to as the Distribution Agreement. Pursuant to the Distribution Agreement, BioSure acquired the right to sell bundled products in the United Kingdom containing our Sure Check HIV 1/2 pouched tests. The Distribution Agreement terminated on April 1, 2019. On September 16, 2019, Systems initiated arbitration in the International Arbitration Tribunal of the International Centre for Dispute Resolution in New York, New York. Systems alleges that BioSure (a) breached various provisions of the Distribution Agreement, (b) misappropriated trade secrets of Systems, (c) engaged in deceptive business acts and practices, and (d) breached the implied covenant of good faith and fair dealing. On November 23, 2020, BioSure requested leave to file a counterclaim seeking recession of the Distribution Agreement based on alleged fraudulent concealment by Systems. Systems opposed BioSure's request for leave to file the counterclaim on procedural and substantive grounds, and on December 11, 2020 the Tribunal denied the request for leave to file the counterclaim. The Tribunal's denial was without prejudice to BioSure's ability to assert its claim in a separate proceeding. BioSure continues to deny the relief sought and alleges certain statements Systems made to third parties about the Distribution Agreement were in bad faith and are a defense to Systems' claims. BioSure also asserts that certain alleged misrepresentations entitle BioSure to "set off" any award Systems might receive from the Tribunal. The parties have completed discovery and submitted their first pre-hearing submissions. Systems intends to vigorously pursue its claims in the arbitration. The final merits hearing took place from April 20, 2021 to April 23, 2021.

Employee Litigation

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

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

On May 20, 2021, we filed our answer and affirmative defenses denying the material allegations of Mr. Sperzel's complaint.

Other

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

Risk Factors

An investment in our common stock involves a high degree of risk. Risks relating to our business, including our products, applicable regulatory requirements, our common stock and our company generally, are contained in our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2021, as filed with the SEC, and in the discussion set below. The risks and uncertainties we describe are not the only ones facing us. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations. If any of these risks were to occur, our business, financial condition or results of operations would likely suffer. In that event, the trading price of our common stock could decline and investors in our common stock could lose all or part of their investments.

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 will require additional capital to fund our operations, which capital may not be available to us on acceptable terms or at all.

Based on our current projection of revenue, expenses, capital expenditures, debt service and cash flows, we will not have sufficient resources to fund our operations and meet the obligations specified in the documents governing our convertible financing for the next twelve months following the filing of this Current Report on Form 8-K. Our diagnostic test products require ongoing funding to continue our current development and operational plans and we have a history of net losses. We intend to continue to expend substantial resources for the foreseeable future in connection with the continued development of our products, to the extent such resources are available to us. These expenditures would include costs associated with research and development activity, corporate administration, business development, debt service, marketing and selling of our products, and shareholder litigation. In addition, other unanticipated costs may arise. As described in "Estimated Cash Position and Related Actions" under "Item 2.02. Results of Operations and Financial Condition," we believe that additional capital will be required to fund our operations.

To fund our operations and obligations, we may need to raise capital in one or more debt and/or equity offerings. However, there can be no assurance 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 acceptable to us, it could have a material adverse effect on our company. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products or one or more of our other research and development initiatives. The outbreak of the COVID-19 pandemic has significantly disrupted world financial markets, negatively impacted U.S. market conditions and may reduce opportunities for us to seek out additional funding. A decline in the market price of our common stock, 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. These reasons also contributed to our determination that there is substantial doubt about our ability to continue as a going concern.

Any 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 doubt about our ability to continue as a going concern may also adversely affect our relationships with current and future employees, suppliers, vendors, customers, 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 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.

We are providing the preliminary estimates of certain operating results for the three months ended June 30, 2021 set forth under “Item 2.02. Results of Operations and Financial Condition” above on a going concern basis, which assumes that we will be able to meet our commitments, realize our assets and discharge our liabilities in the normal course of business. Those preliminary estimates do not include any adjustment to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

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 The U.S. President’s Emergency Plan for AIDS Relief or PEPFAR, the Global Fund to Fight AIDS, Tuberculosis and Malaria, 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 The Oswaldo Cruz Foundation or 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 Brazilian Ministry of Health. 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 U.S. Foreign Corrupt Practices Act, although there can be no assurance of this. In addition, corruption is a problematic factor in doing business in Brazil. 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. Alternatively, new governmental anti-corruption protections and procedures being implemented in Brazil could delay or otherwise modify the product collaboration process.

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 and milestones; (2) stock-based compensation; (3) allowance for uncollectible accounts receivable; (4) inventory reserves and obsolescence; (5) customer sales returns and allowances; (6) contingencies; (7) income taxes; (8) goodwill and intangibles; (9) business acquisitions; and (10) research and development costs.

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

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

Risks Related to Our Business and Our Industry

We face risks related to an ongoing SEC investigation.

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

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

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

We may incur additional costs in connection with the defense, settlement or other resolution of existing and any future shareholder litigation. See "—Legal Matters—Legal Proceedings" above for additional information regarding existing lawsuits. These lawsuits or other future litigation may adversely affect the ability of our technical and management personnel, and our directors, to perform their normal responsibilities. We could incur significant costs in connection with any such litigation, 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.

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 experienced recent employee departures, and expect that we may suffer additional departures, in the light of our current limited cash position as described in "Estimated Cash Position and Related Actions" under "Item 2.02. Results of Operations and Financial Condition" and our other current operating and financial circumstances. Moreover, those current financial circumstances may make it difficult or even infeasible for us to implement retention measures to stem departures of key officers and employees.

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

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

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

In addition, some or all of the funding available under grant awards may be conditioned upon our successfully meeting specified milestones or other conditions, and there can be no assurance that those milestones or conditions will be met. For example, in December 2020 we were awarded the Second Grant pursuant to a contract from BARDA that includes 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. Moreover, we must fund our efforts under grant awards, such as the First Grant and the Second Grant, in advance of receiving any payment for satisfaction of a specified milestone or condition. The amount of such funding may be material to us, particularly in light of our current limited cash position as described in "Estimated Cash Position and Related Actions" under "Item 2.02. Results of Operations Financial Condition," which may delay or inhibit our completion of the work required.

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.

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 and operating costs, which could negatively affect our earnings and liquidity in the short term. A significant order for our products could require material working capital, which, in light of our current limited capital position as described in our current limited cash position as described in "Estimated Cash Position and Related Actions" under "Item 2.02. Results of Operations and Financial Condition," could require that we obtain additional funding, which may not be available to us at all or on terms acceptable to us and, if available, could dilute the ownership interests of existing stockholders or the value of the shares of common stock held by those stockholders.

New manufacturing equipment or facilities may require the FDA, the World Health Organization 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 Regulations

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 facilities must meet quality standards and are subject to inspection by a number of domestic regulatory and other governmental and non-governmental agencies.

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

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

Changes or developments in government regulations, policies or interpretations could increase our costs and could require us to undergo additional trials or procedures, or could make it impractical or impossible for us to market our products for certain uses, in certain markets, or at all. For example, on June 16, 2020, the FDA revoked the EUA it had granted for the DPP COVID-19 IgM/IgG System based in part on performance criteria identified after the EUA was granted on April 14, 2020. We do not currently have an EUA from the FDA for any of the COVID-19 Diagnostic Test Systems, and we do not currently have an application pending for any such EUA. Moreover, FDA regulations, policies and procedures with respect to COVID-19 tests have been 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. In the event we submit an application for any new EUA or 510(k) clearance for the DPP SARS-CoV-2 Antigen test system, any EUA for the DPP Respiratory Panel, or any CLIA waiver for the DPP HIV-Syphilis test system, there can be no assurance that such application will receive timely review or will be ultimately approved, and our ability to pursue approval of any such application may be constrained by our limited cash position as described in "Estimated Cash Position and Related Actions" under "Item 2.02. Results of Operations and Financial Condition."

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 current performance criteria issued subsequent to the granting of our original EUA.

We can manufacture and sell our products only if we comply with regulations and quality standards established by government agencies such as the FDA and the U.S. Department of Agriculture as well as by non-governmental organizations such as the International Organization for Standardization and the World Health Organization. We have implemented a quality control system that is intended to comply with applicable regulations. Although FDA approval is not required for the export of our products, there are export regulations promulgated by the FDA that specifically relate to the export of our products that require compliance with the FDA's quality system requirements and that also require meeting certain documentary requirements regarding the approval of the product in export markets. We also may be subject to import regulations in connection with international sourcing of components and materials incorporated in the manufacturing of our products.

Risks Related to Our Common Stock

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

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

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. During the 18 months prior to the date of this Current Report on Form 8-K, our common stock has traded at a low of $2.25 and a high of $15.89. From the beginning of 2021 through July 16, 2021, our common stock has traded at a low of $2.38 and a high of $8.75. As a result of this volatility, investors could experience losses on their investment in our common stock.

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

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

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

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

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

In order to raise additional capital, we intend to offer shares of common stock in an "at-the-market" offering pursuant to the ATM Agreement (see "Item 1.01. Entry into a Material Definitive Agreement") 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 shares or other securities in the offering made pursuant to the ATM Agreement or any other offering at a price per share that is equal to or greater than the price per share paid by existing stockholders, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock in future transactions may be higher or lower than the price per share you paid. As of the close of business on July 16, 2021, our market capitalization was approximately $49 million, and as a result existing stockholders may experience significant dilution in connection with our issuance and sale of up to $60,000,000 of shares of common stock pursuant to the ATM Agreement. In addition, as of June 30, 2021, 2,502,911 shares of common stock were reserved for future issuance under our 2019 Omnibus Incentive Plan, 1,867,045 shares were subject to outstanding options, and 802,947 shares were subject to outstanding restricted stock units. Stockholders will incur dilution upon vesting of restricted stock units, and they may incur dilution upon exercises of stock options.

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.

Future sales of shares by existing stockholders could cause our stock price to decline.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock, even if there is no relationship between such sales and the performance of our business.

Because we have no current plans to pay cash dividends on our common stock for the foreseeable future, stockholders may not receive any return on their investment in common stock unless they sell their common stock for a price greater than that which they paid for it.

We intend to retain future earnings, if any, for future operations and expansion of our business and have no current plans to pay any cash dividends for the foreseeable future. The declaration, amount and payment of any future dividends on shares of common stock will be at the sole discretion of the board of directors. The board may take into account general and economic conditions, our financial condition and results of operations, our available cash and current and anticipated cash needs, capital requirements, contractual, legal, tax and regulatory restrictions, implications on the payment of dividends by us to our stockholders or by our subsidiaries to us and such other factors as our board of directors may deem relevant. As a result, stockholders may not receive any return on an investment in our common stock unless they sell our common stock for a price greater than that which they paid for it.

