CHEMBIO DIAGNOSTICS, INC.
Form 424B5
February 12, 2018

Filed Pursuant to Rule 424(b)(5)
Registration No. 333-210003

Prospectus Supplement
(to Prospectus dated April 5, 2016)

1,783,760 Shares of Common Stock

Chembio Diagnostics, Inc.

$6.75 per share

Pursuant to this prospectus supplement and the accompanying prospectus, we are offering 1,783,760 shares of our common stock, par value $0.01 per share. Our common stock is traded on the NASDAQ Capital Market under the symbol CEMI. On February 8, 2018, the last reported sale price of our common stock on the NASDAQ Capital Market was $7.75 per share.

Investing in our securities involves a high degree of risk. Please read Risk Factors beginning on page S-3 of this prospectus supplement, page 19 of the accompanying prospectus and the risk factors described in the documents incorporated by reference into this prospectus supplement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Total
Public offering price	$ 6.75	$12,040,380
Underwriting discount(1)	$ 0.47	$842,826
Proceeds, before expenses, to us	$ 6.28	$11,197,553

(1) We refer you to the Underwriting section of this prospectus supplement for additional information regarding total underwriting compensation.

Delivery of the shares will take place on or about February 13, 2018, subject to the satisfaction of customary closing conditions.

Craig-Hallum Capital Group

The date of this prospectus supplement is February 9, 2018

TABLE OF CONTENTS

TABLE OF CONTENTS

TABLE OF CONTENTS

ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus are part of a shelf registration statement on Form S-3 (File No. 333-210003) that we filed with the Securities and Exchange Commission on March 8, 2016 and that was declared effective on April 5, 2016.

This document is in two parts. The first part is this prospectus supplement, which describes the terms of this offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into the accompanying prospectus. The second part is the accompanying prospectus, which gives more general information about the shares of our common stock and other securities we may offer from time to time under our shelf registration statement, some of which do not apply to the securities offered by this prospectus supplement. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or any document incorporated by reference therein, on the other hand, the information in this prospectus supplement shall control.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference herein were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

You should rely only on the information contained or incorporated by reference in this prospectus supplement, the accompanying prospectus and any free writing prospectus that we have authorized for use in connection with this offering. We have not, and the underwriter has not, authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriter is not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement, and any free writing prospectus that we have authorized for use in connection with this offering is accurate only as of the date of those respective documents. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus supplement, and any free writing prospectus that we have authorized for use in connection with this offering when making your investment decision. You should also read and consider the information in the documents we have referred you to in the sections of this prospectus supplement entitled Incorporation of Certain Documents by Reference and Where You Can Find More Information.

Unless the context requires otherwise, in this prospectus supplement and the accompanying prospectus the terms Chembio, the Company, we, us and our refer to Chembio Diagnostics, Inc., a Nevada corporation, including wholly-owned subsidiaries, Chembio Diagnostic Systems Inc., a Delaware corporation, and Chembio Diagnostics Malaysia Sdn Bhd, a Malaysia corporation.

TABLE OF CONTENTS

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights certain information about us, this offering and selected information contained elsewhere in or incorporated by reference into this prospectus supplement and the accompanying prospectus. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in our common stock. For a more complete understanding of Chembio and this offering, we encourage you to read and consider carefully the more detailed information in this prospectus supplement and the accompanying prospectus, including the information incorporated by reference in this prospectus supplement and the accompanying prospectus, and the information included in any free writing prospectus that we have authorized for use in connection with this offering, including the information referred to under the heading Risk Factors in this prospectus supplement.

Our Company

Through our wholly-owned subsidiaries, Chembio Diagnostic Systems Inc. and Chembio Diagnostics Malaysia Sdn Bhd, we develop, manufacture, and commercialize point-of-care diagnostic tests that are used to detect or monitor diseases. All products that are currently being developed are based on the Company s patented DPP® technology, which is a novel point-of-care diagnostic platform that offers certain customer advantages, as compared to traditional lateral flow technology.

Our products are organized in three verticals: sexually transmitted disease, tropical and fever disease, and technology collaborations. In our sexually transmitted disease business, we are commercializing tests for HIV and Syphilis. In our tropical and fever disease business, we are commercializing a test for Zika virus, and developing tests for malaria, dengue virus, chikungunya virus, ebola, lassa, Marburg, leptospirosis, Rickettsia typhi, Burkholderia pseudomallei, and Orientia tsutsugamushi, individually or as part of a fever panel test. Through technology collaborations, we are developing tests for a specific form of cancer, concussion, bovine tuberculosis, and for an undisclosed biomarker, the latter in collaboration with global biopharmaceutical company, AstraZeneca.

Our products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments, both domestically and internationally, under our STAT PAK®, SURE CHECK®, STAT-VIEW® or DPP® registered trademarks, or under the private labels of our marketing partners.

The company has manufacturing facilities in the United States (Medford, NY) and Asia (Kuala Lumpur, Malaysia).

Recent Developments

On February 8, 2018, the Company filed a Form 8-K with the SEC that included a preliminary unaudited estimate of revenue and the ending cash balance for the year ended December 31, 2017. That Form 8-K has been incorporated by reference into this prospectus supplement and the accompanying prospectus. The preliminary financial results provided in the Form 8-K include estimates only, and are subject to change upon completion of the audit of our financial statements as of and for the year ended December 31, 2017. Additional information and disclosures would be required for a more complete understanding of our financial position and results of operations as of December 31, 2017. The Form 8-K filed on February 8, 2017 also includes information concerning certain recent developments in the Company s business.

Corporate Information

Chembio was formed in 1985. Since inception we have been involved in developing, manufacturing, selling and distributing rapid diagnostic tests that are used to detect or monitor diseases. Our principal executive offices are located at 3661 Horseblock Road, Medford, New York 11763. Our telephone number is (631) 924-1135. Our website address is *www.chembio.com.* Information contained on our website is not a part of this prospectus supplement or the accompanying prospectus.

TABLE OF CONTENTS

THE OFFERING

The summary below describes the principal terms of this offering. The Description of Common Stock section in the accompanying prospectus contains a more detailed description of our common stock.

Common stock we are offering

1,783,760 shares

Common stock outstanding immediately after this offering

14,176,053 shares(1)

Net proceeds

The net proceeds to us from the sale of the common stock offered hereby, after deducting underwriting discounts and commissions and estimated offering expenses, will be approximately $11.0 million.

Use of proceeds

We intend to use the net proceeds received from the sale of the securities for business expansion and working capital, including product development, operational expansion or improvements, such as new automated equipment and a facilities update, clinical trials and other related activities, and sales and marketing. See Use of Proceeds of this prospectus supplement for additional information.

NASDAQ Capital Market symbol

CEMI

Participation in offering

The Company s officers and directors may participate in this offering. At this time, the Company s Chief Financial Officer has indicated his intent to purchase approximately $100,000 of the Company s common stock in this offering.

Risk Factors

Investing in our common stock involves substantial risks. See the Risk Factors section of this prospectus supplement and in the accompanying prospectus and in the documents incorporated by reference into this prospectus supplement and the accompanying prospectus for a description of certain of the risks you should consider before investing in our common stock.

(1) The number of shares to be outstanding after this offering is based on 12,392,293 shares of our common stock outstanding as of February 7, 2018 (prior to this offering), and excludes as of that date:

729,373 shares of our common stock subject to outstanding stock options having a weighted average exercise price of $5.1739 per share; and

487,782 shares of our common stock reserved for future issuance pursuant to our existing stock option plan.

Except as otherwise indicated, all information in this prospectus supplement assumes no exercise by the underwriter of its option to purchase additional shares.

TABLE OF CONTENTS

RISK FACTORS

An investment in our Company involves a high degree of risk, and should be considered only by persons who can afford the loss of their entire investment. As a result, you should consider all of the information provided in this prospectus supplement, the accompanying prospectus and the risks discussed below, together with the risks discussed in the accompanying prospectus, including the sections of the accompanying prospectus entitled Special Note Regarding Forward-Looking Statements and Risk Factors, and those set forth under the heading Item 1.A Risk Factors in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 that we have incorporated by reference into this prospectus supplement. Although we believe that these risks are the most important for you to consider, you should read this section in conjunction with our financial statements, the notes to those financial statements and our management s discussion and analysis of financial condition and results of operations included in our periodic reports and incorporated into this prospectus supplement by reference.

Risks Related to this Offering

Management will have broad discretion as to the use of the proceeds from this offering, and we may not use the proceeds effectively.

Our management will have broad discretion in the application of the net proceeds from this offering 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 cause the price of our common stock to decline.

Our Common Stock continues to be illiquid, so investors may not be able to sell as much stock as they want at prevailing market prices.

The average daily trading volume of our Common Stock on the NASDAQ Capital Market was approximately 16,368 shares per day over the three months ended December 31, 2017 as compared with approximately 19,300 shares per day over the three months ended December 31, 2016. The liquidity of our stock depends on several factors, including but not limited to the financial results of the Company 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. Although there is no affiliation between our management and our larger stockholders, they could exercise significant control over the Company if they voted their shares in a similar manner.

You will experience immediate and substantial dilution in the net tangible book value per share of the common stock you purchase.

Since the price per share of our common stock being offered is substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on the public offering price of $6.75 per share, if you purchase shares in this offering, you will suffer immediate and substantial dilution of $5.12 per share in the net tangible book value of the common stock. See the section entitled Dilution below for a more detailed discussion of the dilution you will incur if you purchase common stock in this offering.

You may experience future dilution as a result of future equity offerings and the exercise of outstanding options and warrants.

In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors in this offering, 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 in this offering. As of February 7, 2018, 487,782 shares of common stock were reserved for future issuance under our various employee benefit plans. As of that date, there were also options outstanding to purchase 729,373 shares of our common stock and no warrants outstanding to purchase shares of our common stock. You will incur dilution upon exercise of any outstanding stock options or warrants.

TABLE OF CONTENTS

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and any accompanying prospectus supplements contain or incorporate by reference forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These forward-looking statements represent plans, estimates, objectives, goals, guidelines, expectations, intentions, projections and statements of our beliefs concerning future events, business plans, objectives, expected operating results and the assumptions upon which those statements are based. Forward-looking statements include, without limitation, any statement that may predict, forecast, indicate or imply future results, performance or achievements, and are typically identified with words such as may, could, should, will, would, believe, anticipate, estimate, expect, words or phases of similar meaning. We caution that the forward-looking statements are based largely on our expectations and are subject to a number of known and unknown risks and uncertainties that are subject to change based on factors which are, in many instances, beyond our control. Actual results, performance or achievements could differ materially from those contemplated, expressed, or implied by the forward-looking statements.

The following factors, among others, could cause our financial performance to differ materially from that expressed in such forward-looking statements:

our ability to obtain or maintain necessary regulatory approvals for some of our products;
the timely development of competitive new products and services, and the acceptance of these products and services by new and existing customers;
the lack of availability for alternate third-party suppliers for certain important product components;
the willingness of users to substitute competitors products and services for our products and services;
new developments in health treatments or new non-diagnostic products that reduce or eliminate the demand for our products;
changes in consumer spending and savings habits;
the strength of the United States economy in general and the strength of the local economies in which the Company conducts operations;
geopolitical conditions, including acts or threats of terrorism, actions taken by the United States or other governments in response to acts or threats of terrorism and/or military conflicts, which could impact business and economic conditions in the United States and abroad;
the effects of, and changes in, trade, monetary and fiscal policies and laws, including interest rate policies of the Board of Governors of the Federal Reserve System, or the Federal Reserve Board; inflation, interest rate, market and monetary fluctuations;
availability of resources for introduction and marketing of our products;
technological changes;
our ability to attract and retain key employees;
continued funding of, and our ability to, participate in large testing programs, in the U.S. and worldwide;
uncertainty as to our future profitability;
the impact of changes in financial services policies, laws and regulations, including laws, regulations and policies concerning taxes, banking, securities and insurance, and the application thereof by regulatory bodies;
the effect of acquisitions we may make, including, without limitation, the failure to achieve the expected revenue growth and/or expense savings from such acquisitions;

TABLE OF CONTENTS

the growth and profitability of non-interest or fee income being less than expected; and
unanticipated regulatory or judicial proceedings.

Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail under the heading Risk Factors of this prospectus supplement and in our SEC filings. Also, these forward-looking statements represent our estimates and assumptions only as of the date of the document containing the applicable statement.

You should read this prospectus supplement, the accompanying prospectus, the documents we have filed with the SEC that are incorporated by reference and any free writing prospectus that we have authorized for use in connection with this offering completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in the foregoing documents by these cautionary statements. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

TABLE OF CONTENTS

USE OF PROCEEDS

We estimate that the net proceeds from the sale of the shares of our common stock offered by this prospectus supplement, after deducting underwriting discounts and commissions and estimated offering expenses, will be approximately $11.0 million. We will use the proceeds from the sale of the securities described in this prospectus supplement for business expansion and working capital including product development, operational expansion or improvements, such as new automated equipment and a facilities update, clinical trials and other related activities, and sales and marketing. The specific uses will depend upon the Company s needs as determined by the board of directors, at the time, and may vary from the uses described herein. Pending such use, we may temporarily invest the proceeds or use them to reduce short-term indebtedness.

TABLE OF CONTENTS

DILUTION

If you invest in our common stock, you will experience dilution to the extent of the difference between the price per share you pay in this offering and the net tangible book value per share of our common stock immediately after this offering.

Our net tangible book value as of September 30, 2017, was approximately $12.1 million, or $0.98 per share of common stock. Net tangible book value per share is equal to our total tangible assets minus total tangible liabilities, all divided by the number of shares of common stock outstanding as of September 30, 2017. After giving effect to the sale of 1,783,760 shares of common stock by us at a price of $6.75 per share, and after deducting underwriting fees and discounts and estimated offering expenses payable by us, our as adjusted net tangible book value would have been approximately $23.1 million or approximately $1.63 per share of common stock, as of September 30, 2017. This represents an immediate increase in net tangible book value of approximately $0.65 per share to existing stockholders and an immediate dilution of approximately $5.12 per share to new investors. The following table illustrates this calculation on a per share basis:

Public offering price per share	$ 6.75
Net tangible book value per share as of September 30, 2017	$ 0.98
Increase per share attributable to this offering	$ 0.65
As adjusted net tangible book value per share after this offering	$ 1.63
Dilution per share to new investors	$ 5.12

The number of shares of common stock shown above to be outstanding after this offering is based on 12,392,293 shares outstanding as of February 7, 2018, and excludes:

729,373 shares of our common stock subject to outstanding stock options having a weighted average exercise price of $5.1739 per share; and

487,782 shares of our common stock reserved for future issuance pursuant to our existing stock option plan.

The above illustration of dilution per share to investors participating in this offering assumes no exercise of outstanding options to purchase shares of our common stock. The exercise of outstanding options having an exercise price less than the offering price will increase dilution to new investors.

In addition, we may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

TABLE OF CONTENTS

PRICE RANGE OF OUR COMMON STOCK

Our common stock trades on the NASDAQ Capital Market under the symbol CEMI. The following table sets forth, for the periods indicated, the reported high and low sales prices per share of our common stock on the NASDAQ Capital Market. Such prices reflect interdealer prices, without retail mark-up, mark-down or commission, and may not necessarily represent actual transactions.

Period	High	Low
Year Ending December 31, 2018		
First Quarter through February 8, 2018	$ 9.09	$ 7.60
Year Ended December 31, 2017		
First Quarter	$ 6.80	$ 5.30
Second Quarter	$ 6.05	$ 5.30
Third Quarter	$ 6.20	$ 6.05
Fourth Quarter	$ 8.20	$ 6.20
Year Ended December 31, 2016		
First Quarter	$ 6.10	$ 4.03
Second Quarter	$ 9.40	$ 5.87
Third Quarter	$ 8.48	$ 5.08
Fourth Quarter	$ 7.45	$ 6.10

On February 8, 2018, the closing sale price for our common stock was $7.75 per share, as reported on the NASDAQ Capital Market. The foregoing table shows only historical comparisons. The comparisons may not provide meaningful information to you in determining whether to purchase our common stock. You are urged to obtain current market quotations for our common stock and to review carefully the other information contained in this prospectus supplement, the accompany prospectus and the documents incorporated by reference in each. See Where You Can Find More Information and Incorporation of Certain Documents By Reference in this prospectus supplement.

DIVIDEND POLICY

We have never paid cash dividends on our common stock and do not anticipate paying any cash dividends in the foreseeable future, but intend to retain our capital resources for reinvestment in our business.

TABLE OF CONTENTS

FDA AND CLIA REQUIREMENTS

Government Regulation of Medical Devices for Human Subjects

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

FDA Approval/Clearance Requirements

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

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

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

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

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

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

TABLE OF CONTENTS

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

Rapid HIV tests intended for diagnostic use are regulated as Class III devices. Responsibility for assuring the safety and effectiveness of these tests lies within the Center for Biologics Evaluation and Research s Office of Blood Research and Review, with oversight by the Blood Products Advisory Committee (BPAC). Approved Rapid HIV tests must meet the regulations in the 21 CFR 800 series subparts, under the Investigational Device exemption (IDE) and PMA pathways.

Premarket Approval Pathway

Chembio manufactures, markets, and distributes three rapid HIV tests in the U.S: our HIV 1/2 STAT-PAK® Assay, SURE CHECK® HIV 1/2 Assay, and DPP® HIV 1/2 Assay, all of which have received FDA PMA approval. A PMA application must be submitted if a device cannot be cleared through the 510(k) process. A PMA application must be supported by extensive data including, but not limited to, analytical, preclinical, clinical trials, manufacturing, statutory preapproval inspections, and labeling to demonstrate to the FDA s satisfaction the safety and effectiveness of the device for its intended use. Before a PMA is submitted, a manufacturer must apply for an investigational device exemption, or IDE. If the device presents a significant risk, as defined by the FDA, to human health, the FDA requires the device sponsor to file an IDE application with the FDA and obtain IDE approval prior to initiation of enrollment of human subjects for clinical trials. The IDE provides the manufacturer with a legal pathway to perform clinical trials on human subjects where without the IDE, only approved medical devices may be used on human subjects.

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

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

After a PMA application is sufficiently complete, the FDA will accept the application and begin an in-depth review of the submitted information. By statute, the FDA has 180 days to review the accepted application, although, generally, review of the application can take between one and three years, but it may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also, during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The preapproval inspections conducted by the FDA include an evaluation of the manufacturing facility to ensure compliance with the Quality Systems Regulations (QSR), as well as inspections of the clinical trial sites by the Bioresearch Monitoring group to evaluate compliance with good clinical practice and human subject protections. New PMA applications or

PMA supplements are required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device s indication for use, manufacturing process, labeling and design. Significant changes to an approved PMA require a 180-day supplement, whereas less substantive changes may utilize a 30-day notice, or a 135-day supplement. Premarket approval supplements often require submission of the same type of information as a premarket approval application, except that the supplement is limited to information needed to support any changes from the device covered by the original premarket approval application, and it may not require as extensive clinical data or the convening of an advisory panel.

TABLE OF CONTENTS

Our HIV 1/2 STAT-PAK® Assay PMA application number BP050009/0 and our SURE CHECK® 1/2 HIV Assay PMA application number BP050010/0 were approved by the FDA on May 25, 2006. Our DPP® HIV 1/2 Assay PMA application number BP120032/0 was approved by the FDA on December 19, 2012.

510(k) Clearance Pathway

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

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

If the FDA requires us to submit a new 510(k) or PMA for any modifications to a previously cleared product, or if we obtain 510(k) clearance for a device in the future, we may be required to submit a separate new 510(k) or PMA application for such modifications.

Clinical Laboratory Improvement Amendments of 1988 (CLIA)

A manufacturer of a test categorized as moderately complex may request that categorization of the test as waived through a CLIA Waiver by Application (CW) submission to the FDA. When a test is categorized as waived, it may be performed by laboratories with a Certificate of Waiver, such as a physician s office outreach setting. In a CW submission, the manufacturer provides evidence to the FDA that a test meets the CLIA statutory criteria for waiver, 42 U.S.C. 263a(d)(3). Congress passed CLIA in 1988, which provided CMS authority over all laboratory testing, except research that is performed on humans in the United States. The Division of Laboratory Services, within the Survey and Certification Group, under the CMS, has the responsibility for implementing the CLIA program.

The CLIA program is designed to establish quality laboratory testing by ensuring the accuracy, reliability and timeliness of patient test results. Under CLIA, a laboratory is a facility that does laboratory testing on specimens derived from humans and used to provide information for the diagnosis, prevention or treatment of disease, or impairment of, or assessment of health. Under the CLIA program, unless waived, laboratories must be certified by the government, satisfy governmental quality and personnel standards, undergo proficiency testing, be subject to inspections and pay fees. We have received a CLIA waiver for both of our lateral flow rapid HIV tests that we market in the U.S. Specifically, the CLIA waiver was granted by the FDA for HIV 1/2 STAT-PAK® on November 20, 2006 and for SURE CHECK® HIV 1/2 on October 22, 2007. In 2008 the FDA revised its CLIA waiver requirements so that an additional prospective trial is required in order to demonstrate clinical utility by showing that the device is capable of identifying new infections when used by untrained users. Our DPP® HIV 1/2 test received a CLIA waiver under these newer requirements on October 29, 2014.

Pervasive and Continuing FDA Regulation

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

TABLE OF CONTENTS

A noncomprehensive list of the regulatory requirements that apply to our approved products classified as medical devices or IVDs include:

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

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

21st Century Cures Act

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

Government Regulation of Medical Devices for Animal Subjects

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

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

TABLE OF CONTENTS

UNDERWRITING

We are offering the shares of common stock described in this prospectus supplement and the accompanying prospectus through the underwriter listed below. Craig-Hallum Capital Group LLC is acting as the sole book-running manager of this offering. The underwriter named below has agreed to buy, subject to the terms of the underwriting agreement, the number of shares of common stock listed opposite its names below. The underwriter is committed to purchase and pay for all of the shares if any are purchased.

Underwriter	Number of Shares
Craig-Hallum Capital Group LLC	1,783,760
Total	

The underwriter has advised us that it proposes to offer the shares of common stock to the public at a price of $6.75 per share. The underwriter proposes to offer the shares of common stock to certain dealers at the same price less a concession of not more than $0.28 per share. After the offering, these figures may be changed by the underwriter.