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

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

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

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
5.1	Opinion of Ballard Spahr LLP
10.1	At the Market Offering Agreement, dated July 19, 2021, between Chembio Diagnostics, Inc. and Craig-Hallum Capital Group LLC
23.1	Consent of Ballard Spahr LLP (including in Exhibit 5.1)
104	Cover Page Interactive Data File (embedded within the XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be filed on its behalf by the undersigned hereunto duly authorized.

CHEMBIO DIAGNOSTICS, INC.

Dated: July 19, 2021

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

Exhibit 5.1

Ballard Spahr LLP

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

July 19, 2021

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

Re: Chembio Diagnostics, Inc.
Registration Statement on Form S-3

Ladies and Gentlemen:

We have acted as counsel to Chembio Diagnostics, Inc., a Nevada corporation (the "Company"), in connection with the Company's Registration Statement on Form S-3, as filed with the United States Securities and Exchange Commission (the "Commission") on March 12, 2021, and as further amended or supplemented from time to time to the date hereof (the "Registration Statement") under the Securities Act of 1933, as amended (the "Securities Act"), as amended for the inclusion of the Prospectus Supplement dated June 16, 2021 (the "Prospectus Supplement"), for the offer and sale of up to $60,000,000 of shares (the "Securities") of the Company's common stock, $0.001 par value per share ("Common Stock").

We have examined, and relied upon the accuracy of factual matters contained in, as applicable, executed original or counterparts of the following documents: (a) the Articles of Incorporation of the Company (formerly Trading Solutions.Com, Inc.) filed with the Nevada Secretary of State on May 14, 1999, as amended (the "Articles"); (b) the Amended and Restated Bylaws of the Company; (c) the resolutions adopted by the Company's board of directors authorizing the issuance and sale of the Securities pursuant to the Registration Statement, amongst other items (the "Directors' Resolutions"); and (d) the Registration Statement and the Prospectus Supplement. We have also examined such corporate records and other agreements, documents and instruments, and such certificates or comparable documents of public officials and officers and representatives of the Company and have made such inquiries of such officers and representatives and have considered such matters of law as we have deemed appropriate as the basis for the opinion hereinafter set forth.

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

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

On the basis of the foregoing, and subject to the qualifications, assumptions, and limitations set forth herein, we are of the opinion that the Securities have been duly authorized and, when, as and if, issued and paid for as described in the Registration Statement and the Prospectus Supplement, in accordance with the Directors' Resolutions, such Securities will be validly issued, fully paid and nonassessable.

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

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

We hereby consent to the filing of this opinion letter as an exhibit to the Company's Current Report on Form 8-K dated July 19, 2021 and the Registration Statement and to the reference to us under the heading "Legal Matters" in the prospectus forming part of the Registration Statement and the Prospectus Supplement. In giving such consent, we do not admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations promulgated thereunder.

Very truly yours,
/s/Ballard Spahr LLP

Exhibit 10.1

AT THE MARKET OFFERING AGREEMENT

July 19, 2021

Craig-Hallum Capital Group LLC
222 South 9th Street, Suite 350
Minneapolis, MN 55402

Ladies and Gentlemen:

Chembio Diagnostics, Inc., a corporation organized under the laws of Nevada (the "Company"), confirms its agreement (this "Agreement") with Craig-Hallum Capital Group LLC (the "Manager") as follows:

1. Definitions. The terms that follow, when used in this Agreement and any Terms Agreement, shall have the meanings indicated.

"Act" shall mean the Securities Act of 1933, as amended, and the rules and regulations of the Commission promulgated thereunder.

"Action" shall have the meaning ascribed to such term in Section 3(p).

"Affiliate" shall have the meaning ascribed to such term in Section 3(o).

"Applicable Time" shall mean, with respect to any Shares, the time of sale of such Shares pursuant to this Agreement or any relevant Terms Agreement.

"Auditor" shall mean Ernst & Young LLP, the Company's independent auditor.

"Base Prospectus" shall mean the base prospectus contained in the Registration Statement at the Execution Time.

"Board" shall have the meaning ascribed to such term in Section 2(b)(iii).

"Broker Fee" shall have the meaning ascribed to such term in Section 2(b)(v).

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

"Commission" shall mean the United States Securities and Exchange Commission.

"Common Stock" shall have the meaning ascribed to such term in Section 2.

"Common Stock Equivalents" shall have the meaning ascribed to such term in Section 3(g).

"Company Counsel" shall have the meaning ascribed to such term in Section 4(l).

"DTC" shall have the meaning ascribed to such term in Section 2(b)(vii).

"Effective Date" shall mean each date and time that the Registration Statement and any post-effective amendment or amendments thereto became or becomes effective.

"Exchange Act" shall mean the Securities Exchange Act of 1934, as amended, and the rules and regulations of the Commission promulgated thereunder.

"Execution Time" shall mean the date and time that this Agreement is executed and delivered by the parties hereto.

"Free Writing Prospectus" shall mean a free writing prospectus, as defined in Rule 405.

"GAAP" shall have the meaning ascribed to such term in Section 3(m).

"Incorporated Documents" shall mean the documents or portions thereof filed with the Commission on or prior to the Effective Date that are incorporated by reference in the Registration Statement or the Prospectus and any documents or portions thereof filed with the Commission after the Effective Date that are deemed to be incorporated by reference in the Registration Statement or the Prospectus.

"Intellectual Property Rights" shall have the meaning ascribed to such term in Section 3(v).

"Issuer Free Writing Prospectus" shall mean an issuer free writing prospectus, as defined in Rule 433.

"Losses" shall have the meaning ascribed to such term in Section 7(d).

"Material Adverse Effect" shall have the meaning ascribed to such term in Section 3(b).

"Material Permits" shall have the meaning ascribed to such term in Section 3(t).

"Maximum Amount" shall have the meaning ascribed to such term in Section 2.

"Net Proceeds" shall have the meaning ascribed to such term in Section 2(b)(v).

"Permitted Free Writing Prospectus" shall have the meaning ascribed to such term in Section 4(g).

"Placement" shall have the meaning ascribed to such term in Section 2(c).

"Proceeding" shall have the meaning ascribed to such term in Section 3(b).

"Prospectus" shall mean the Base Prospectus, as supplemented by the most recently filed Prospectus Supplement (if any).

"Prospectus Supplement" shall mean each prospectus supplement relating to the Shares prepared and filed pursuant to Rule 424(b) from time to time.

"Registration Statement" shall mean the shelf registration statement (File Number 333-254261) on Form S-3, including exhibits and financial statements and any prospectus supplement relating to the Shares that is filed with the Commission pursuant to Rule 424(b) and deemed part of such registration statement pursuant to Rule 430B, as amended on each Effective Date and, in the event any post-effective amendment thereto becomes effective, shall also mean such registration statement as so amended.

"Representation Date" shall have the meaning ascribed to such term in Section 4(k).

"Required Approvals" shall have the meaning ascribed to such term in Section 3(e).

"Rule 158", "Rule 164", "Rule 172", "Rule 173", "Rule 405", "Rule 415", "Rule 424", "Rule 430B" and "Rule 433" refer to such rules under the Act.

"Sales Notice" shall have the meaning ascribed to such term in Section 2(b)(i).

"SEC Reports" shall have the meaning ascribed to such term in Section 3(m).

"Settlement Date" shall have the meaning ascribed to such term in Section 2(b)(vii).

"Subsidiary" shall have the meaning ascribed to such term in Section 3(a).

"Terms Agreement" shall have the meaning ascribed to such term in Section 2(a).

"Time of Delivery" shall have the meaning ascribed to such term in Section 2(c).

"Trading Day" means a day on which the Trading Market is open for trading.

"Trading Market" means the Nasdaq Capital Market.

2. Sale and Delivery of Shares. The Company proposes to issue and sell through or to the Manager, as sales agent and/or principal, up to $60,000,000 of Shares (the "Shares") of the Company's common stock, $0.01 par value per share ("Common Stock"), from time to time during the term of this Agreement and on the terms set forth herein; provided, however, that in no event shall the Company issue or sell through the Manager such number of shares that (a) exceeds the number or dollar amount of shares of Common Stock registered on the Registration Statement, pursuant to which the offering is being made, (b) exceeds the number of authorized but unissued shares of Common Stock', or (c) would cause the Company or the offering of the Shares to not satisfy the eligibility and transaction requirements for use of Form S-3, including, if applicable, General Instruction I.B.6 of Registration Statement on Form S-3 (the lesser of (a), (b) and (c), the "Maximum Amount"). Notwithstanding anything to the contrary contained herein, the parties hereto agree that compliance with the limitations set forth in this Section 2 on the number and aggregate sales price of Shares issued and sold under this Agreement shall be the sole responsibility of the Company and that the Manager shall have no obligation in connection with such compliance.

(a) Appointment of Manager as Selling Agent; Terms Agreement. For purposes of selling the Shares through the Manager, the Company hereby appoints the Manager as exclusive agent of the Company for the purpose of soliciting purchases of the Shares from the Company pursuant to this Agreement and the Manager agrees to use its commercially reasonable efforts to act as sales agent for the Company, the Shares on the terms and subject to the conditions stated herein. The Company agrees that, whenever it determines to sell the Shares directly to the Manager as principal, it will enter into a separate agreement (each, a "Terms Agreement") in substantially the form of Annex I hereto, relating to such sale in accordance with Section 2 of this Agreement.

(b) Agent Sales. Subject to the terms and conditions and in reliance upon the representations and warranties set forth in this Agreement, the Company will issue and agrees to sell the Shares from time to time through the Manager, acting as sales agent, and the Manager agrees to use its commercially reasonable efforts to sell the Shares, as sales agent for the Company, on the following terms:

(i) The Shares are to be sold on a daily basis or otherwise as shall be agreed to by the Company and the Manager on any day that (A) is a Trading Day, (B) the Company has instructed the Manager by telephone (confirmed promptly by electronic mail) to make such sales ("Sales Notice") and (C) the Company has satisfied its obligations under Section 6 of this Agreement. The Company will designate the maximum number of the Shares to be sold by the Manager daily (subject to the limitations set forth in Section 2(d)) and the minimum price per Share at which such Shares may be sold, provided that the Sales Notice may specify a number of Shares to be sold on each of several successive days. Subject to the terms and conditions hereof, the Manager shall use its commercially reasonable efforts to sell on a particular day all of the Shares designated for the sale by the Company on such day. The gross sales price of the Shares sold under this Section 2(b) shall be the market price for the shares of Common Stock sold by the Manager under this Section 2(b) on the Trading Market at the time of sale of such Shares.

(ii) The Company acknowledges and agrees that (A) there can be no assurance that the Manager will be successful in selling the Shares, (B) the Manager will incur no liability or obligation to the Company or any other person or entity if it does not sell the Shares for any reason other than a failure by the Manager to use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable law and regulations to sell such Shares as required under this Agreement, and (C) the Manager shall be under no obligation to purchase Shares on a principal basis pursuant to this Agreement, except as otherwise specifically agreed by the Manager and the Company pursuant to a Terms Agreement.