The shares sold in this offering are expected to be ready for delivery on or about February 13, 2018, against payment in immediately available funds. The underwriter may reject all or part of any order.

The table below summarizes the underwriting discounts that we will pay to the underwriter. In addition to the underwriting discount, we have agreed to pay up to $100,000 of the fees and expenses of the underwriter, which may include the fees and expenses of counsel to the underwriter. The fees and expenses of the underwriter that we have agreed to reimburse are not included in the underwriting discounts set forth in the table below. The underwriting discount and reimbursable expenses the underwriter will receive were determined through arms length negotiations between us and the underwriter.

	Per Share	Total
Underwriting discount to be paid by us	$ 0.47	$ 842,826

We estimate that the total expenses of this offering, excluding underwriting discounts, will be $235,000. This includes $100,000 of fees and expenses of the underwriter. These expenses are payable by us.

We also have agreed to indemnify the underwriter against certain liabilities, including civil liabilities under the Securities Act of 1933, as amended, or to contribute to payments that the underwriter may be required to make in respect of those liabilities.

Our officers and directors may participate in this offering. At this time, the Company s Chief Financial Officer has indicated his intent to purchase approximately $100,000 of the Company s common stock in this offering. However, because indications of interest are not binding agreements or commitments to purchase, this individual may determine to increase or reduce the amount of his indication of interest, or otherwise elect not to purchase any shares. It is also possible that the number of shares, if any, allocated to any investor in the offering may be smaller than the amount of that investor s indication of interest. Any allocation of shares in the offering to any officer or director will be made at our direction. The underwriter will receive the same underwriting discount on any shares purchased by officers and directors as they will on any other shares sold to the public in this offering.

We and each of our directors and officers have agreed not to offer, sell, agree to sell, directly or indirectly, or otherwise dispose of any shares of common stock or any securities convertible into or exchangeable for shares of common stock without the prior written consent of Craig-Hallum Capital Group LLC for a period of 90 days after the date of this prospectus supplement. These lock-up agreements provide limited exceptions and their restrictions may be waived at any time by Craig-Hallum Capital Group LLC.

To facilitate this offering, the underwriter may engage in transactions that stabilize, maintain or otherwise affect the price of our common stock during and after the offering. Specifically, the underwriter may over-allot or otherwise create a short position in our common stock for its own account by selling more shares of common stock than we have sold to the underwriter. The underwriter may close out any short position by either exercising its option to purchase additional shares or purchasing shares in the open market.

TABLE OF CONTENTS

In addition, the underwriter may stabilize or maintain the price of our common stock by bidding for or purchasing shares in the open market and may impose penalty bids. If penalty bids are imposed, selling concessions allowed to broker-dealers participating in this offering are reclaimed if shares previously distributed in this offering are repurchased, whether in connection with stabilization transactions or otherwise. The effect of these transactions may be to stabilize or maintain the market price of our common stock at a level above that which might otherwise prevail in the open market. The imposition of a penalty bid may also affect the price of our common stock to the extent that it discourages resales of our common stock. The magnitude or effect of any stabilization or other transactions is uncertain. These transactions may be effected on the NASDAQ Capital Market or otherwise and, if commenced, may be discontinued at any time.

In connection with this offering, the underwriter and any selling group members may also engage in passive market making transactions in our common stock on the NASDAQ Capital Market. Passive market making consists of displaying bids on the NASDAQ Capital Market limited by the prices of independent market makers and effecting purchases limited by those prices in response to order flow. Rule 103 of Regulation M promulgated by the SEC limits the amount of net purchases that each passive market maker may make and the displayed size of each bid. Passive market making may stabilize the market price of our common stock at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

Neither we nor the underwriter make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor the underwriter make any representation that the underwriter will engage in these transactions or that any transaction, if commenced, will not be discontinued without notice.

The underwriter and its affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriter may in the future engage in investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. The underwriter may in the future receive customary fees and commissions for these transactions.

In the ordinary course of their various business activities, the underwriter and its affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of the issuer. The underwriter and its affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

The underwriter may facilitate the marketing of this offering online directly or through one of their affiliates. In those cases, prospective investors may view offering terms and a prospectus supplement online and place orders online or through their financial advisors.

Selling Restrictions

Canada. The offering of the common stock in Canada is being made on a private placement basis in reliance on exemptions from the prospectus requirements under the securities laws of each applicable Canadian province where the common stock may be offered and sold, and therein may only be made with investors that are purchasing as principal and that qualify as both an accredited investor as such term is defined in National Instrument

45-106 Prospectus Exemptions (NI 45-106) (if the investor is resident in Ontario, it is an accredited investor as defined in NI 45-106 and in section 73.3 of the Securities Act (Ontario)) and as a permitted client as such term is defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any offer and sale of the common stock in any province of Canada may only be made through a dealer that is properly registered under the securities legislation of the applicable province wherein the common stock is offered and/or sold or, alternatively, by a dealer that qualifies under and is relying upon an exemption from the registration requirements therein.

TABLE OF CONTENTS

Any resale of the common stock by an investor resident in Canada must be made in accordance with applicable Canadian securities laws, which may require resales to be made in accordance with prospectus and registration requirements, statutory exemptions from the prospectus and registration requirements or under a discretionary exemption from the prospectus and registration requirements granted by the applicable Canadian securities regulatory authority. These resale restrictions may under certain circumstances apply to resales of the common stock outside of Canada.

TABLE OF CONTENTS

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the informational requirements of the Exchange Act, and file annual, quarterly and current reports, proxy statements and other information required by the Exchange Act with the SEC. You may read and copy any reports, proxy statements and other information we file at the SEC s public reference room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. You may also access filed documents at the SEC s web site at *http://www.sec.gov*.

We are incorporating by reference some information about us that we file with the SEC. We are disclosing important information to you by referencing those filed documents. Any information that we reference this way is considered part of this prospectus supplement. The information in this prospectus supplement supersedes statements made in the accompanying prospectus and information incorporated by reference that we have filed with the SEC prior to the date of this prospectus supplement, while information that we file with the SEC after the date of this prospectus supplement that is incorporated by reference will automatically update and supersede this information.

TABLE OF CONTENTS

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference the information that we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus supplement. These documents may include periodic reports, such as Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as Proxy Statements.

This prospectus supplement incorporates by reference the documents listed below that we previously have filed with the SEC and any additional documents that we may file with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus supplement and prior to the termination of the offering covered by this prospectus supplement, except to the extent that any information contained in such filings is deemed furnished in accordance with SEC rules, including, but not limited to, information furnished under Items 2.02 and 7.01 of any Current Report on Form 8-K including related exhibits:

our Annual Report on Form 10-K for the year ended December 31, 2016, filed with the SEC on March 7, 2017;
the portions of our definitive proxy statement on Schedule 14A that are deemed filed with SEC under the Exchange Act, filed on March 24, 2017;
our Current Reports on Form 8-K filed with the SEC on January 10, 2017, April 6, 2017, May 16, 2017, May 31, 2017, June 20, 2017, June 27, 2017, July 10, 2017, August 17, 2017, September 19, 2017, September 29, 2017, October 5, 2017, December 20, 2017 (filed at 10:24 a.m.), February 8, 2018 (both the Form 8-Ks filed at 5:03 p.m. and 5:16 p.m.) and February 9, 2018;
our Quarterly Report for the quarter ended March 31, 2017, filed with the SEC on May 9, 2017;
our Quarterly Report for the quarter ended June 30, 2017, filed with the SEC on August 9, 2017;
our Quarterly Report for the quarter ended September 30, 2017, filed with the SEC on November 8, 2017; and
the description of our common stock contained in our Registration Statement on Form 8-A12B filed under the Exchange Act on June 6, 2012, including any amendment or report filed for the purpose of updating such description.

You can obtain a copy of any or all of the documents incorporated by reference in this prospectus (other than an exhibit to a document unless that exhibit is specifically incorporated by reference into that document) from the SEC on its web site at *http://www.sec.gov.* You also can obtain these documents from us without charge by visiting our internet web site *http://www.chembio.com* or by requesting them in writing, by email or by telephone at the following address:

Neil A. Goldman
Chief Financial Officer
3661 Horseblock Road
Medford, New York 11763
(631) 924-1135
InvestorRelations@chembio.com

TABLE OF CONTENTS

LEGAL MATTERS

Certain matters concerning this offering will be passed upon for us by Haynes and Boone, LLP, Denver, Colorado. The validity of the common stock offered hereby has been passed upon for us by Ballard Spahr LLP, Las Vegas, Nevada. Certain matters will be passed upon for the underwriter by Faegre Baker Daniels LLP, Minneapolis, Minnesota. As of the date of this prospectus supplement, certain partners of Haynes and Boone, LLP held 29,497 shares of our common stock.

EXPERTS

The consolidated financial statements and schedule as of December 31, 2016 and 2015 and for each of the three years in the period ended December 31, 2016 and management's assessment of the effectiveness of internal control over financial reporting as of December 31, 2016 incorporated by reference in this Prospectus have been so incorporated in reliance on the reports of BDO USA, LLP, an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

TABLE OF CONTENTS

PROSPECTUS

$35,000,000

Common Stock, Preferred Stock,
Warrants and Units

We may offer from time to time common stock (including Preferred Share Purchase Rights), preferred stock, warrants and units. We may also issue any of the common stock, preferred stock, warrants or units upon the conversion, exchange or exercise of any of the securities listed above. The aggregate initial offering price of the securities that we offer will not exceed $35,000,000.

We will offer the securities in amounts, at prices and on terms to be determined by market conditions at the time of the offering. We will provide the specific terms of these securities in supplements to this prospectus. You should read this prospectus and the accompanying prospectus supplement carefully before you invest.

Pursuant to General Instruction I.B.6. of the General Instructions to Form S-3, the aggregate market value of our outstanding voting and non-voting common equity, held by non-affiliates, which consists solely of voting common stock, was $47,000,000 as of the last business day of the Company's most recently completed second fiscal quarter. During the 12-month period ending on the date of this Prospectus, we have not offered any securities pursuant to General Instruction I.B.6.

Our common stock, together with its associated Preferred Share Purchase Rights, is listed on NASDAQ under the symbol CEMI.

We may offer and sell these securities to or through one or more underwriters, dealers and agents, or directly to purchasers, on a continuous or delayed basis.

You should refer to the risk factors that may be included in a prospectus supplement and in our periodic reports and other information we file with the U.S. Securities and Exchange Commission, and you should carefully consider that information before investing in our securities.

Neither the U.S. Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined that this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is April 5, 2016.

TABLE OF CONTENTS

TABLE OF CONTENTS

TABLE OF CONTENTS

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the U.S. Securities and Exchange Commission, or the SEC, utilizing the shelf registration process. Under this shelf process, we may sell, either separately or together, any combination of the securities described in this prospectus in one or more offerings for cash. We may also issue any of the common stock, preferred stock, warrants or units upon conversion, exchange or exercise of any of the securities mentioned above. The aggregate amount of securities that we may offer under the registration statement is $35,000,000, denominated in U.S. dollars or the equivalent in foreign currencies, currency units or composite currencies. The Company is subject to the provisions of General Instruction I.B.6. of the General Instructions to Form S-3, which provides that as long as the aggregate market value of the Company's outstanding voting and non-voting common equity held by non-affiliates of the Company is less than $75 million, then the aggregate market value of securities sold by or on behalf of the Company on Form S-3, during the period of 12 calendar months immediately prior to, and including, the sale, is no more than one-third of the aggregate market value of the voting and non-voting common equity held by non-affiliates of the Company. The Company has no outstanding non-voting common equity.

This prospectus provides you with a general description of the securities that we may offer. Each time we sell or otherwise issue securities pursuant to this prospectus, we will provide a prospectus supplement that will contain specific information about the offering and the specific terms of the securities being offered. The prospectus supplement also may add, update or change information contained in this prospectus. You should read both this prospectus and the applicable prospectus supplement, together with the additional information described under the heading Where You Can Find More Information.

The registration statement that contains this prospectus, including the exhibits to the registration statement, contains additional information about us and the securities offered under this prospectus. That registration statement can be read at the SEC website, our website, or at the SEC offices, which are referred to in this prospectus under the heading Where You Can Find More Information.

The words we, our, us, the Company, Chembio, and Registrant refer to Chembio Diagnostics, Inc., unless we otherwise.

TABLE OF CONTENTS

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and any accompanying prospectus supplements contain or incorporate by reference forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These forward-looking statements represent plans, estimates, objectives, goals, guidelines, expectations, intentions, projections and statements of our beliefs concerning future events, business plans, objectives, expected operating results and the assumptions upon which those statements are based. Forward-looking statements include without limitation, any statement that may predict, forecast, indicate or imply future results, performance or achievements, and are typically identified with words such as may, could, should, will, would, believe, anticipate, estimate, expect, words or phases of similar meaning. We caution that the forward-looking statements are based largely on our expectations and are subject to a number of known and unknown risks and uncertainties that are subject to change based on factors which are, in many instances, beyond our control. Actual results, performance or achievements could differ materially from those contemplated, expressed, or implied by the forward-looking statements.

The following factors, among others, could cause our financial performance to differ materially from that expressed in such forward-looking statements:

the strength of the United States economy in general and the strength of the local economies in which the Company conducts operations;
geopolitical conditions, including acts or threats of terrorism, actions taken by the United States or other governments in response to acts or threats of terrorism and/or military conflicts, which could impact business and economic conditions in the United States and abroad;
the effects of, and changes in, trade, monetary and fiscal policies and laws, including interest rate policies of the Board of Governors of the Federal Reserve System, or the Federal Reserve Board; inflation, interest rate, market and monetary fluctuations;
the timely development of competitive new products and services, and the acceptance of these products and services by new and existing customers;
the willingness of users to substitute competitors' products and services for our products and services;
the impact of changes in financial services policies, laws and regulations, including laws, regulations and policies concerning taxes, banking, securities and insurance, and the application thereof by regulatory bodies;
technological changes;
the effect of acquisitions we may make, including, without limitation, the failure to achieve the expected revenue growth and/or expense savings from such acquisitions;
the growth and profitability of non-interest or fee income being less than expected;
changes in consumer spending and savings habits; and
unanticipated regulatory or judicial proceedings.

If one or more of the factors affecting our forward-looking information and statements proves incorrect, then our actual results, performance or achievements could differ materially from those expressed in, or implied by, forward-looking information and statements contained in this prospectus and in the information incorporated by reference herein. Therefore, we caution you not to place undue reliance on our forward-looking information and statements. We will not update the forward-looking statements to reflect actual results or changes in the factors affecting the forwarding-looking statements.

TABLE OF CONTENTS

ABOUT CHEMBIO

Our Corporate Information

Chembio Diagnostic Systems Inc. was formed in 1985. Since inception we have been involved in developing, manufacturing, selling and distributing medical diagnostic tests, including rapid tests that detect a number of infectious diseases. Our principal executive offices are located at 3661 Horseblock Road, Medford, New York 11763. Our telephone number is (631) 924-1135. Our website address is *www.chembio.com.*

Our Business

General

The Company (Chembio Diagnostics, Inc. and its wholly-owned subsidiary Chembio Diagnostic Systems, Inc. are collectively referred to herein as the Company) develops, manufactures, markets and licenses rapid point-of-care diagnostic tests (POCTs) that detect infectious diseases. The Company's main products presently commercially available are rapid tests for the detection of HIV 1/2 antibodies, and a multiplex rapid test for the detection of HIV and Syphilis antibodies. The HIV 1/2 rapid tests employ in-licensed and proprietary lateral flow technologies (see Our Rapid Test Technologies), can be used with all blood matrices as samples, and are manufactured in a standard cassette format, a dipstick format, and a proprietary barrel format. The tests employing the cassette and proprietary barrel formats were approved by the FDA in 2006. The barrel format is exclusively distributed by a distributor in the United States and by Chembio and its designated distributors outside the United States. The exclusive U.S. distribution agreement for the barrel product terminates in accordance with its terms on May 31, 2016. Chembio and any newly designated distributors will distribute the product in the U.S. after May 31, 2016. The Cassette format is distributed by Chembio and its designated distributors worldwide. Our latest generation HIV 1/2 rapid antibody detection test incorporates our patented Dual Path Platform® (DPP®) POCT technology, and this POCT platform does not require in-licensing. The DPP® HIV 1/2 Assay detects antibodies to HIV 1 & 2 in oral fluid samples as well as in all blood matrices. We have sold this product in Brazil since 2009 where it was approved by ANVISA, through our agreement with the Oswaldo Cruz Foundation (FIOCRUZ), and we received United States FDA regulatory approval for this product in December 2012 and CLIA waiver in October 2014. We launched it in the United States under Chembio's brand in the fourth quarter of 2014.

Our product pipeline, which currently includes a multiplex rapid test for earlier detection of HIV by detecting P-24 antigen as well as antibodies, a test for Hepatitis-C, and a multiplex test that detects HIV and Syphilis specific antibodies (which we are already selling outside the U.S.), is based on this DPP® technology for which we were issued a United States patent in 2007 and for which additional patent protection has issued or is pending in a number of other countries. With the patented DPP® and the lateral flow platform, we participate in the estimated $8 billion point-of-care market segment of the estimated nearly $50 billion global in-vitro diagnostic market that has an overall growth rate exceeding 3% per annum. POCTs, by providing prompt and early diagnosis, can reduce patient stays, lower overall costs, improve therapeutic interventions and improve patient outcomes. POCTs can also prevent needless hospital admissions, simplify testing procedures, avoid delays from central lab batching, and eliminate the need for return visits.

In the areas of infectious and sexually transmitted diseases (such as HIV and syphilis), the utility of a rapid point-of-care (POC) test, particularly in identifying patients unaware of their disease status, has been well established.

Large and growing markets have been established for these kinds of tests, initially in high prevalence regions where they are indispensable for large scale prevention and treatment programs. More recently introduced in the United States in 2004, rapid HIV tests now also present a significant segment of the U.S. market for HIV clinical testing, which is still dominated by laboratory tests. We have focused our product development activity within areas where the availability of rapid, point-of-care screening, diagnostic, or confirmatory results can improve health outcomes. More generally we believe there is and will continue to be a growing demand for diagnostic products that can provide accurate, actionable diagnostic information in a rapid, cost-effective manner at the point of care.

TABLE OF CONTENTS

PRODUCTS

Lateral Flow Rapid HIV Tests

All three of our lateral flow rapid HIV antibody detection tests are qualitative yes/no tests for the detection of antibodies to HIV 1 & 2 with visually interpreted results (one line negative ; one line positive) available within approximately 15 minutes. The tests are simple to use, have a shelf life of 24 months, and do not require refrigeration. The tests differ principally only in the method of test procedure, convenience and cost. One of our FDA-approved lateral flow HIV tests incorporates a proprietary plastic barrel device that houses the lateral flow strip. This barrel format enables collection of samples directly (usually from a finger-stick whole blood sample) into the barrel's capillary tip. A sealed unitized buffer vial, assembled onto the top of the barrel, is removed and seated into a stand; the seal is then pierced by the barrel's capillary tip, thereby initiating the upward flow of the resulting sample-buffer solution through a filter, up into the vertical device's chamber and onto the lateral flow strip. This results in a unique unitized and closed device system that can reduce the chance of exposure to potentially infectious samples.

In January 2015, the Company entered into an agreement with StatSure Diagnostic Systems, Inc. (SDS) to acquire SDS' interest in the barrel device format, also known as Chembio's SURE CHECK® HIV 1/2 Assay, effective June 1, 2016. Beginning June 1, 2016, Chembio will own full rights related to the SURE CHECK® HIV 1/2 Assay, including sales, marketing, distribution and trademark rights, subject to the terms of the existing marketing and distribution agreement with Alere, Inc., which grants Alere U.S. marketing and distribution rights through May 31, 2016. Prior to this newly-executed agreement between SDS and Chembio, SDS has owned a 50 percent interest in the rights to the SURE CHECK® HIV 1/2 Assay that would have continued after May 31, 2016, also subject to the existing marketing and distribution agreement with Alere. The new agreement with SDS also resolves all other matters between Chembio and SDS, including their respective sharing ratios, until June 1, 2016, concerning net revenues from sale of the SURE CHECK® product outside the U.S.

The Company's SURE CHECK® HIV 1/2 Assay is marketed exclusively in the U.S. as Clearview® Complete pursuant to an exclusive distribution agreement that terminates in accordance with its terms on May 31, 2016. After May 31, 2016, it will be marketed in the U.S. as Sure Check® HIV 1/2 Assay. Outside the U.S., Chembio markets the SURE CHECK® HIV 1/2 Assay primarily through distributors. The SURE CHECK® HIV 1/2 Assay is Food & Drug Administration (FDA) approved, CLIA-waived, European CE-marked, and has been pre-qualified by the World Health Organization (WHO). Results are obtained in 15 minutes via a 2.5uL blood sample (i.e., fingerstick, serum, plasma, or venipuncture whole blood). The assay is stable at room temperature and provides 99.7% sensitivity and 99.9% specificity.

Our other FDA-approved lateral flow HIV test uses a more conventional rectangular plastic cassette format that houses the lateral flow strip. In this case, a sample is transferred by use of a separately provided transfer device (loop) into a sample well or port of the cassette that houses the lateral flow strip, which is positioned horizontally or flat.

Our third lateral flow HIV test, the HIV 1/2 STAT PAK® Dipstick, is our most cost competitive and compact format. It does not have any plastic housing so that 30 test strips can be packaged into a small vial that is ideal for transporting into remote settings. The test procedure is similar to the cassette format except that a user-applied adhesive backing is provided as a more cost-effective and compact surface on which to run the test.

Regulatory Status of the lateral flow HIV tests

The FDA approved our Pre-Market Applications (hereinafter PMA ; see Governmental Regulations and Glossary) in April 2006 for our SURE CHECK® HIV 1/2 (and also now Alere Clearview® Complete HIV 1/2) and for our HIV 1/2 STAT-PAK® products. Waivers under the Clinical Laboratory Improvement Act (hereinafter CLIA ; see Governmental Regulations) were granted by the FDA for these two FDA-approved products in 2006 and 2007, respectively. A CLIA waiver is required in order for health care providers to administer these tests in the settings where they are most suited and needed, such as public health testing clinics, hospital emergency rooms and physicians' offices. The SURE CHECK® and HIV 1/2 STAT-PAK® products received CE Marks in July 2013 and March 2014, respectively, and the CE Marking for the DPP®

TABLE OF CONTENTS

HIV 1/2 Assay described below is expected in 2016. We have also updated our filing for CE Marking to reflect the new tradename of STAT-VIEW® HIV 1/2 Assay for sale in the EU market. Our HIV 1/2 STAT-PAK® Dipstick, although not FDA-approved, qualifies under FDA export regulations [See Government Regulation] to sell to customers outside the United States, subject to any required approval by the importing country. CE Mark has not been pursued for this product.