(iii) The Company shall not authorize the issuance and sale of, and the Manager shall not be obligated to use its commercially reasonable efforts to sell, any Share at a price lower than the minimum price therefor designated from time to time by the Company's Board of Directors (the "Board"), or a duly authorized committee thereof, or such duly authorized officers of the Company, and notified to the Manager in writing. The Company or the Manager may, upon notice to the other party hereto by telephone (confirmed promptly by electronic mail), suspend the offering of the Shares for any reason and at any time; provided, however, that such suspension or termination shall not affect or impair the parties' respective obligations with respect to the Shares sold hereunder prior to the giving of such notice.

(iv) The Manager may sell Shares by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415, including without limitation sales made directly on the Trading Market, on any other existing trading market for the Common Stock or to or through a market maker. The Manager may also sell Shares in privately negotiated transactions, provided that the Manager receives the Company's prior written approval for any sales in privately negotiated transactions and if so provided in the "Plan of Distribution" section of the Prospectus Supplement or a supplement to the Prospectus Supplement or a new Prospectus Supplement disclosing the terms of such privately negotiated transaction.

(v) The compensation to the Manager for sales of the Shares under this Section 2(b) shall be a placement fee of 3.5% of the gross sales price of the Shares sold pursuant to this Section 2(b) ("Broker Fee"). The foregoing rate of compensation shall not apply when the Manager acts as principal, in which case the Company may sell Shares to the Manager as principal at a price agreed upon at the relevant Applicable Time pursuant to a Terms Agreement. The remaining proceeds, after deduction of the Broker Fee and deduction of any transaction fees imposed by any clearing firm, execution broker, or governmental or self-regulatory organization in respect of such sales, shall constitute the net proceeds to the Company for such Shares (the "Net Proceeds").

(vi) The Manager shall provide written confirmation (which may be by facsimile or electronic mail) to the Company following the close of trading on the Trading Market each day in which the Shares are sold under this Section 2(b) setting forth the number of the Shares sold on such day, the aggregate gross sales proceeds and the Net Proceeds to the Company, and the compensation payable by the Company to the Manager with respect to such sales.

(vii) Unless otherwise agreed between the Company and the Manager, settlement for sales of the Shares will occur at 10:00 a.m. (New York City time) on the second (2nd) Trading Day (or such earlier day as is industry practice for regular-way trading) following the date on which such sales are made (each, a "Settlement Date"). On or before the Trading Day prior to each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Shares being sold by crediting the Manager's or its designee's account (provided that the Manager shall have given the Company written notice of such designee at least one Trading Day prior to the Settlement Date) at The Depository Trust Company ("DTC") through its Deposit and Withdrawal at Custodian System or by such other means of delivery as may be mutually agreed upon by the parties hereto which Shares in all cases shall be freely tradable, transferable, registered shares in good deliverable form. On each Settlement Date, the Manager will deliver the related Net Proceeds in same day funds to an account designated by the Company on, or prior to, the Settlement Date. The Company agrees that, if the Company, or its transfer agent (if applicable), defaults in its obligation to deliver duly authorized Shares on a Settlement Date, in addition to and in no way limiting the rights and obligations set forth in Section 7 hereto, the Company will (i) hold the Manager harmless against any loss, claim, damage, or reasonable, documented expense (including reasonable and documented legal fees and expenses), as incurred, arising out of or in connection with such default by the Company, and (ii) pay to the Manager (without duplication) any commission, discount or other compensation to which the Manager would otherwise have been entitled absent such default.

(viii) At each Applicable Time, Settlement Date, and Representation Date, the Company shall be deemed to have affirmed each representation and warranty contained in this Agreement as if such representation and warranty were made as of such date, modified as necessary to relate to the Registration Statement and the Prospectus as amended as of such date. Any obligation of the Manager to use its commercially reasonable efforts to sell the Shares on behalf of the Company shall be subject to the continuing accuracy of the representations and warranties of the Company herein, to the performance by the Company of its obligations hereunder and to the continuing satisfaction of the additional conditions specified in Section 6 of this Agreement.

(ix) If the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution" and the record date for the determination of stockholders entitled to receive the Distribution, the "Record Date"), the Company hereby covenants that, in connection with any sales of Shares pursuant to a Sales Notice on the Record Date, the Company covenants and agrees that the Company shall issue and deliver such Shares to the Manager on the Record Date and the Record Date shall be the Settlement Date and the Company shall cover any additional costs of the Manager in connection with the delivery of Shares on the Record Date.

(c) Term Sales. If the Company wishes to sell the Shares pursuant to this Agreement but other than as set forth in Section 2(b) of this Agreement (each, a "Placement"), the Company will notify the Manager of the proposed terms of such Placement. If the Manager, acting as principal, wishes to accept such proposed terms (which it may decline to do for any reason in its sole discretion) or, following discussions with the Company, wishes to accept amended terms, the Manager and the Company will enter into a Terms Agreement setting forth the terms of such Placement. The terms set forth in a Terms Agreement will not be binding on the Company or the Manager unless and until the Company and the Manager have each executed such Terms Agreement accepting all of the terms of such Terms Agreement. In the event of a conflict between the terms of this Agreement and the terms of a Terms Agreement, the terms of such Terms Agreement will control. A Terms Agreement may also specify certain provisions relating to the reoffering of such Shares by the Manager. The commitment of the Manager to purchase the Shares pursuant to any Terms Agreement shall be deemed to have been made on the basis of the representations and warranties of the Company herein contained and shall be subject to the terms and conditions herein set forth. Each Terms Agreement shall specify the number of the Shares to be purchased by the Manager pursuant thereto, the price to be paid to the Company for such Shares, any provisions relating to rights of, and default by, underwriters acting together with the Manager in the reoffering of the Shares, and the time and date (each such time and date being referred to herein as a "Time of Delivery") and place of delivery of and payment for such Shares. Such Terms Agreement shall also specify any requirements for opinions of counsel, accountants' letters and officers' certificates pursuant to Section 6 of this Agreement and any other information or documents required by the Manager.

(d) Maximum Number of Shares. Under no circumstances shall the Company cause or request the offer or sale of any Shares if, after giving effect to the sale of such Shares, the aggregate amount of Shares sold pursuant to this Agreement would exceed the lesser of (A) together with all sales of Shares under this Agreement, the Maximum Amount, (B) the amount available for offer and sale under the currently effective Registration Statement and (C) the amount authorized from time to time to be issued and sold under this Agreement by the Board, a duly authorized committee thereof or a duly authorized executive committee, and notified to the Manager in writing. Under no circumstances shall the Company cause or request the offer or sale of any Shares pursuant to this Agreement at a price lower than the minimum price authorized from time to time by the Board, a duly authorized committee thereof or a duly authorized executive officer, and notified to the Manager in writing. Further, under no circumstances shall the Company cause or permit the aggregate offering amount of Shares sold pursuant to this Agreement to exceed the Maximum Amount.

(e) Regulation M Notice. Unless the exceptive provisions set forth in Rule 101(c)(1) of Regulation M under the Exchange Act are satisfied with respect to the Shares, the Company shall give the Manager at least one Business Day's prior notice of its intent to sell any Shares in order to allow the Manager time to comply with Regulation M.

3. Representations and Warranties. Except as disclosed in the Registration Statement or Prospectus (including the Incorporated Documents), the Company represents and warrants to, and agrees with, the Manager at the Execution Time and on each such time that the following representations and warranties are repeated or deemed to be made pursuant to this Agreement, as set forth below.

(a) Subsidiaries. All of the direct and indirect subsidiaries (individually, a "Subsidiary") of the Company are set forth on Exhibit 21.1 to the Company's most recent Annual Report on Form 10-K filed with the Commission. Except as set forth in the Registration Statement and the Prospectus (including the Incorporated Documents), the Company owns, directly or indirectly, all of the capital stock or other equity interests of each Subsidiary which ownership is free and clear of any "Liens" (which for purposes of this Agreement shall mean a lien, charge, security interest, encumbrance, right of first refusal, preemptive right or other restriction), and all of the issued and outstanding shares of capital stock of each Subsidiary are validly issued and are fully paid, non-assessable and free of preemptive and similar rights to subscribe for or purchase securities.

(b) Organization and Qualification. The Company and each of the Subsidiaries is an entity duly incorporated or otherwise organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization, with the requisite power and authority to own and use its properties and assets and to carry on its business as described in the Incorporated Documents. Neither the Company nor any Subsidiary is in violation or default of any of the provisions of its respective certificate or articles of incorporation, bylaws or other organizational or charter documents. Each of the Company and the Subsidiaries is duly qualified to conduct business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, could not reasonably be expected to result in: (i) a material adverse effect on the legality, validity or enforceability of this Agreement, (ii) a material adverse effect on the results of operations, assets, business, prospects or condition (financial or otherwise) of the Company and the Subsidiaries, taken as a whole, from that set forth in the Registration Statement, the Base Prospectus, any Prospectus Supplement, the Prospectus or the Incorporated Documents, or (iii) a material adverse effect on the Company's ability to perform in any material respect on a timely basis its obligations under this Agreement (any of (i), (ii) or (iii), a "Material Adverse Effect") and no "Proceeding" (which for purposes of this Agreement shall mean any action, claim, suit, investigation or proceeding (including, without limitation, an informal investigation or partial proceeding, such as a deposition), whether commenced or threatened) has been instituted in any such jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification.

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

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

(e) Filings, Consents and Approvals. The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any court or other federal, state, local or other governmental authority or other "Person" (defined as an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind, including the Trading Market) in connection with the execution, delivery and performance by the Company of this Agreement, other than (i) the filings required by this Agreement, (ii) the filing with the Commission of the Prospectus Supplement, (iii) the filing of application(s) to the Trading Market for the listing of the Shares for trading thereon in the time and manner required thereby, and (iv) such filings as are required to be made under applicable state securities laws and the rules and regulations of the Financial Industry Regulatory Authority, Inc. ("FINRA") (collectively, the "Required Approvals").

(f) Issuance of Shares. The Shares are duly authorized and, when issued and paid for in accordance with this Agreement, will be duly and validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company. The Company has reserved or will reserve from its duly authorized capital stock the maximum number of shares of Common Stock issuable pursuant to this Agreement. The issuance by the Company of the Shares has been registered under the Act and all of the Shares are freely transferable and tradable by the purchasers thereof without restriction (other than any restrictions arising solely from an act or omission of such a purchaser). The Shares are being issued pursuant to the Registration Statement and the issuance of the Shares has been registered by the Company under the Act. The "Plan of Distribution" section within the Registration Statement permits the issuance and sale of the Shares as contemplated by this Agreement. Upon receipt of the Shares, the purchasers of such Shares will have good and marketable title to such Shares and the Shares will be freely tradable on the Trading Market.

(g) Capitalization. The capitalization of the Company is as set forth in the SEC Reports. The Company has not issued any capital stock since its most recently filed periodic report under the Exchange Act, other than pursuant to the exercise of employee stock options or other equity grants under the Company's equity incentive plan or inducement grants made outside of the Company's equity incentive plans, pursuant to the conversion and/or exercise of securities exercisable, exchangeable or convertible into Common Stock ("Common Stock Equivalents"), pursuant to the 2019 Brazil Consulting Agreement entered into as of November 25, 2019 among the Company, Orangelife Comercio e Industria Ltda. and the consultant named therein (the "Brazil Consulting Agreement") or pursuant to the Amended and Restated Agency & Commission Agreement entered into as of November 25, 2019 between Chembio Diagnostic Systems, Inc., a wholly owned subsidiary of the Company, and Marco Collovati (the "Agency & Commission Agreement"). No Person has any right of first refusal, preemptive right, right of participation, or any similar right to participate in the transactions contemplated by this Agreement. Except (i) pursuant to the Company's equity incentive plans, (ii) inducement grants made outside of the Company's equity incentive plans in accordance with the rules of the Trading Market and disclosed in the SEC Reports, (iii) as set forth in the Registration Statement or Prospectus (including the Incorporated Documents), (iv) pursuant to the Brazil Consulting Agreement or (v) pursuant to the Agency & Commission Agreement, there are no outstanding options, warrants, scrip rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire, any shares of Common Stock or the capital stock of any Subsidiary, or contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to issue additional shares of Common Stock or Common Stock Equivalents or capital stock of any Subsidiary. The issuance and sale of the Shares will not obligate the Company or any Subsidiary to issue shares of Common Stock or other securities to any Person. There are no outstanding securities or instruments of the Company or any Subsidiary with any provision that adjusts the exercise, conversion, exchange or reset price of such security or instrument upon an issuance of securities by the Company or any Subsidiary. There are no outstanding securities or instruments of the Company or any Subsidiary that contain any redemption or similar provisions, and there are no contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to redeem a security of the Company or such Subsidiary. The Company does not have any stock appreciation rights or "phantom stock" plans or agreements or any similar plan or agreement. All of the outstanding shares of capital stock of the Company are duly authorized, validly issued, fully paid and nonassessable, have been issued in compliance with all federal and state securities laws, and none of such outstanding shares was issued in violation of any preemptive rights or similar rights to subscribe for or purchase securities. No further approval or authorization of any stockholder, the Board or others is required for the issuance and sale of the Shares. There are no stockholders agreements, voting agreements or other similar agreements with respect to the Company's capital stock to which the Company is a party or, to the knowledge of the Company, between or among any of the Company's stockholders.

(h) Registration Statement. The Company meets the requirements for use of Form S-3 under the Act and has prepared and filed with the Commission the Registration Statement, including a related Base Prospectus, for registration under the Act of the offering and sale of the Shares. Such Registration Statement is effective and available for the offer and sale of the Shares as of the date hereof. As filed, the Base Prospectus contains all information required by the Act and the rules thereunder, and, except to the extent the Manager shall agree in writing to a modification, shall be in all substantive respects in the form furnished to the Manager prior to the Execution Time or prior to any such time this representation is repeated or deemed to be made. The Registration Statement, at the Execution Time, each such time this representation is repeated or deemed to be made, and at all times during which a prospectus is required by the Act to be delivered (whether physically or through compliance with Rule 172, Rule 173 or any similar rule) in connection with any offer or sale of the Shares, meets the requirements set forth in Rule 415(a)(1)(x). The initial Effective Date of the Registration Statement was not earlier than the date three years before the Execution Time. The Company meets the transaction requirements as set forth in General Instruction I.B.1 of Form S-3.

(i) Accuracy of Incorporated Documents. The Incorporated Documents, when they were filed with the Commission, conformed in all material respects to the requirements of the Exchange Act and the rules thereunder, and none of the Incorporated Documents, when they were filed with the Commission, contained any untrue statement of a material fact or omitted to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made not misleading; and any further documents so filed and incorporated by reference in the Registration Statement, the Base Prospectus, the Prospectus Supplement or the Prospectus, when such documents are filed with the Commission, will conform in all material respects to the requirements of the Exchange Act and the rules thereunder, as applicable, and will not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, provided, however, this representation shall not apply to any such untrue statement or alleged untrue statement or omission or alleged omission made therein in reliance upon and in conformity with written information furnished to the Company by the Manager specifically for inclusion therein.

(j) Ineligible Issuer. (i) At the earliest time after the filing of the Registration Statement that the Company or another offering participant made a bona fide offer (within the meaning of Rule 164(h)(2)) of the Shares and (ii) as of the Execution Time and on each such time this representation is repeated or deemed to be made (with such date being used as the determination date for purposes of this clause (ii)), the Company was not and is not an Ineligible Issuer (as defined in Rule 405), without taking account of any determination by the Commission pursuant to Rule 405 that it is not necessary that the Company be considered an Ineligible Issuer.

(k) Free Writing Prospectus. The Company is eligible to use Issuer Free Writing Prospectuses. Each Issuer Free Writing Prospectus does not include any information the substance of which conflicts with the information contained in the Registration Statement, including any Incorporated Documents and any prospectus supplement deemed to be a part thereof that has not been superseded or modified; and each Issuer Free Writing Prospectus does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The foregoing sentence does not apply to statements in or omissions from any Issuer Free Writing Prospectus based upon and in conformity with written information furnished to the Company by the Manager specifically for use therein. Any Issuer Free Writing Prospectus that the Company is required to file pursuant to Rule 433(d) has been, or will be, filed with the Commission in accordance with the requirements of the Act and the rules thereunder. Each Issuer Free Writing Prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) or that was prepared by or behalf of or used by the Company complies or will comply in all material respects with the requirements of the Act and the rules thereunder. The Company will not, without the prior consent of the Manager, which consent shall not be unreasonably withheld, prepare, use or refer to, any Issuer Free Writing Prospectuses.

(l) Proceedings Related to Registration Statement. The Registration Statement is not the subject of a pending proceeding or examination under Section 8(d) or Section 8(e) of the Act, and the Company is not the subject of a pending proceeding under Section 8A of the Act in connection with the offering of the Shares. The Company has not received any notice that the Commission has issued or intends to issue a stop-order with respect to the Registration Statement or that the Commission otherwise has suspended or withdrawn the effectiveness of the Registration Statement, either temporarily or permanently, or intends or has threatened in writing to do so.

(m) SEC Reports. The Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company under the Act and the Exchange Act, including pursuant to Section 13(a) or Section 15(d) thereof, for the two years preceding the date hereof (or such shorter period as the Company was required by law or regulation to file such material) (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, together with the Prospectus and the Prospectus Supplement, being collectively referred to herein as the "SEC Reports") on a timely basis or has received a valid extension of such time of filing and has filed any such SEC Reports prior to the expiration of any such extension. The financial statements of the Company incorporated by reference into the Registration Statement, the Prospectus or the Incorporated Documents and any amendments thereof or supplements thereto comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved ("GAAP"), except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnote disclosures required by GAAP, and fairly present in all material respects the financial position of the Company and its consolidated Subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments.

(n) Material Adverse Events. Except as disclosed in the SEC Reports, since the date of the latest audited financial statements included within the SEC Reports, (i) there has been no event, occurrence or development that has had or that would reasonably be expected to result in a Material Adverse Effect, (ii) the Company has not incurred any liabilities (contingent or otherwise) that are material to the Company other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company's financial statements pursuant to GAAP or required to be disclosed in filings made with the Commission, (iii) the Company has not altered its method of accounting, (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock and (v) the Company has not issued any equity securities to any officer, director or "Affiliate" (defined as any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 144 under the Act), except pursuant to existing Company equity compensation plans. The Company does not have pending before the Commission any request for confidential treatment of information. Except for the issuance of the Shares contemplated by this Agreement, no event, liability, fact, circumstance, occurrence or development has occurred or exists with respect to the Company or its Subsidiaries or their respective businesses, prospects, properties, operations, assets or financial condition that would be required to be disclosed by the Company under applicable securities laws at the time this representation is made or deemed made that has not been publicly disclosed (i) with respect to representations made on the date of this Agreement, the date of this Agreement, and (ii) with respect to representations made other than on the date of this Agreement, at least one Trading Day prior to the date that this representation is made.

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

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

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

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

(s) Regulatory Permits. The Company and the Subsidiaries possess all certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct their respective businesses as described in the SEC Reports, except where the failure to possess such permits could not reasonably be expected to result in a Material Adverse Effect ("Material Permits"), and neither the Company nor any Subsidiary has received any notice of proceedings relating to the revocation or modification of any Material Permit.

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

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

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

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

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

(y) Certain Fees. Other than payments to be made to the Manager, no brokerage or finder's fees or commissions are or will be payable by the Company or any Subsidiary to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by this Agreement. The Manager shall have no obligation with respect to any fees or with respect to any claims made by or on behalf of other Persons for fees of a type contemplated in this Section that may be due in connection with the transactions contemplated by this Agreement.

(z) No Other Sales Agency Agreement. The Company has not entered into any other sales agency agreements or other similar arrangements with any agent or any other representative in respect of at the market offerings of the Shares.

(aa) Listing and Maintenance Requirements. The Common Stock is listed on the Trading Market and the issuance of the Shares as contemplated by this Agreement does not contravene the rules and regulations of the Trading Market. The Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the Commission is contemplating terminating such registration. The Company has not, in the 12 months preceding the date hereof, received notice from any Trading Market on which the Common Stock is or has been listed or quoted to the effect that the Company is not in compliance with the listing or maintenance requirements of such Trading Market. The Company is in material compliance with all such listing and maintenance requirements. The Common Stock is currently eligible for electronic transfer through the Depository Trust Company or another established clearing corporation and the Company is current in payment of the fees to the Depository Trust Company (or such other established clearing corporation) in connection with such electronic transfer.

(bb) Application of Takeover Protections. Except as set forth in the SEC Reports, the Company and the Board have taken all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Company's certificate of incorporation (or similar charter documents) or the laws of its state of incorporation that is or could become applicable to the Shares.