All three of our lateral flow HIV tests have qualified for procurement under the President's Emergency Plan for AIDS Relief (PEPFAR). The cassette and dipstick versions of the STAT-PAK® and the SURE CHECK® assays are also pre-qualified by the World Health Organization (WHO) for procurements by the second largest global program, known as the Global Fund, as well as other related programs funded by agencies affiliated with the United Nations, such as UNICEF and UNITAIDS (see Glossary), through qualification with the WHO bulk procurement scheme.

DPP® HIV 1/2 Assay

As in the case of our lateral flow HIV tests, our DPP® HIV 1/2 Assay is also a qualitative yes/no test for the detection of antibodies to HIV 1& 2, delivers visual results within as little as 15 minutes, is simple to use, has a shelf life of 23 months, and does not require refrigeration. This product, which is our first FDA-approved product incorporating our patented DPP® technology, can be used with oral fluid samples, as well as with all blood matrices. This product also incorporates our patent-pending oral fluid collection and storage system that enables samples to be fully extracted in buffer solution before application to the test device, and also enables the extracted sample to be stored and retested or potentially tested for multiple conditions in future product applications. Clinical and laboratory studies demonstrated the ability of the test to accurately detect the presence of antibodies in individuals down to two years of age. Studies have also shown this product to have improved performance compared with all of the current FDA-approved CLIA-waived lateral flow rapid tests, even including our own lateral flow tests. FDA-approved label claims include sensitivity/specificity on oral fluid and finger-stick whole blood of 98.9%/99.9% and 99.9%/100% respectively. Oral fluid sensitivity was 100% among HIV-positive patients not taking anti-retroviral medication.

Regulatory Status of the DPP® HIV 1/2 Assay

In December 2012, we received FDA approval of our Pre-Marketing Approval. In October of 2014 the FDA granted CLIA-waiver status.

The DPP® HIV 1/2 Assay product is qualified for procurement under the President's Emergency Plan for AIDS Relief (PEPFAR) for use with all sample matrices, and we are pursuing WHO qualification in order to enable procurement of this product by the Global Fund and United Nations agencies, including programs underwritten by them. In October 2014, we completed a three-day on-site inspection by the WHO as follow-up to pre-qualification activities of our products with no major non-conformances noted during the audit. The WHO laboratory evaluation for the blood matrix is complete, while oral fluid is in progress and expected to be complete in 2016. In May 2015 we received approval for a CE Mark for the DPP® HIV 1/2 Assay for Oral Fluid, Serum, Plasma, Fingerstick Whole Blood and Venous Whole Blood.

In June 2010, ANVISA approved the DPP® HIV 1/2 Assay that is being marketed in Brazil through our collaboration with the Oswaldo Cruz Foundation, Brazil's leading public health institute (see Oswaldo Cruz Foundation OEM DPP® Agreements). Since this time, we have sold and marketed millions of DPP® HIV tests to Brazil through this partnership.

DPP® HIV-Syphilis Multiplex Test

This product, launched in 2013, allows for the detection of antibodies to both HIV and Syphilis on a single test device within approximately 15 minutes. In certain global/public health settings (see Target Markets), this product may provide a more convenient and cost-effective means of rapid detecting both markers in a single test procedure at the point of care as compared with performing separate rapid tests for each indication. This product takes advantage of the multiplexing feature of DPP® which provides for a more robust reaction between the sample and biomarkers being tested for (HIV and Syphilis antibodies in this case), resulting in a greater ability by the user to visually interpret test results. We launched this product in Mexico in the fourth quarter of 2013 as a unitized product, meaning that each test kit was separately packaged to

TABLE OF CONTENTS

include each of the other components necessary to run this test, as compared with other configurations where a test kit of 20 or 30 devices is accompanied by one bottle of running buffer. The initial results of this launch have been very positive, and we experienced good results in Mexico during 2014 from the program. Building on this initial success, we continue to pursue commercialization efforts for this product in a number of additional international markets, where there is a great need to detect Mother-to-Child-Transmission of HIV and Syphilis globally. According to the CDC website, approximately 370,000 babies are born with HIV, mostly in sub-Saharan Africa. Without treatment, more than half of these children will die before the age of 2. Through key interventions, such as routinely testing pregnant women for HIV, providing antiretroviral medications to HIV-infected pregnant women and their exposed infants, and promoting safe infant feeding practices, mother-to-child transmission of HIV can be decreased from about 35% to less than 5%. Another prominent cause of infant mortality is untreated maternal syphilis, which still accounts for more than 500,000 stillbirths and infant deaths annually despite the fact that these deaths could be prevented through routine detection and treatment of syphilis during antenatal care .

Regulatory Status of the DPP® HIV-Syphilis Test

DPP® HIV-Syphilis We have developed this product for international and U.S. marketing. For the international market, the product has been registered in Mexico, and successfully launched and sold in this region.

In February 2015, this product was granted approval from the Brazilian ANVISA. We have submitted this product both for evaluation by the CDC, acting on behalf of the United States Agency of International Development, and the WHO, which has accepted this product to be evaluated for pre-qualification in its global procurement scheme. In October 2014, WHO conducted a three-day audit of our facilities as follow up to pre-qualification activities for the DPP HIV-Syphilis Assay, including other products submitted for pre-qualification through WHO. No major non-conformances were identified during this audit, and we continue to work with WHO to obtain pre-qualification approval status for this device.

We are developing a U.S. version of the DPP® HIV-Syphilis Assay, designed to meet the performance requirements for the reverse algorithm that is currently in clinical use for syphilis testing in the United States. We have completed our pre-clinical studies for this product with encouraging results, and are in the final stages of clinical site selection for our U.S. clinical studies. We plan to begin this clinical trial in the U.S. during first quarter of 2016, and expect that the trial will be completed in six to nine months from initiation.

DPP® TECHNOLOGY & DEVELOPMENT

Chembio is executing its strategy to leverage the DPP® intellectual property and product development and manufacturing experience to create new collaborations where Chembio serves as an exclusive development and manufacturing partner. Examples of such collaboration include the following:

The Company entered into an agreement to develop a POC diagnostic test for dengue fever virus, the DPP® Dengue Fever Assay, which would be able to detect IgG/IGM and NS1 antigens in October 2014.
A collaboration also announced in October 2014, with an international diagnostics company to develop a POC diagnostic test for the early detection and monitoring of a specific type of cancer. At that time, the cancer project represented the first application of the DPP® technology outside the infectious disease field.
The Company entered into a follow-on, milestone-based development agreement with a private contracting organization acting on behalf of the United States Centers for Disease Control and Prevention (CDC), for a multiplex POC influenza immunity test utilizing Chembio's patented Dual Path Platform (DPP®) technology.

In January 2015, Chembio entered into an agreement with the Concussion Science Group (CSG) Division of Perseus Science Group LLC, to utilize Chembio's patented DPP® technology to develop a POC diagnostic test for traumatic brain injury (TBI), including sports-related concussion. Under terms of the agreement, CSG's patented biomarker will be combined with Chembio's proprietary

TABLE OF CONTENTS

DPP® platform to develop a semi-quantitative or quantitative point-of-care test to diagnose TBI. CSG agreed to pay Chembio milestone development payments during 2015.

In January 2015, Chembio was awarded a grant from The Bill & Melinda Gates Foundation to expedite the feasibility testing and development of a DPP® Malaria POC rapid diagnostic to accurately identify individuals infected with Plasmodium falciparum parasite. Chembio's DPP® technology was selected for this grant due to its exceptional sensitivity and potential to aid the foundation in its goal of eradicating malaria. To achieve this goal, diagnostics must be capable of detecting the malaria parasite in infected, but asymptomatic, people. Current POC rapid diagnostics tests lack sufficient sensitivity to identify all individuals with transmissible infections.

In October 2015, Chembio was awarded a grant from the Paul G. Allen Foundation to develop a POC test to identify multiple life-threatening febrile illnesses. Under the $2.1 million dollar grant, Chembio will use its patented DPP® technology to develop a DPP® Fever Panel Assay, a POC multiplex assay to simultaneously detect Malaria, Dengue, Ebola, Lassa and Marburg. The multiplex assay that is planned to be designed to include a quality control test band and seven tests bands with specific antibodies to detect different pathogens, including multiple serotypes of the same pathogen: Malaria PAN-PLDH antigen (Plasmodium falciparum, Plasmodium vivax, Plasmodium malariae, Plasmodium ovale), Malaria Falciparum HRP2 antigen, Ebola Virus PAN (Zaire, Sudan, Bundibugyo Virus), Marburg Virus, Lassa Virus, Dengue Virus (Dengue 1, Dengue 2, Dengue 3, Dengue 4) and Chikungunya Virus. In many parts of the world, these diseases are commonly misdiagnosed, resulting in a delay of treatment or failure to properly treat the underlying infection. Misdiagnosis may be due to the fact that these diseases have similar symptoms that are difficult to distinguish. Currently available POC diagnostics lack the ability to test for multiple diseases simultaneously. Further, existing POC diagnostics may lack the sensitivity and specificity required to detect infected but asymptomatic patients information that is critical for preventing the spread of disease.

Also in October 2015, Chembio signed an agreement with opTricon (Berlin, Germany), a leading developer of mobile analysis devices for rapid diagnostic tests. Through this exclusive agreement, subject to certain terms, and covering the fields of sexually transmitted diseases, certain fever diseases, and a specific form of cancer, Chembio will launch the DPP® Micro Reader, a point-of-care instrument designed specifically to complement Chembio's patented DPP® technology as applied to those diseases. The DPP® Micro Reader will include an innovative image sensor to provide a quantitative interpretation of diagnostic results when combined with Chembio's proprietary DPP® immunoassay technology. Using a state-of-the-art camera system, the DPP® Micro Reader is designed to provide definitive diagnostic results for low analyte concentrations, which may otherwise result in faint or ambiguous test results. In addition, the DPP® Micro Reader will provide customers with various options to capture, record, transmit and store test results. With one-button operation, the palm-sized and battery-operated DPP® Micro Reader is simple, fast, portable and cost-effective.

PARTNERS INVOLVED IN MARKETING OUR PRODUCTS

Alere

On September 29, 2006, we executed marketing and license agreements with Alere. The marketing agreements (the Barrel Agreement and the Cassette Agreement) provide Alere with a 10-year exclusive right (until May 31, 2016) to market our rapid HIV tests in the United States under Alere's brands. The agreements also provide Chembio a non-exclusive license to certain Alere lateral flow patents that may be applicable to our lateral flow products, including for manufacture of the HIV tests in the United States for sales outside the United States and even for sale in the United States should Alere enter the U.S. market with a competitive rapid HIV test product and in such case we choose to market our products directly as provided in the agreements in such event of a competitive rapid HIV test product. Simultaneous with the execution of the agreements, we also settled litigation with StatSure Diagnostics, Inc. (SDS), that had been ongoing relating to the proprietary barrel device which is incorporated into one of our two FDA-approved rapid HIV tests (See Lateral Flow HIV Tests above). SDS, pursuant to the settlement, is a party to the 3-way Barrel Agreement. As a result, until now, it is through the agreements with Alere that we have been

participating in the growth of the rapid HIV test market in the United States.