(cc) Solvency. Except as set forth in the Registration Statement or the Prospectus (including the Incorporated Documents), based on the consolidated financial condition of the Company as of the date hereof, (i) the fair saleable value of the Company's assets exceeds the amount that will be required to be paid on or in respect of the Company's existing debts and other liabilities (including known contingent liabilities) as they mature, (ii) the Company's assets do not constitute unreasonably small capital to carry on its business as now conducted and as proposed to be conducted including its capital needs taking into account the particular capital requirements of the business conducted by the Company, consolidated and projected capital requirements and capital availability thereof, and (iii) the current cash flow of the Company, together with the proceeds the Company would receive, were it to liquidate all of its assets, after taking into account all anticipated uses of the cash, would be sufficient to pay all amounts on or in respect of its liabilities when such amounts are required to be paid. The Company does not intend to incur debts beyond its ability to pay such debts as they mature (taking into account the timing and amounts of cash to be payable on or in respect of its debt). The SEC Reports sets forth as of the date hereof all outstanding secured and unsecured Indebtedness of the Company or any Subsidiary, or for which the Company or any Subsidiary has commitments. For the purposes of this Agreement, "Indebtedness" means (x) any liabilities for borrowed money or amounts owed in excess of $50,000 (other than accrued liabilities and trade accounts payable incurred in the ordinary course of business), (y) all material guaranties, endorsements and other contingent obligations in respect of indebtedness of others, whether or not the same are or should be reflected in the Company's consolidated balance sheet (or the notes thereto), except guaranties by endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business; and (z) the present value of any lease payments in excess of $50,000 due under leases required to be capitalized in accordance with GAAP. Neither the Company nor any Subsidiary is in default with respect to any Indebtedness.

(dd) Tax Status. Except for matters that would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect, the Company and its Subsidiaries each (i) has made or filed all United States federal, state and local income and all foreign income and franchise tax returns, reports and declarations required by any jurisdiction to which it is subject, (ii) has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations and (iii) has set aside on its books provision reasonably adequate for the payment of all material taxes for periods subsequent to the periods to which such returns, reports or declarations apply. There are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction, and the officers of the Company or of any Subsidiary know of no basis for any such claim.

(ee) Foreign Corrupt Practices. Neither the Company nor any Subsidiary, nor to the knowledge of the Company or any Subsidiary, any agent or other person acting on behalf of the Company or any Subsidiary, has (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company or any Subsidiary (or made by any person acting on its behalf of which the Company is aware) which is in violation of law, or (iv) violated in any material respect any provision of the Foreign Corrupt Practices Act of 1977, as amended.

(ff) Auditor. To the knowledge and belief of the Company, the Auditor is a registered public accounting firm as required by the Exchange Act. The Auditor has been engaged by the Company to express an opinion with respect to the financial statements to be included in the Company's Annual Report on Form 10-K for the fiscal year ending December 31, 2021.

(gg) Regulation M Compliance. The Company has not, and to its knowledge no one acting on its behalf has, (i) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the Shares, (ii) sold, bid for, purchased, or, paid any compensation for soliciting purchases of, any of the Shares, or (iii) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of the Company, other than, in the case of clauses (ii) and (iii), compensation paid to the Manager in connection with the Shares.

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

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

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

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

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

(mm) FINRA Member Shareholders. There are no affiliations with any FINRA member firm among the Company's officers, directors or, to the actual knowledge of the Company without investigation, any five percent (5%) or greater stockholder of the Company, except as set forth in the Registration Statement or the Prospectus (including the Incorporated Documents); provided that BlackRock, Inc., a holder of greater than five percent (5%) of Common Stock, and one or more affiliates of BlackRock, Inc. may be a FINRA member firm.

4. Agreements. The Company agrees with the Manager that:

(a) Right to Review Amendments and Supplements to Registration Statement and Prospectus. During any period when the delivery of a prospectus relating to the Shares is required (including in circumstances where such requirement may be satisfied pursuant to Rule 172, Rule 173 or any similar rule) to be delivered under the Act in connection with the offering or the sale of Shares, the Company will not file any amendment to the Registration Statement or supplement (including any Prospectus Supplement) to the Base Prospectus unless the Company has furnished to the Manager a copy for its review prior to filing and will not file any such proposed amendment or supplement to which the Manager reasonably objects (provided, however, that the Company will have no obligation to provide the Manager any advance copy of such file or to provide the Manager an opportunity to object to such filing if the filing does not name the Manager and does not relate to the transaction herein provided). The Company has properly completed the Prospectus, in a form approved by the Manager, and filed such Prospectus, as amended at the Execution Time, with the Commission pursuant to the applicable paragraph of Rule 424(b) by the Execution Time and will cause any supplement to the Prospectus to be properly completed, in a form approved by the Manager, and will file such supplement with the Commission pursuant to the applicable paragraph of Rule 424(b) within the time period prescribed thereby and will provide evidence reasonably satisfactory to the Manager of such timely filing. The Company will promptly advise the Manager (i) when the Prospectus, and any supplement thereto, shall have been filed (if required) with the Commission pursuant to Rule 424(b), (ii) when, during any period when the delivery of a prospectus (whether physically or through compliance with Rule 172, Rule 173 or any similar rule) is required under the Act in connection with the offering or sale of the Shares, any amendment to the Registration Statement shall have been filed or become effective (other than any annual report of the Company filed pursuant to Section 13(a) or Section 15(d) of the Exchange Act), (iii) of any request by the Commission or its staff for any amendment of the Registration Statement, or for any supplement to the Prospectus or for any additional information, (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or of any notice objecting to its use or the institution or threatening of any proceeding for that purpose and (v) of the receipt by the Company of any notification with respect to the suspension of the qualification of the Shares for sale in any jurisdiction or the institution or threatening of any proceeding for such purpose. The Company will use its commercially reasonable efforts to prevent the issuance of any such stop order or the occurrence of any such suspension or objection to the use of the Registration Statement and, upon such issuance, occurrence or notice of objection, to obtain as soon as possible the withdrawal of such stop order or relief from such occurrence or objection, including, if necessary, by filing an amendment to the Registration Statement or a new registration statement and using its commercially reasonable efforts to have such amendment or new registration statement declared effective as soon as practicable.

(b) Subsequent Events. If, at any time on or after an Applicable Time but prior to the related Settlement Date, any event occurs as a result of which the Registration Statement or Prospectus would include any untrue statement of a material fact or omit to state any material fact necessary to make the statements therein in the light of the circumstances under which they were made or the circumstances then prevailing not misleading, the Company will (i) notify promptly the Manager so that any use of the Registration Statement or Prospectus may cease until such are amended or supplemented; (ii) amend or supplement the Registration Statement or Prospectus to correct such statement or omission; and (iii) supply any amendment or supplement to the Manager in such quantities as the Manager may reasonably request; provided, however, that the Company may delay any such amendment or supplement if, in the good faith judgment of the Company, it is in the best interests of the Company to do so.

(c) Notification of Subsequent Filings. During any period when the delivery of a prospectus relating to the Shares is required (including in circumstances where such requirement may be satisfied pursuant to Rule 172, Rule 173 or any similar rule) to be delivered under the Act, if any event occurs as a result of which the Prospectus as then supplemented would include any untrue statement of a material fact or omit to state any material fact necessary to make the statements therein in the light of the circumstances under which they were made not misleading, or if it shall be necessary to amend the Registration Statement, file a new registration statement or supplement the Prospectus to comply with the Act or the Exchange Act or the respective rules thereunder, including in connection with use or delivery of the Prospectus, the Company promptly will (i) notify the Manager of any such event, (ii) subject to Section 4(a), prepare and file with the Commission an amendment or supplement or new registration statement which will correct such statement or omission or effect such compliance, (iii) use commercially reasonable efforts to have any amendment to the Registration Statement or new registration statement declared effective as soon as practicable in order to avoid any disruption in use of the Prospectus and (iv) supply any supplemented Prospectus to the Manager in such quantities as the Manager may reasonably request.

(d) Earnings Statements. As soon as practicable, the Company will make generally available to its security holders and to the Manager an earnings statement or statements of the Company and its Subsidiaries which will satisfy the provisions of Section 11(a) of the Act and Rule 158. For the avoidance of doubt, the Company’s compliance with the reporting requirements of the Exchange Act shall be deemed to satisfy the requirements of this Section 4(d).

(e) Delivery of Registration Statement. Upon the reasonable request of the Manager, the Company will furnish to the Manager and counsel for the Manager, without charge, signed copies of the Registration Statement (including exhibits thereto) and, so long as delivery of a prospectus by the Manager or dealer may be required by the Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172, Rule 173 or any similar rule), as many copies of the Prospectus and each Issuer Free Writing Prospectus and any supplement thereto as the Manager may reasonably request. The Company will pay the expenses of printing or other production of all documents relating to the offering.

(f) Qualification of Shares. The Company will arrange, if necessary, for the qualification of the Shares for sale under the laws of such jurisdictions as the Manager may reasonably designate and will maintain such qualifications in effect so long as required for the distribution of the Shares; provided that in no event shall the Company be obligated to qualify to do business in any jurisdiction where it is not now so qualified or to take any action that would subject it to service of process in suits, other than those arising out of the offering or sale of the Shares, in any jurisdiction where it is not now so subject.

(g) Free Writing Prospectus. The Company agrees that, unless it has or shall have obtained the prior written consent of the Manager, such consent not to be unreasonably withheld or delayed, and the Manager agrees with the Company that, unless it has or shall have obtained, as the case may be, the prior written consent of the Company, it has not made and will not make any offer relating to the Shares that would constitute an Issuer Free Writing Prospectus or that would otherwise constitute a "free writing prospectus" (as defined in Rule 405) required to be filed by the Company with the Commission or retained by the Company under Rule 433. Any such free writing prospectus consented to by the Manager or the Company is hereinafter referred to as a "Permitted Free Writing Prospectus." The Company agrees that (i) it has treated and will treat, as the case may be, each Permitted Free Writing Prospectus as an Issuer Free Writing Prospectus and (ii) it has complied and will comply, as the case may be, with the requirements of Rules 164 and 433 applicable to any Permitted Free Writing Prospectus, including in respect of timely filing with the Commission, legending and record keeping.

(h) Subsequent Equity Issuances. The Company shall not deliver any Sales Notice hereunder (and any Sales Notice previously delivered shall not apply during such three Business Days) for at least three (3) Business Days prior to any date on which the Company or any Subsidiary offers, sells, issues, contracts to sell, contracts to issue or otherwise disposes of, directly or indirectly, any other shares of Common Stock or any Common Stock Equivalents (other than the Shares), subject to Manager's right to waive this obligation, provided that, without compliance with the foregoing obligation, the Company may issue and sell Common Stock pursuant to any employee equity plan, stock ownership plan or dividend reinvestment plan of the Company in effect at the Execution Time and the Company may issue Common Stock issuable upon the conversion or exercise of Common Stock Equivalents outstanding at the Execution Time.

(i) Market Manipulation. Until the termination of this Agreement, the Company will not take, directly or indirectly, any action designed to or that would constitute or that might reasonably be expected to cause or result in, under the Exchange Act or otherwise, stabilization or manipulation in violation of the Act, Exchange Act or the rules and regulations thereunder of the price of any security of the Company to facilitate the sale or resale of the Shares or otherwise violate any provision of Regulation M under the Exchange Act.

(j) Notification of Incorrect Certificate. The Company will, at any time during the term of this Agreement, as supplemented from time to time, advise the Manager immediately after it shall have received notice or obtained knowledge thereof, of any information or fact that would alter or affect any opinion, certificate, letter and other document provided to the Manager pursuant to Section 6 herein.

(k) Certification of Accuracy of Disclosure. Upon commencement of the offering of the Shares under this Agreement (and upon the recommencement of the offering of the Shares under this Agreement following the termination of a suspension of sales hereunder lasting more than 30 Trading Days), and each time that (i) the Registration Statement or Prospectus shall be amended or supplemented, other than by means of Incorporated Documents, (ii) the Company files its Annual Report on Form 10-K under the Exchange Act, (iii) the Company files its quarterly reports on Form 10-Q under the Exchange Act, (iv) the Company files a Current Report on Form 8-K containing amended financial information (other than information that is furnished and not filed), if the Manager reasonably determines that the information in such Current Report on Form 8-K is material, or (v) the Shares are delivered to the Manager as principal at the Time of Delivery pursuant to a Terms Agreement (such commencement or recommencement date and each such date referred to in (i), (ii), (iii), (iv) and (v) above, a "Representation Date"), unless waived by the Manager, the Company shall furnish or cause to be furnished to the Manager forthwith a certificate dated and delivered on the Representation Date, in form reasonably satisfactory to the Manager to the effect that the statements contained in the certificate referred to in Section 6 of this Agreement which were last furnished to the Manager are true and correct at the Representation Date, as though made at and as of such date (except that such statements shall be deemed to relate to the Registration Statement and the Prospectus as amended and supplemented to such date) or, in lieu of such certificate, a certificate of the same tenor as the certificate referred to in said Section 6, modified as necessary to relate to the Registration Statement and the Prospectus as amended and supplemented to the date of delivery of such certificate.

(l) Bring Down Opinions; Negative Assurance. At each Representation Date, unless waived by the Manager, the Company shall furnish or cause to be furnished forthwith to the Manager and to counsel to the Manager a written opinion of outside counsel and special Nevada outside counsel to the Company (collectively, "Company Counsel") addressed to the Manager and dated and delivered on such Representation Date, in form and substance substantially similar to the opinion delivered by Company Counsel pursuant to Section 6(b) and reasonably satisfactory to the Manager, including a negative assurance representation. The requirement to furnish or cause to be furnished an opinion (but not with respect to a negative assurance representation) under this Section 4(l) shall be automatically waived for any Representation Date other than a Representation Date on which a material amendment to the Registration Statement or Prospectus is made or the Company files its Annual Report on Form 10-K or a material amendment thereto under the Exchange Act, unless the Manager reasonably requests such deliverable required this Section 4(l) in connection with a Representation Date, upon which request such deliverable shall be deliverable hereunder.

(m) Auditor Bring Down "Comfort" Letter. At each Representation Date, unless waived by the Manager, the Company shall cause (1) the Auditor (or any successor thereto), or other independent accountants satisfactory to the Manager forthwith to furnish the Manager a letter, and (2) the Chief Financial Officer of the Company forthwith to furnish the Manager a certificate, in each case dated on such Representation Date, in form satisfactory to the Manager, of the same tenor as the letters and certificate referred to in Section 6 of this Agreement but modified to relate to the Registration Statement and the Prospectus, as amended and supplemented to the date of such letters and certificate; provided, however, that the requirement to furnish or cause to be furnished a "comfort" letter under this Section 4(m) shall be automatically waived for any Representation Date other than a Representation Date on which a material amendment to the Registration Statement or Prospectus is made or the Company files its Annual Report on Form 10-K or a material amendment thereto under the Exchange Act, unless the Manager reasonably requests the deliverables required by this Section 4(m) in connection with a Representation Date, upon which request such deliverable shall be deliverable hereunder. The Company will not be required to cause the Auditor to furnish such letters to the Manager in connection with the filing of a Current Report on Form 8-K unless (i) such Current Report on Form 8-K is filed at any time during which a prospectus relating to the Shares is required to be delivered under the Act, and (ii) the Manager has reasonably requested such letter based upon the event or events reported in such Current Report on Form 8-K.

(n) Due Diligence Session. Upon commencement of the offering of the Shares under this Agreement (and upon the recommencement of the offering of the Shares under this Agreement following the termination of a suspension of sales hereunder lasting more than 30 Trading Days), and in connection with each Representation Date, unless waived by the Manager, the Company will conduct a due diligence session, in form and substance, reasonably satisfactory to the Manager, which shall include representatives of management and Auditor. The Company shall cooperate timely with any reasonable due diligence request from or review conducted by the Manager or its agents from time to time in connection with the transactions contemplated by this Agreement, including, without limitation, providing information and available documents and access to appropriate corporate officers and the Company's agents during regular business hours, and timely furnishing or causing to be furnished such certificates, letters and opinions from the Company, its officers and its agents, as the Manager may reasonably request.

(o) Acknowledgment. The Company is aware that the Manager and its affiliates are engaged in a broad range of transactions which may involve interests that differ from those of the Company and the Manager has no obligation to disclose such interests and transactions to the Company by virtue of any fiduciary, advisory, or agency relationship or otherwise.

(p) Disclosure of Shares Sold. The Company will disclose in its Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q, as applicable, the number of Shares sold through the Manager under this Agreement, the Net Proceeds to the Company and the compensation paid by the Company with respect to sales of Shares pursuant to this Agreement during the relevant quarter; and, if required by any subsequent change in Commission policy or request, more frequently by means of a Current Report on Form 8-K or a further Prospectus Supplement.

(q) Rescission Right. If to the knowledge of the Company, the conditions set forth in Section 6 shall not have been satisfied as of the applicable Settlement Date, the Company will offer to any person who has agreed to purchase Shares from the Company as the result of an offer to purchase solicited by the Manager the right to refuse to purchase and pay for such Shares.

(r) Bring Down of Representations and Warranties. Each acceptance by the Company of an offer to purchase the Shares hereunder, and each execution and delivery by the Company of a Terms Agreement, shall be deemed to be an affirmation to the Manager that the representations and warranties of the Company contained in or made pursuant to this Agreement are true and correct as of the date of such acceptance or of such Terms Agreement as though made at and as of such date, and an undertaking that such representations and warranties will be true and correct as of the Settlement Date for the Shares relating to such acceptance or as of the Time of Delivery relating to such sale, as the case may be, as though made at and as of such date (except that such representations and warranties shall be deemed to relate to the Registration Statement and the Prospectus as amended and supplemented relating to such Shares).

(s) Reservation of Shares. The Company shall ensure that there are at all times sufficient shares of Common Stock to provide for the issuance, free of any preemptive rights, out of its authorized but unissued shares of Common Stock or shares of Common Stock held in treasury, of the maximum aggregate number of Shares authorized for issuance by the Board pursuant to the terms of this Agreement. The Company will use its commercially reasonable efforts to cause the Shares to be listed for trading on the Trading Market and to maintain such listing.

(t) Obligation Under Exchange Act. During any period when the delivery of a prospectus relating to the Shares is required (including in circumstances where such requirement may be satisfied pursuant to Rule 172, 173 or any similar rule) to be delivered under the Act, the Company will file all documents required to be filed with the Commission pursuant to the Exchange Act within the time periods required by the Exchange Act and the regulations thereunder.

(u) DTC Facility. The Company shall cooperate with Manager and use its reasonable efforts to permit the Shares to be eligible for clearance and settlement through the facilities of DTC.

(v) Use of Proceeds. The Company will apply the Net Proceeds from the sale of the Shares in the manner set forth in the Prospectus.

(w) Filing of Prospectus Supplement. If any sales are made pursuant to this Agreement which are not made in "at the market" offerings as defined in Rule 415, including, without limitation, any Placement pursuant to a Terms Agreement, the Company shall file a Prospectus Supplement describing the terms of such transaction, the amount of Shares sold, the price thereof, the Manager's compensation, and such other information as may be required pursuant to Rule 424 and Rule 430B, as applicable, within the time required by Rule 424.

(x) Additional Registration Statement. To the extent that the Registration Statement is not available for the sales of the Shares as contemplated by this Agreement (other than as a result of reaching the limitation set forth in General Instruction I.B.6 of Form S-3), the Company shall file a new registration statement with respect to any additional shares of Common Stock necessary to complete such sales of the Shares and shall cause such registration statement to become effective as promptly as practicable. After the effectiveness of any such registration statement, all references to "Registration Statement" included in this Agreement shall be deemed to include such new registration statement, including all documents incorporated by reference therein pursuant to Item 12 of Form S-3, and all references to "Base Prospectus" included in this Agreement shall be deemed to include the final form of prospectus, including all documents incorporated therein by reference, included in any such registration statement at the time such registration statement became effective.

5. Payment of Expenses. The Company agrees to pay the costs and expenses incident to the performance of its obligations under this Agreement, whether or not the transactions contemplated hereby are consummated, including without limitation: (i) the preparation, printing or reproduction and filing with the Commission of the Registration Statement (including financial statements and exhibits thereto), the Prospectus and each Issuer Free Writing Prospectus, and each amendment or supplement to any of them; (ii) the printing (or reproduction) and delivery (including postage, air freight charges and charges for counting and packaging) of such copies of the Registration Statement, the Prospectus, and each Issuer Free Writing Prospectus, and all amendments or supplements to any of them, as may, in each case, be reasonably requested for use in connection with the offering and sale of the Shares; (iii) the preparation, printing, authentication, issuance and delivery of certificates for the Shares, including any stamp or transfer taxes in connection with the original issuance and sale of the Shares; (iv) the printing (or reproduction) and delivery of this Agreement, any blue sky memorandum and all other agreements or documents printed (or reproduced) and delivered in connection with the offering of the Shares; (v) the registration of the Shares under the Exchange Act, if applicable, and the listing of the Shares on the Trading Market; (vi) any registration or qualification of the Shares for offer and sale under the securities or blue sky laws of the several states (including filing fees and the reasonable fees and expenses of counsel for the Manager relating to such registration and qualification); (vii) the transportation and other expenses incurred by or on behalf of Company representatives in connection with presentations to prospective purchasers of the Shares; (viii) the fees and expenses of the Company's accountants and the fees and expenses of counsel (including local and special counsel) for the Company; (ix) the filing fee under FINRA Rule 5110; (x) the reasonable fees and expenses of the Manager's counsel, not to exceed $100,000; and (xi) all other costs and expenses of the Company incident to the performance by the Company of its obligations hereunder.