TABLE OF CONTENTS

In late July 2013, we received notice from Alere that it intends to commercialize its own rapid HIV test (see Competition), which test had just received FDA approval as a moderate complexity product (i.e. not CLIA-waived though this was granted in late 2014), in the United States. Under the Barrel Agreement and the Cassette Agreement such product is considered to be a Permitted Competing Product (PCP). Each of the two aforementioned agreements provides that, in the case of notice of a PCP, Chembio may make certain elections (jointly with SDS in the case of the Barrel Agreement), or elect to continue each agreement without taking any further action. Under the Cassette Agreement, Chembio may, at any time, terminate such agreement, which termination would become effective 60 days after the date notice was made. Under the Barrel Agreement, Chembio and SDS may jointly issue a non-exclusivity notice, which notice shall be effective immediately. In the event that Chembio makes this election with respect to the cassette product, or that both Chembio and SDS make this election with respect to the cassette product, then the electing party or parties could sell that respective product in the United States market under its own brand, and in such case, the lateral flow license that Chembio has from Alere for international sales would be expanded to include sales in the United States. See Lateral Flow Technology and Reagent Licenses. In April 2014, the Company gave notice to Alere of its intent to terminate the Cassette Agreement and 60 days later, the Company began marketing in the United States under the Chembio brand of HIV 1/2 STAT-PAK® assay. The barrel product continues to be marketed exclusively by Alere in the U.S only, although on May 31, 2016, the Barrel Agreement will expire pursuant to its terms, and Chembio will also market the barrel product in the U.S. under the brand of SureCheck® HIV 1/2 Assay.

We have developed our own sales and marketing departments for the sales of our products in the U.S. We have appointed distributors internationally for our lateral flow HIV tests. Our largest markets outside the U.S. for our lateral flow HIV rapid tests are certain countries in Africa, Asia, and South America, as well as Mexico. Internationally, most of the demand for our products is based on governmental and non-governmental prevention and treatment efforts. Given this, these programs can and do often result in large orders, but also can result in periods of relatively lower demand, based on the variations associated with this kind of demand.

OEM DPP® Products

Oswaldo Cruz Foundation OEM DPP® Agreements

During 2008 2010 we signed five separate agreements, each of which is titled and constitutes a Technology Transfer Agreement , with the Oswaldo Cruz Foundation (FIOCRUZ) in Brazil. FIOCRUZ includes the Institute of Technology on Immunobiologicals/Bio-Manguinhos, which is the FIOCRUZ unit that produces vaccines and diagnostic kits. FIOCRUZ and Bio-Manguinhos are referred to herein interchangeably. Each of the five agreements relates to a different specific product or group of products based on our DPP® technology. FIOCRUZ is the leading public health organization in Brazil, and it is affiliated with Brazil's Ministry of Health, which is its principal client. It has extensive research, educational and manufacturing facilities for drugs and vaccines, as well as for diagnostic products.

Each of the agreements grants to FIOCRUZ the right, but not the obligation, to earn the right to request a technology transfer to be able to license and manufacture that product on its own. FIOCRUZ is not required to earn this right, but if it desires to do so, then it needs to purchase a stated amount of the product as set forth in the respective agreement for that product.

During 2010 and 2011, all of the initial products contemplated under the five agreements were approved for marketing by the applicable regulatory agencies in Brazil. The agreements between the Company and FIOCRUZ are unique examples of technology transfer collaborations between a private sector rapid test manufacturer and a public health organization. The five products categories for which FIOCRUZ can earn a separate right to request a technology transfer for that product only are: DPP® products for HIV screening, HIV Confirmatory, Leishmaniasis, Leptospirosis

and Syphilis. Each technology transfer, and the provision by Chembio of the information and training that is required for this to occur, will occur only if FIOCRUZ purchases from Chembio the amount of that product that is specified in the respective agreement for that product. The actual amount of purchases for each product is totally at the discretion and option of FIOCRUZ and may be more or less than the amount needed to qualify for a technology transfer.

TABLE OF CONTENTS

More specifically, the five agreements, although separate and independent of one another, are structurally similar according to the following:

Each agreement states: the object of this Agreement is for the Transfer of Technology from Chembio to Bio-Manguinhos, the license by Chembio to Bio-Manguinhos for the Chembio Patents applied or granted in Brazil or other Mercosur countries for the term of the patents and the transfer of all the technical information related to the DPP® technology and the process to obtain the product by the DPP® technology. This Agreement contemplates the scientific and technological co-operation between Chembio and Bio-Manguinhos for such activities so that Bio-Manguinhos will be able to manufacture the Product in Brazil.

Each agreement provides that Chembio will supply free of charge to Bio-Manguinhos prototypes of the product to demonstrate performance characteristics that are necessary for evaluation by the Brazilian Ministry of Health and for registration with ANVISA. ANVISA is the Agencia Nacional de Vigilancia Sanitaria, or the National Sanitary Vigilance Agency. The number of prototypes ranges from 15,000 to 45,000 in the various agreements.

Each agreement provides that the prototypes will be utilized both for a performance study that follows a protocol prepared and approved by Bio-Manguinhos and the Brazilian Ministry of Health, and also will be used for studies in Brazil for the registration procedures at ANVISA. Bio-Manguinhos will then apply to ANVISA to register the product. Within 120 days of the registration of the product with ANVISA, Bio-Manguinhos will make an advance technology transfer payment to Chembio (the Advance Payment), in an amount specified in that particular agreement. All five of the Advance Payments provided for in the agreements were made in 2010 and 2011.

At such time, if any, that the product for a particular agreement has been successfully registered with ANVISA, then Bio-Manguinhos has the right to qualify for the full technology transfer for that product by purchasing the amount of the product, and at the price, specified in the agreement.

Bio-Manguinhos is not required to purchase any amount of any product. For each product, it only needs to purchase that product, in the amount specified in the agreement, only if it desires to be able to complete the technology transfer process in order to manufacture and sell that product on its own. Chembio does not have recourse against Bio-Manguinhos if Bio-Manguinhos does not purchase the qualifying purchase amount of any product. In that case, Chembio can only suspend further phases of the technology transfer, attempt to renegotiate the agreement, and/or retain any amounts previously paid by Bio-Manguinhos. Chembio cannot force Bio-Manguinhos to purchase any amount of any product.

As a result of the terms of these agreements, Bio-Manguinhos has never been required to, and is not now required to, purchase any amount of any of the products.

As of December 31, 2015 Bio-Manguinhos had earned the status described below with respect to each of the five products:

1. With respect to Chembio's DPP® HIV1/2 Screen test, Bio-Manguinhos had qualified to request the technology transfer. It has requested, and has received, the technology transfer information. Bio-Manguinhos purchased $880,175, $4,990,840 and $291,235 of this product in 2011, 2012 and 2013, respectively, all of which applied to the qualifying amount to obtain the right to the technology transfer (the Qualifying Amount) for this product. In 2013, 2014 and 2015, Bio-Manguinhos made $3,320,010, $4,799,250 and $5,410,350, respectively, of purchases in excess of the Qualifying Amount.

2. With respect to Chembio's Canine Leishmania test, Bio-Manguinhos had qualified to request the technology transfer and did so request. Submission of the technology transfer information is in process at this time. Bio-Manguinhos purchased $2,000,817 and $99,183 of this product in 2011 and 2012 respectively, of this product in that applied to the Qualifying Amount.

TABLE OF CONTENTS

In addition, Bio-Manguinhos made purchases in excess of the Qualifying Amount equal to $1,314,117, $1,736,700, $2,394,000 and $3,772,482 in 2012, 2013, 2014 and 2015, respectively.

3.

a. With respect to the three variations of Chembio's DPP® Syphilis test, all of which are covered by a single agreement, Bio-Manguinhos had qualified to request the technology transfer with respect to Trep only, and intends to do so in the near future. Bio-Manguinhos purchased $1,194,250, $165,750 of this product in 2011 and 2012, respectively that applied to the Qualifying Amount. In addition, Bio-Manguinhos made purchases in excess of the Qualifying Amount equal to $2,817,750, $646,340, $4,617,891 and $833,631 in 2012, 2013, 2014 and 2015, respectively.

b. With respect to the two variations of Chembio's Screen & Confirm Test, Bio-Manguinhos had not made any purchases in 2011, 2012, 2013, 2014 or 2015, and therefore had not qualified to request the technology transfer for either of them. This agreement was terminated in December 2015.

c. This syphilis agreement was terminated during the fourth quarter of 2015.

4. With respect to Chembio's DPP® Confirmatory test, Bio-Manguinhos had not qualified to request the technology transfer. Bio-Manguinhos made purchases of $560,000, $819,000, $390,000, $390,000 and $156,000 of this product in 2011, 2012, 2013, 2014 and 2015 respectively, all of which applied to the Qualifying Amount. In order to qualify for the technology transfer, Bio-Manguinhos would need to purchase an additional $39,000 of this product.

5. With respect to Chembio's DPP® Leptospirosis test, Bio-Manguinhos had not qualified to request the technology transfer. Bio-Manguinhos made purchases of $135,000 of this product in 2011, and it made -0- purchases in 2012, $45,000 in 2013 and it made -0- purchases in 2014 and -0- in 2015. In order to qualify for the technology transfer, Bio-Manguinhos would need to purchase an additional $225,000 of this product.

As stated above, Bio-Manguinhos is not obligated to make any purchases. After the specified level of sales for a particular product has been achieved, FIOCRUZ may request that the technology for that product be transferred to FIOCRUZ together with an exclusive license to produce and sell that product in a defined territory. The license is to provide that Chembio will receive a royalty on all sales. Chembio does not release the amount of this royalty because it could have an adverse effect on negotiations concerning royalties in potential transactions with other parties.

All the agreements expire five years after the date of the technology transfer. If terminated earlier by default of FIOCRUZ, FIOCRUZ must stop all activity; if terminated earlier by default of Chembio, or if terminated by natural expiry, FIOCRUZ can continue to produce and commercialize the product without paying royalties.

Other OEM And License Agreements Related to DPP® Technology

In addition to our agreements with FIOCRUZ, we have entered into certain OEM and license agreements with other parties with respect to certain products that we have developed based on our DPP® technology. In 2008 we entered into a product development and license agreement with Bio-Rad Laboratories, Inc. (Bio-Rad), a leading multinational life sciences company, for the first ever POC test for the confirmation of HIV (reflex test used after initial screening test(s) are positive). This product utilizes our DPP® technology, capitalizing on its multiplexing advantages, and is much simpler to perform than the legacy confirmatory platform, known as western blot, which requires a substantial amount of technical training and hands-on time and which is more expensive to manufacture and distribute. This product was CE marked and was launched by Bio-Rad in the second quarter of 2013 in Europe under their Geenius® brand; and an FDA PMA approval was received in 2014.

In 2013 we entered into collaboration with Labtest, a private company in Brazil, for the distribution of a number of products in Brazil that would be co-branded with Labtest and Chembio trademarks. Under this

TABLE OF CONTENTS

agreement, upon request from Labtest, for which there is no requirement, Chembio will sell the appropriate DPP® components to Labtest for further manufacture and assembly in Brazil.