6. Conditions to the Obligations of the Manager. The obligations of the Manager under this Agreement and any Terms Agreement shall be subject to (i) the accuracy of the representations and warranties in all material respects on the part of the Company contained herein as of the Execution Time, each Representation Date, and as of each Applicable Time, Settlement Date and Time of Delivery, (ii) the performance by the Company of its obligations hereunder and (iii) the following additional conditions:

(a) Filing of Prospectus Supplement. The Prospectus, and any supplement thereto, required by Rule 424 to be filed with the Commission shall have been filed in the manner and within the time period required by Rule 424(b) with respect to any sale of Shares; each Prospectus Supplement shall have been filed in the manner required by Rule 424(b) within the time period required hereunder and under the Act; any other material required to be filed by the Company pursuant to Rule 433(d) under the Act, shall have been filed with the Commission within the applicable time periods prescribed for such filings by Rule 433; and no stop order suspending the effectiveness of the Registration Statement or any notice objecting to its use shall have been issued and no proceedings for that purpose shall have been instituted or threatened.

(b) Delivery of Opinions. Subject to Section 4(l), the Company shall have caused (i) K&L Gates LLP, outside counsel to the Company, to furnish to the Manager its opinion and negative assurance statement, dated as of such date and addressed to the Manager in form and substance reasonably acceptable to the Manager and (ii) Ballard Spahr LLP, special Nevada outside counsel for the Company, to furnish to the Manager its opinion, dated as of such date and addressed to the Manager in form and substance reasonably acceptable to the Manager.

(c) Delivery of Officer's Certificate. The Company shall have furnished or caused to be furnished to the Manager a certificate of the Company signed by the Chief Executive Officer or the President and the principal financial or accounting officer of the Company, dated as of such date, to the effect that the signers of such certificate have carefully examined the Registration Statement, the Prospectus, any Prospectus Supplement and any documents incorporated by reference therein and any supplements or amendments thereto and this Agreement and that:

(i) the representations and warranties of the Company in this Agreement are true and correct on and as of such date with the same effect as if made on such date and the Company has complied with all the agreements and satisfied all the conditions on its part to be performed or satisfied at or prior to such date;

(ii) no stop order suspending the effectiveness of the Registration Statement or any notice objecting to its use has been issued and no proceedings for that purpose have been instituted or, to the Company's knowledge, threatened; and

(iii) since the date of the most recent financial statements included in the Registration Statement, the Prospectus and the Incorporated Documents, there has been no Material Adverse Effect on the condition (financial or otherwise), earnings, business or properties of the Company and its Subsidiaries, taken as a whole, whether or not arising from transactions in the ordinary course of business, except as set forth in the Registration Statement or the Prospectus (including the Incorporated Documents).

(d) Delivery of Auditor's "Comfort" Letter. Subject to Section 4(m), the Company shall have requested and caused the Auditor to have furnished to the Manager letters (which may refer to letters previously delivered to the Manager), dated as of such date, in form and substance satisfactory to the Manager, confirming that they are independent accountants within the meaning of the Act and the Exchange Act and the respective applicable rules and regulations adopted by the Commission thereunder and that they have performed a review of any unaudited interim financial information of the Company included or incorporated by reference in the Registration Statement and the Prospectus and provide customary "comfort" as to such review in form and substance satisfactory to the Manager.

(e) No Material Adverse Event. Since the respective dates as of which information is disclosed in the Registration Statement, the Prospectus and the Incorporated Documents, except as otherwise stated therein, there shall not have been (i) any change or decrease in previously reported results specified in the letter or letters referred to in paragraph (d) of this Section 6 or (ii) any change, or any development involving a prospective change, in or affecting the condition (financial or otherwise), earnings, business or properties of the Company and its subsidiaries taken as a whole, whether or not arising from transactions in the ordinary course of business, except as set forth in or contemplated in the Registration Statement, the Prospectus and the Incorporated Documents (exclusive of any amendment or supplement thereto) the effect of which, in any case referred to in clause (i) or (ii) above, is, in the reasonable judgment of the Manager, so material and adverse as to make it impractical or inadvisable to proceed with the offering or delivery of the Shares as contemplated by the Registration Statement (exclusive of any amendment thereof), the Incorporated Documents and the Prospectus (exclusive of any amendment or supplement thereto).

(f) Payment of All Fees. The Company shall have paid the required Commission filing fees relating to the Shares within the time period required by Rule 456(b)(1)(i) of the Act without regard to the proviso therein and otherwise in accordance with Rule 456(b) and Rule 457(r) of the Act and, if applicable, shall have updated the "Calculation of Registration Fee" table in accordance with Rule 456(b)(1)(ii) either in a post-effective amendment to the Registration Statement or on the cover page of a prospectus filed pursuant to Rule 424(b).

(g) No FINRA Objections. FINRA shall not have raised any objection with respect to the fairness and reasonableness of the terms and arrangements under this Agreement.

(h) Shares Listed on Trading Market. The Shares shall have been listed and admitted and authorized for trading on the Trading Market, and satisfactory evidence of such actions shall have been provided to the Manager.

(i) Other Assurances. Prior to each Settlement Date and Time of Delivery, as applicable, the Company shall have furnished to the Manager such further information, certificates and documents as the Manager may reasonably request.

If any of the conditions specified in this Section 6 shall not have been fulfilled when and as provided in this Agreement, or if any of the opinions and certificates mentioned above or elsewhere in this Agreement shall not be reasonably satisfactory in form and substance to the Manager and counsel for the Manager, this Agreement and all obligations of the Manager hereunder may be canceled at, or at any time prior to, any Settlement Date or Time of Delivery, as applicable, by the Manager. Notice of such cancellation shall be given to the Company in writing or by telephone or facsimile confirmed in writing.

The documents required to be delivered by this Section 6 shall be delivered to the office of Ellenoff Grossman & Schole LLP, counsel for the Manager, at 1345 Avenue of the Americas, New York, New York 10105, email: capmkts@egsllp.com, on each such date as provided in this Agreement.

7. Indemnification and Contribution.

(a) Indemnification by Company. The Company agrees to indemnify and hold harmless the Manager, the directors, officers, employees and agents of the Manager and each person who controls the Manager within the meaning of either the Act or the Exchange Act against any and all losses, claims, damages or liabilities, joint or several, to which they or any of them may become subject under the Act, the Exchange Act or other Federal or state statutory law or regulation, at common law or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement for the registration of the Shares as originally filed or in any amendment thereof, or in the Base Prospectus, any Prospectus Supplement, the Prospectus, any Issuer Free Writing Prospectus, or in any amendment thereof or supplement thereto, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, and agrees to reimburse each such indemnified party for the legal expenses of one counsel or other expenses reasonably incurred by them in connection with investigating or defending any such loss, claim, damage, liability or action; provided, however, that the Company will not be liable in any such case to the extent that any such loss, claim, damage or liability arises out of or is based upon any such untrue statement or alleged untrue statement or omission or alleged omission made therein in reliance upon and in conformity with written information furnished to the Company by the Manager specifically for inclusion therein. This indemnity agreement will be in addition to any liability that the Company may otherwise have.

(b) Indemnification by Manager. The Manager agrees to indemnify and hold harmless the Company, each of its directors, each of its officers, and each person who controls the Company within the meaning of either the Act or the Exchange Act, to the same extent as the foregoing indemnity from the Company to the Manager, but only with reference to written information relating to the Manager furnished to the Company by the Manager specifically for inclusion in the documents referred to in the foregoing indemnity; provided, however, that in no case shall the Manager be responsible for any amount in excess of the Broker Fee applicable to the Shares and paid hereunder. This indemnity agreement will be in addition to any liability which the Manager may otherwise have.

(c) Indemnification Procedures. Promptly after receipt by an indemnified party under this Section 7 of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against the indemnifying party under this Section 7, notify the indemnifying party in writing of the commencement thereof; but the failure so to notify the indemnifying party (i) will not relieve it from liability under paragraphs (a) or (b) above unless and to the extent it did not otherwise learn of such action and such failure results in the forfeiture by the indemnifying party of substantial rights and defenses and (ii) will not, in any event, relieve the indemnifying party from any obligations to any indemnified party other than the indemnification obligation provided in paragraph (a) or (b) above. The indemnifying party shall be entitled to appoint counsel of the indemnifying party's choice at the indemnifying party's expense to represent the indemnified party in any action for which indemnification is sought (in which case the indemnifying party shall not thereafter be responsible for the fees and expenses of any separate counsel retained by the indemnified party or parties except as set forth below); provided, however, that such counsel shall be reasonably satisfactory to the indemnified party. Notwithstanding the indemnifying party's election to appoint counsel to represent the indemnified party in an action, the indemnified party shall have the right to employ one separate counsel (including local counsel), and the indemnifying party shall bear the documented and reasonable fees, costs and expenses of such separate counsel if (i) the use of counsel chosen by the indemnifying party to represent the indemnified party would present such counsel with a conflict of interest, (ii) the actual or potential defendants in, or targets of, any such action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded that there may be legal defenses available to it and/or other indemnified parties which are different from or additional to those available to the indemnifying party, (iii) the indemnifying party shall not have employed counsel reasonably satisfactory to the indemnified party to represent the indemnified party within a reasonable time after notice of the institution of such action or (iv) the indemnifying party shall authorize the indemnified party to employ separate counsel at the expense of the indemnifying party. An indemnifying party will not, without the prior written consent of the indemnified parties, settle or compromise or consent to the entry of any judgment with respect to any pending or threatened claim, action, suit or proceeding in respect of which indemnification or contribution may be sought hereunder (whether or not the indemnified parties are actual or potential parties to such claim or action) unless such settlement, compromise or consent includes an unconditional release of each indemnified party from all liability arising out of such claim, action, suit or proceeding.

(d) Contribution. In the event that the indemnity provided in paragraphs (a), (b) or (c) of this Section 7 is unavailable to or insufficient to hold harmless an indemnified party for any reason, the Company and the Manager agree to contribute to the aggregate losses, claims, damages and liabilities (including legal or other expenses reasonably incurred in connection with investigating or defending the same) (collectively "Losses") to which the Company and the Manager may be subject in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and by the Manager on the other from the offering of the Shares; provided, however, that in no case shall the Manager be responsible for any amount in excess of the Broker Fee applicable to the Shares and paid hereunder. If the allocation provided by the immediately preceding sentence is unavailable for any reason, the Company and the Manager severally shall contribute in such proportion as is appropriate to reflect not only such relative benefits but also the relative fault of the Company on the one hand and of the Manager on the other in connection with the statements or omissions which resulted in such Losses as well as any other relevant equitable considerations. Benefits received by the Company shall be deemed to be equal to the total net proceeds from the offering (before deducting expenses) received by it, and benefits received by the Manager shall be deemed to be equal to the Broker Fee applicable to the Shares and paid hereunder as determined by this Agreement. Relative fault shall be determined by reference to, among other things, whether any untrue or any alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information provided by the Company on the one hand or the Manager on the other, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such untrue statement or omission. The Company and the Manager agree that it would not be just and equitable if contribution were determined by pro rata allocation or any other method of allocation which does not take account of the equitable considerations referred to above. Notwithstanding the provisions of this paragraph (d), no person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 7, each person who controls the Manager within the meaning of either the Act or the Exchange Act and each director, officer, employee and agent of the Manager shall have the same rights to contribution as the Manager, and each person who controls the Company within the meaning of either the Act or the Exchange Act, each officer of the Company and each director of the Company shall have the same rights to contribution as the Company, subject in each case to the applicable terms and conditions of this paragraph (d).

8. Termination.

(a) The Company shall have the right, by giving written notice as hereinafter specified, to terminate the provisions of this Agreement relating to the solicitation of offers to purchase the Shares in its sole discretion at any time upon five (5) Business Days' prior written notice. Any such termination shall be without liability of any party to any other party except that (i) with respect to any pending sale, through the Manager for the Company, the obligations of the Company, including in respect of compensation of the Manager, shall remain in full force and effect notwithstanding the termination and (ii) the provisions of Sections 5, 7, 8, 9, 10, 12, the second sentence of 13 and 14 of this Agreement shall remain in full force and effect notwithstanding such termination.

(b) The Manager shall have the right, by giving written notice as hereinafter specified, to terminate the provisions of this Agreement relating to the solicitation of offers to purchase the Shares in its sole discretion at any time. Any such termination shall be without liability of any party to any other party except that the provisions of Sections 5, 7, 8, 9, 10, 12, the second sentence of 13 and 14 of this Agreement shall remain in full force and effect notwithstanding such termination.

(c) This Agreement shall remain in full force and effect until such date that this Agreement is terminated pursuant to Sections 8(a) or (b) above or otherwise by mutual agreement of the parties, provided that any such termination by mutual agreement shall in all cases be deemed to provide that Sections 5, 6, 7, 8, 9, 10, 12, the second sentence of 13 and 14 shall remain in full force and effect.

(d) Any termination of this Agreement shall be effective on the date specified in such notice of termination, provided that such termination shall not be effective until the close of business on the date of receipt of such notice by the Manager or the Company, as the case may be. If such termination shall occur prior to the Settlement Date or Time of Delivery for any sale of the Shares, such sale of the Shares shall settle in accordance with the provisions of Section 2(b) of this Agreement.

(e) In the case of any purchase of Shares by the Manager pursuant to a Terms Agreement, the obligations of the Manager pursuant to such Terms Agreement shall be subject to termination, in the absolute discretion of the Manager, by prompt oral notice given to the Company prior to the Time of Delivery relating to such Shares, if any, and confirmed promptly by facsimile or electronic mail, if since the time of execution of the Terms Agreement and prior to such delivery and payment, (i) trading in the Common Stock shall have been suspended by the Commission or the Trading Market or trading in securities generally on the Trading Market shall have been suspended or limited or minimum prices shall have been established on such exchange, (ii) a banking moratorium shall have been declared either by Federal or New York State authorities or (iii) there shall have occurred any outbreak or escalation of hostilities, declaration by the United States of a national emergency or war, or other calamity or crisis the effect of which on financial markets is such as to make it, in the reasonable judgment of the Manager, impractical or inadvisable to proceed with the offering or delivery of the Shares as contemplated by the Prospectus (exclusive of any amendment or supplement thereto).

9. Representations and Indemnities to Survive. The respective agreements, representations, warranties, indemnities and other statements of the Company or its officers and of the Manager set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation made by the Manager or the Company or any of the officers, directors, employees, agents or controlling persons referred to in Section 7, and will survive delivery of and payment for the Shares.

10. Notices. All communications hereunder will be in writing and effective only on receipt, and will be mailed, delivered, e-mailed or facsimiled to the addresses of the Company and the Manager, respectively, set forth on the signature page hereto.

11. Successors. This Agreement will inure to the benefit of and be binding upon the parties hereto and their respective successors and the officers, directors, employees, agents and controlling persons referred to in Section 7, and no other person will have any right or obligation hereunder. Nothing in this Agreement, express or implied, is intended to confer upon any party, other than the parties hereto or their respective successors and permitted assigns, any rights, remedies, obligations or liabilities under or by reason of obligations under this Agreement without the prior written consent of the parties hereto.

12. No Fiduciary Duty. The Company hereby acknowledges that (a) the purchase and sale of the Shares pursuant to this Agreement is an arm's-length commercial transaction between the Company, on the one hand, and the Manager and any affiliate through which it may be acting, on the other, (b) the Manager is acting solely as sales agent and/or principal in connection with the purchase and sale of the Company's securities and not as a fiduciary of the Company and (c) the Company's engagement of the Manager in connection with the offering and the process leading up to the offering is as independent contractors and not in any other capacity. Furthermore, the Company agrees that it is solely responsible for making its own judgments in connection with the offering (irrespective of whether the Manager has advised or is currently advising the Company on related or other matters). The Company agrees that it will not claim that the Manager has rendered advisory services of any nature or respect, or owe an agency, fiduciary or similar duty to the Company, in connection with such transaction or the process leading thereto.

13. Integration. This Agreement and any Terms Agreement supersede all prior agreements and understandings (whether written or oral) between the Company and the Manager with respect to the subject matter hereof. Notwithstanding anything herein to the contrary, the letter agreement, dated July 1, 2021, by and between the Company and the Manager shall continue to be effective and the terms therein shall continue to survive and be enforceable by the Manager in accordance with its terms, provided that, in the event of a conflict between the terms of the letter agreement and this Agreement, the terms of this Agreement shall prevail.

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

15. Applicable Law. This Agreement and any Terms Agreement will be governed by and construed in accordance with the laws of the State of New York applicable to contracts made and to be performed within the State of New York. Each of the Company and the Manager: (i) agrees that any legal suit, action or proceeding arising out of or relating to this Agreement shall be instituted exclusively in New York Supreme Court, County of New York, or in the United States District Court for the Southern District of New York, (ii) waives any objection which it may have or hereafter to the venue of any such suit, action or proceeding, and (iii) irrevocably consents to the jurisdiction of the New York Supreme Court, County of New York, and the United States District Court for the Southern District of New York in any such suit, action or proceeding. Each of the Company and the Manager further agrees to accept and acknowledge service of any and all process which may be served in any such suit, action or proceeding in the New York Supreme Court, County of New York, or in the United States District Court for the Southern District of New York and agrees that service of process upon the Company mailed by certified mail to the Company's address shall be deemed in every respect effective service of process upon the Company, in any such suit, action or proceeding, and service of process upon the Manager mailed by certified mail to the Manager's address shall be deemed in every respect effective service process upon the Manager, in any such suit, action or proceeding. If either party shall commence an action or proceeding to enforce any provision of this Agreement, then the prevailing party in such action or proceeding shall be reimbursed by the other party for its reasonable attorney's fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

16. WAIVER OF JURY TRIAL. EACH OF THE MANAGER AND THE COMPANY HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT, ANY TERMS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY.

17. Counterparts. This Agreement and any Terms Agreement may be signed in one or more counterparts, each of which shall constitute an original and all of which together shall constitute one and the same agreement, which may be delivered by facsimile or in .pdf file via e-mail.

18. Headings. The section headings used in this Agreement and any Terms Agreement are for convenience only and shall not affect the construction hereof.

19. Use of Information. The Manager may not provide any information gained in connection with this Agreement and the transactions contemplated by this Agreement, including due diligence, to any third party other than its legal counsel advising it on this Agreement unless expressly approved by the Company in writing; provided, however, the Manager may disclose such information pursuant to any governmental, judicial or administrative order, subpoena, or discovery request or inquiry of a regulatory or self-regulatory body, provided that the Manager, to the extent legally permitted, uses commercially reasonable efforts to provide written notice thereof to the Company.

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If the foregoing is in accordance with your understanding of our agreement, please sign and return to us the enclosed duplicate hereof, whereupon this letter and your acceptance shall represent a binding agreement among the Company and the Manager.

Very truly yours,

CHEMBIO DIAGNOSTICS, INC.

By: /s/ Richard L. Eberly
Name: Richard L. Eberly
Title: Chief Executive Officer and President

Address for Notice:
Richard L. Eberly
Chief Executive Officer and President
Chembio Diagnostics, Inc.
555 Wireless Boulevard
Hauppauge, NY 11788

The foregoing Agreement is hereby confirmed and accepted as of the date first written above.

CRAIG-HALLUM CAPITAL GROUP LLC

By: /s/ Rick Hartfiel
Name: Rick Hartfiel
Title: Managing Partner

Address for Notice:

ANNEX I

CHEMBIO DIAGNOSTICS, INC.

TERMS AGREEMENT

Dear Sirs:

Chembio Diagnostics, Inc. (the "Company") proposes, subject to the terms and conditions stated herein and in the At The Market Offering Agreement, dated July 19, 2021 (the "At The Market Offering Agreement"), between the Company and Craig-Hallum Capital Group LLC ("Manager"), to issue and sell to Manager the securities specified in the Schedule I hereto (the "Purchased Shares").

Each of the provisions of the At The Market Offering Agreement not specifically related to the solicitation by the Manager, as agent of the Company, of offers to purchase securities is incorporated herein by reference in its entirety, and shall be deemed to be part of this Terms Agreement to the same extent as if such provisions had been set forth in full herein. Each of the representations and warranties set forth therein shall be deemed to have been made at and as of the date of this Terms Agreement and the Time of Delivery, except that each representation and warranty in Section 3 of the At The Market Offering Agreement which makes reference to the Prospectus (as therein defined) shall be deemed to be a representation and warranty as of the date of the At The Market Offering Agreement in relation to the Prospectus, and also a representation and warranty as of the date of this Terms Agreement and the Time of Delivery in relation to the Prospectus as amended and supplemented to relate to the Purchased Shares.

An amendment to the Registration Statement (as defined in the At The Market Offering Agreement), or a supplement to the Prospectus, as the case may be, relating to the Purchased Shares, in the form heretofore delivered to the Manager is now proposed to be filed with the Securities and Exchange Commission.

Subject to the terms and conditions set forth herein and in the At The Market Offering Agreement which are incorporated herein by reference, the Company agrees to issue and sell to the Manager and the latter agrees to purchase from the Company the number of shares of the Purchased Shares at the time and place and at the purchase price set forth in the Schedule I hereto.

If the foregoing is in accordance with your understanding, please sign and return to us a counterpart hereof, whereupon this Terms Agreement, including those provisions of the At The Market Offering Agreement incorporated herein by reference, shall constitute a binding agreement between the Manager and the Company.

CHEMBIO DIAGNOSTICS, INC.

By: /s/ Richard L. Eberly
Name: Richard L. Eberly
Title: Chief Executive Officer and President

ACCEPTED as of the date first written above.

CRAIG-HALLUM CAPITAL GROUP LLC

By: /s/ Rick Hartfiel
Name: Rick Hartfiel
Title: Managing Partner