In February 2014, Chembio entered into a technology transfer and license agreement with RVR Diagnostics SDN BHD (RVR), a privately-held company in Malaysia. The agreement supports Chembio's strategy of establishing a market presence in Asia, in collaboration with RVR as a licensee, distributor, and contract manufacturer, depending on the circumstances. The agreements grant exclusive distribution rights to RVR in certain countries in the region and enable RVR to manufacture Chembio's DPP® HIV 1/2 Assay and DPP® HIV-Syphilis Assay, and potentially other products developed by Chembio, such as Dengue, incorporating its patented DPP® technology as indicated in the DPP® Technology & Development section above.

Our Rapid Test Technologies

All of our commercially available current products employ either in-licensed lateral flow technology or our own patented Dual Path Platform (DPP®) technology. Both lateral flow technology and DPP® allow the development of accurate, low cost, easy-to-perform, single-use diagnostic tests for rapid, visual detection of specific antigen-antibody complexes on a test strip. These formats provide a test that is simple (requires neither electricity nor expensive equipment for test execution or reading, nor skilled personnel for test interpretation), rapid (turnaround time approximately 15 minutes), safe (minimizes handling of potentially infected specimens), non-invasive (requires 5 20 micro liters of whole blood easily obtained with a finger prick, or alternatively, serum or plasma), stable (24 months at room temperature storage in the case of our HIV tests), and highly reproducible.

We believe that products developed using DPP® technology can provide superior diagnostic performance as compared with products that use lateral flow technology. The reason for this is that one of the major differences between the two platforms is that in DPP® samples are allowed to incubate with the target analyte in the test zone before introduction of the labeling reagent/conjugate, whereas in lateral flow, samples are combined with the labeling reagent to form a complex before coming in contact with the target analyte. We believe that this complex can compromise test performance. Also, because of the usage in DPP® of a separately connected sample strip, the control and delivery of sample material is substantially improved. This feature is critical in the development of multiplex tests, as well as tests that involve viscous sample material (such as oral fluid) that can be impeded when forced to combine with labeling reagents before migration on the test strip to the test zone area.

Multiplexing is significantly improved as a result of the design of DPP® and this provides a significant advantage. For example, the HIV confirmatory test we developed for Bio-Rad that is described above employs six different markers related to various epitopes of the HIV antigen. We have a number of other products in development, including those being developed in sponsored development programs that involve the use of multiple (e.g. eight) test bands. Although all of these products could be visually read, we can also use handheld and desktop readers with our DPP® products to objectively measure, quantify, record and report DPP® test results. Certain of the products we have and/or are developing incorporate some of these readers, and we are developing other products that may be used with or will require use of a reader. Also, platforms can incorporate labeling reagents that cannot be visually read except by employing a reader, such as fluorescence, though no products are currently utilizing such reagents.

We are pursuing additional capabilities and technologies that will complement our current product portfolio and business strategy. This activity includes pursing development, license or acquisition of diagnostic technologies that complement our existing platforms, proprietary biomarkers that can result in new product applications of our existing platforms, and new platforms that would complement our commercial strategy.

Target Markets

Rapid HIV Tests

A large percentage of individuals that are HIV positive worldwide are unaware of their status. Part of the reason for this is that even those that do get tested in public health settings will often not return or call back for their test results when samples have to be sent out to a laboratory which can take up to several days to process. The increased availability, greater efficacy and reduced costs for anti-retroviral treatments (ARVs) for

TABLE OF CONTENTS

HIV has increased the demand for testing, as the stigma associated with the disease is lessened, and the ability to resume normal activities is substantially improved, providing a positive message to those potentially infected. The impact that rapid HIV testing has had on prevention efforts has in turn increased the demand for testing, particularly by public health programs worldwide, which have also become more effective in reducing the number of annual new infections in many, but by no means all, high prevalence regions.

Despite less attention to HIV by the media as compared with prior years, there are still approximately 50,000 new diagnoses of HIV infection in the United States each year, according to the CDC. CDC estimates that approximately 1.1 million individuals in the U.S. are living with HIV, with an estimated 1 of 8 of these U.S. individuals, or almost 13%, unaware that they are infected. It is transmissions from these infected people that are reported to account for the majority of all new infections per year. Part of the reason for this is that even those individuals that do get tested in public health settings will often not return or call back for their test results if their blood samples have to be sent out to and tested in a laboratory and then reported back, a process which can take up to several days to complete. Making more people aware of their HIV status at the point-of-care reduces the number of HIV transmissions.

Rapid HIV testing in the United States has now developed into an estimated 7.5 million test market at an average price of $10, or a total of $75 million. Public health programs, currently funded by grants distributed to states by the CDC, account for an estimated 45% of the market, with hospitals (40%) and doctor's offices (15%) comprising the other estimated market segments. Chembio's rapid HIV tests represent approximately a 20% share of this market. OraSure Technologies, Inc., which was the first FDA-approved rapid HIV test, maintains approximately 50% of this market. Trinity Biotech has an estimated 15% market share and Alere, Biolytical Laboratories, Medmira and Bio-Rad share the remaining 10%.

In 2006, the outlook for HIV testing was given a big boost with the release by the CDC of new recommendations for HIV testing. These new CDC recommendations were/are that an HIV test should be given as a routine test like any other for all patients between 13 and 64 years of age, regardless of risk, with an opt-out screening option and focused testing procedural (pre- and post-test counseling) guidelines. Though not mandatory, gradual adoption in whole or in part of the 2006 CDC recommendations by a number of states continues to have an increasing impact. Finally, in 2013, the United States Preventive Services Task Force (USPSTF) fully embraced these CDC routine HIV testing recommendations. This USPSTF recommendation, which was given an A grade under their recommendation grading system based on the benefits of this practice and the nearly 600,000 AIDS-related deaths in the United States, requires insurance coverage under the Affordable Care Act (the ACA) as a preventive screening test without any co-payment required. We expect this to result in an increase in HIV testing in the United States in the coming years, which we believe will include point-of-care HIV testing utilizing the Company's products. Although as stated above, currently most public health testing in the United States is funded by grants allocated to high prevalence areas by the CDC, we believe this will shift to an insurance-funded model under the ACA in the years to come, increasing the amount of testing done in doctor's offices and community health centers.

In the international market, we sell our products directly and through distributors to large screening programs overseen by ministries of health and NGOs, most but not all of which are funded by large bi-lateral and multi-lateral AIDS relief programs, the largest of which is the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). Established by President George Bush as a 5-year $15 billion program in 2003, PEPFAR was reauthorized in 2008 and again in 2013. In 2012 PEPFAR directly supported HIV testing and counseling for more than 11 million pregnant women, and testing and counseling for more than 49 million people overall. The U.S. is also the first and largest donor to the Global Fund to Fight AIDS, Tuberculosis and Malaria. To date, the U.S. has provided more than $7 billion to the Fund.

In December 2013 President Obama signed into law the PEPFAR Stewardship and Oversight Act, which is the most recent reauthorization of PEPFAR. However, unlike the 2008 PEPFAR authorization, which authorized approximately $45 billion, the new law doesn't authorize a specific dollar amount for funding. Nevertheless it is widely anticipated that PEPFAR will continue to enjoy strong funding; the FY14 budget had $6 billion for global HIV/AIDS assistance, including $4 billion for PEPFAR.

Chembio, with its four U.S.-manufactured rapid HIV tests, all of which are FDA-approved, is recognized as a reputable and dependable supplier of high quality products that are available at reasonably competitive

TABLE OF CONTENTS

prices. As a result, certain of our products have been selected in the testing protocols in countries (national algorithms) that are large beneficiaries of PEPFAR and the Global Fund. As mentioned above, these programs can and do often result in large orders, but also can result in periods of relatively lower demand, based on the variations associated with this kind of demand. Also, even though the United States taxpayer is funding the largest share of global AIDS relief, U.S. companies do not receive any preference for these procurements, and therefore must compete with foreign suppliers that manufacture competitive products with lower costs, including those related to quality, regulatory, intellectual property, and costs of manufacturing.

Oral fluid testing is an established alternative to blood testing for diagnostic tests, including HIV tests. It is also often patient preferred, providing a more comfortable, less invasive test. In certain public health clinics, staffs choose not to handle blood specimens; thus, oral sample collection provides a viable alternative. The most well-established market for oral fluid HIV testing is the United States. Given the premium price required for an oral fluid test as compared with blood tests, the higher volume programs will not specify an oral fluid test. However, segments of these programs may want to have an oral fluid testing option, and certain programs that have greater resources may also choose to incorporate oral fluid testing into the testing protocol.

There is also now an over-the-counter market for HIV self-testing in the United States. OraSure Technologies Inc. received FDA approval for an over-the-counter (self-testing) version of its previously professional-market-approved (test performed on an individual by a health care professional) HIV test. The FDA approval was granted in July 2012, and OraSure has been investing heavily in developing this market. Initial results after over two years of marketing are well below expectations. The costs for such over-the-counter approval, including primarily the associated clinical trials, are estimated to be at least $5 million and they may take two to three years to complete, not to mention the cost of distribution. OraSure's initial results are not convincing of a large market, although this possibility remains. If it appears that there is an attractive market, we believe we are very well positioned to participate in this market.

Rapid HIV-Syphilis Test

There are significant risks relating to transmission of Syphilis from a pregnant mother to child, just as there are for transmission of HIV. Therefore we believe there is a significant opportunity to improve prevention efforts in pregnant mother to child transmission testing programs (PMTCT) that are currently not doing any or nearly enough testing for syphilis even though they are testing for HIV. In the United States, we believe there is also a significant need for this product in some of the highest HIV prevalence populations, such as among men that have sex with men (MSM), as data show high degrees of HIV and Syphilis co-infection in this segment of the population.

Marketing Strategy

Our marketing strategy is to:

Market our DPP® HIV 1/2 Assay, HIV 1/2 STAT-PAK® Assay and future DPP® based new products in the US through our internal sales and marketing organization and selected channel partners (e.g., McKesson/PSS, Fisher Healthcare, Henry Schein, etc.). Chembio, following the June 2014 termination of the STAT-PAK® agreement with Alere, does not have to share any portion of the net sales proceeds for STAT-PAK® with Alere. This decision resulted in incurring expenditures related to hiring sales representatives, establishing agreements and associated discounts with distributors, incurring advertising and marketing expenditures, warehousing, customer service and technical support. If Alere's new competitive product is indeed successful, our ability to retain a significant share of the market that has been established for our products may be enhanced by our having control of the marketing of our products, rather than relying on Alere to sell both our products while it is also selling its own competing product. We

are leveraging the same sales force for U.S. Sales of DPP® HIV 1/2 Assay.

We will support, review and assess the marketing and distribution efforts of our rapid HIV barrel test in the U.S. Outside the U.S., we will market our products primarily through commercial collaborators and distribution partners.

TABLE OF CONTENTS

Leverage our DPP® intellectual property and product development and manufacturing experience to continue creating new collaborations where Chembio can be the exclusive development and manufacturing partner supporting leading marketing organizations.

Establish strong distribution relationships for our Chembio-branded products in the U.S and abroad, and establish a direct sales and marketing organization that is focused in the public health market segment, and that utilizes distributors for other market segments, primarily the acute care market which, together with public health, are the main market segments for rapid HIV tests in the United States. We believe that creation of a Chembio public health brand and marketing organization is fundamental to the creation of shareholder value over the long-term.

We have increased our commercial activities and efforts in Africa, Europe and Asia for our HIV tests and product pipeline. We believe these efforts will enable us to be more closely engaged with opportunities to engage with customers and partners and to participate in the national testing algorithms that are established and revised from time to time by countries that are beneficiaries of PEPFAR, Global Fund and/or other bilateral or multilateral donor funding. In Europe, where there are a larger percentage of HIV positive people unaware of their status than in the United States, we believe that there is an emerging public health outreach opportunity, and there are relatively few strong competitors that are CE-marked. Most recently we have established new sales and marketing positions in the Company to support our efforts to increase brand awareness globally and to lead our direct sales effort in the U.S. market.

Competition

The diagnostics industry is a multi-billion dollar international industry and is intensely competitive. Many of our competitors are substantially larger and have greater financial, research, manufacturing and marketing resources. Industry competition in general is based on the following:

Scientific and technological capability;
Proprietary know-how;
The ability to develop and market products and processes;
The ability to obtain FDA or other required regulatory approvals;
The ability to manufacture products that meet applicable FDA requirements, (i.e. FDA's Quality System Regulations) (see Governmental Regulation section);
The ability to manufacture products cost-effectively;
Access to adequate capital;
The ability to attract and retain qualified personnel; and
The availability of patent protection.

We believe our scientific and technological capabilities and our proprietary know-how relating to our in-licensed lateral flow technology rapid tests and to our proprietary know-how related to our patented DPP® technology, particularly for the development and manufacture of tests for the detection of antibodies to infectious diseases such as HIV, are very strong.

Our ability to develop and market other products is in large measure dependent on our having additional resources and/or collaborative relationships. Some of our product development efforts have been funded on a project or milestone basis. We believe that our proprietary know-how in lateral flow technology and in our DPP® technology has been instrumental in our obtaining the collaborations we have and that we continue to pursue. We believe that the patent protection that we have with our DPP® technology enhances our ability to develop more profitable collaborative relationships and to license out the technology. However there are a number of competitive technologies used and/or seeking to be used in point-of-care settings. These technologies may be based on immunoassay principles such as the Company's products or other technologies, such as molecular-based technologies.

13

TABLE OF CONTENTS

We launched our FDA-approved DPP® HIV 1/2 Assay, which test also can be used with either oral fluid or blood samples, in the U.S. market under a Chembio brand in the fourth quarter of 2014. OraSure Technologies manufactures the only other rapid, oral fluid HIV test that is FDA-approved, and OraSure has enjoyed this position for approximately 10 years. OraSure has lost a significant share of this market as certain customers have been indifferent to using blood or oral fluid samples, because the blood tests, including those made/marketed by Chembio and marketed by Alere, are priced lower and/or are as or more accurate than the performance of OraSure's product on blood samples. OraSure has primarily retained those customers for whom the oral fluid sample feature is a strong preference, and this is an estimated $35 million business for OraSure. Although we believe we can capture a meaningful portion of this OraSure market share, we also anticipate that OraSure will defend this business aggressively.

In 2006 Alere acquired a division from Abbott Diagnostic located in Japan that manufactured and marketed a rapid HIV test product line called Determine®. The Determine® format was developed for the developing world and remote settings and, central to the needs of that market, the format is essentially a test strip that is integrated into a thin foil wrapper that, when opened, the underside of the wrapper serves as the test surface for applying the blood sample and performing the test. This design reduces costs and shipping weights and volumes and is an advantage for the developing world markets it has served. Some of the disadvantages of the platform are the amount of blood sample that is needed (50 microliters versus 2.5, 5 and 10 for our lateral flow barrel, lateral flow cassette, and DPP® products respectively), the open nature of the test surface, and the absence of a true control that differentiates biological from other kinds of samples.

The so-called "3rd generation" version of this product has been marketed for many years and is the leading rapid HIV test that is used in a large majority of the national algorithms of countries funded by PEPFAR and the Global Fund, as well as many other countries in the world. That product is not FDA-approved though it is CE-marked. The newest Determine® HIV version, which was developed and manufactured at Alere's subsidiary in Israel, Orgenics, is the so-called "4th Generation" version Determine® test. According to its claims, this product detects HIV antibodies and P24 HIV antigens. Since the P24 antigen is known to occur in HIV-positive individuals' blood samples before antibodies do, based on its performance claims, the 4th generation Determine® test is therefore able to detect HIV infection earlier than tests that solely rely on antibody detection. Chembio's tests, as well as all of the other currently FDA-approved rapid HIV tests, only detect antibodies. There are however laboratory tests that are FDA-approved that are "4th generation" tests, but they are of course neither rapid nor point-of-care.

The initial "4th generation" Alere Determine® rapid test product that was also CE-marked and that Alere launched internationally some years ago has not been successfully commercialized to the best of our knowledge and at least certain published studies were not favorable for this product. However the 4th generation product that is now FDA-approved was apparently modified as compared to the initial international version of it, and it may perform more satisfactorily. Alere received FDA approval of this modified product in August 2013 and CLIA-waiver for it in the fourth quarter of 2014. There is support by a number of key opinion leaders for the public health value of such 4th generation tests, and it represents a significant competitive threat to Chembio as well as to each of the other rapid HIV test manufacturers (OraSure and Trinity primarily).

During 2011 Biolytical, Inc. of Vancouver, Canada received FDA approval and in 2012 received CLIA waiver of a flow-through rapid HIV test called "INSTI". The technology used in the INSTI test, flow-through, is older than lateral flow, and it requires handling of multiple components (3 vials of solution) to perform the test in multiple steps. However, these steps can be accomplished in less than ten minutes, and the actual test results occur in only one minute after those steps are completed. Therefore sample-to-result time is shorter than any of the competitive products. There are settings where that reduced total test time, despite the multiple steps required, may be a distinct advantage, and we believe Biolytical has made some progress in penetrating certain public health markets.

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

TABLE OF CONTENTS

Research and Development

During 2015 and 2014, we spent $6.40 million and $4.80 million, respectively, on research and development (including regulatory activities). These expenses were in part underwritten by funding from R&D and milestones revenues of $2.30 million in 2015 and $1.70 million in 2014. All of our new product development activities involve employment of our DPP® technology. These activities include completing development of certain products and making significant progress toward the development of additional products.

Employees

At December 31, 2015, we employed approximately 155 people. We have entered into employment contracts with our Chief Executive Officer and President, John J. Sperzel, our Chief Operating Officer, Sharon Klugewicz, and our Chief Science and Technology Officer, Javan Esfandiari. Due to the specific knowledge and experience of these executives regarding the industry, technology and market, the loss of the services of any one of them would likely have a material adverse effect on the Company. The contract with Ms. Klugewicz, has a term of two years ending May 2017. The contract with Mr. Esfandiari has a term of three years ending March 2019. We have obtained a key man insurance policy for Mr. Esfandiari. The contract with Mr. Sperzel provides that Mr. Sperzel will serve as the Chief Executive Officer and President of the Company through March 2017.

Governmental Regulation

The manufacturing and marketing of the Company's existing and proposed diagnostic products are regulated by the United States Food and Drug Administration (FDA), United States Department of Agriculture (USDA), certain state and local agencies, and/or comparable regulatory bodies in other countries. These regulations govern almost all aspects of development, production and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing and record keeping. The Company's FDA and USDA regulated products require some form of action by each agency before they can be marketed in the United States, and, after approval or clearance, the Company must continue to comply with other FDA requirements applicable to marketed products, e.g. Quality Systems (for medical devices). Failure to comply with the FDA's requirements can lead to significant penalties, both before and after approval or clearance.

There are two review procedures by which medical devices can receive FDA clearance or approval. Some products may qualify for clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, in which the manufacturer provides a pre-market notification that it intends to begin marketing the product, and shows that the product is substantially equivalent to another legally marketed product (i.e., that it has the same intended use and is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness). In some cases, the submission must include data from human clinical studies. Marketing may commence when the FDA issues a clearance letter finding such substantial equivalence. FDA clearance of our DPP® Syphilis Screen & Confirm test will be by means of a 510(k) submission.

If the medical device does not qualify for the 510(k) procedure (either because it is not substantially equivalent to a legally marketed device or because it is required by statute and the FDA's implementing regulations have an approved application), the FDA must approve a Pre-Marketing Application (PMA) before marketing can begin. PMA's must demonstrate, among other matters, that the medical device provides a reasonable assurance of safety and effectiveness. A PMA application is typically a complex submission, including the results of non-clinical and clinical studies. Preparing a PMA application is a much more expensive, detailed and time-consuming process as compared with a

510(K) pre-market notification. The Company has approved PMAs for the two rapid HIV tests now marketed in the U.S.: both our HIV 1/2 STAT-PAK® and also our test that currently is marketed in the U.S. by Alere Medical as Clearview® Complete HIV 1/2 and Clearview® HIV 1/2 STAT PAK®.

TABLE OF CONTENTS

FDA approval of our DPP® HIV screening assay for use with oral fluid or blood samples also was achieved by means of a PMA application. The Clinical Laboratory Improvement Act of 1988 (CLIA) prohibits laboratories from performing in-vitro tests for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of, the health of human beings unless there is in effect for such laboratories a certificate issued by the United States Department of Health and Human Services (via the FDA) applicable to the category of examination or procedure performed. Although a certificate is not required for the Company, it considers the applicability of the requirements of CLIA in the design and development of its products. The statutory definition of laboratory is very broad, and many of our customers are considered labs. A CLIA waiver will remove certain quality control and other requirements that must be met for certain customers to use the Company's products and this is critical to the marketability of a product into the point-of-care diagnostics market. The Company has received a CLIA waiver for each of the two lateral flow rapid HIV tests now marketed in the U.S. The CLIA waiver was granted by the FDA for HIV 1/2 STAT-PAK® on November 20, 2006 and for the Clearview® Complete HIV 1/2 on October 22, 2007. In 2008 the FDA revised its CLIA waiver requirements so that an additional prospective trial need be conducted in order to demonstrate clinical utility by showing that the device is capable of identifying new infections when used by untrained users. Our DPP® HIV 1/2 test received CLIA waiver in October of 2014.

In addition, the FDA regulates the export of medical devices that have not been approved for marketing in the United States. The Federal Food, Drug and Cosmetic Act contains general requirements for any medical device that may not be sold in the United States and is intended for export. Specifically, a medical device intended for export is not deemed to be adulterated or misbranded if the product: (1) complies with the specifications of the foreign purchaser; (2) is not in conflict with the laws of the country to which it is intended for export; (3) is prominently labeled on the outside of the shipping package that it is intended for export; and (4) is not sold or offered for sale in the United States. However, the Federal Food, Drug and Cosmetic Act does permit the export of devices to any country in the world, if the device complies with the laws of the importing country and has valid marketing authorization in one of several listed countries under the theory that these listed countries have sophisticated mechanisms for the review of medical devices for safety and effectiveness.

The Company is also subject to regulations in foreign countries governing products, human clinical trials and marketing, and may need to obtain approval or evaluations by international public health agencies, such as the World Health Organization, in order to sell diagnostic products in certain countries. Approval processes vary from country to country, and the length of time required for approval or to obtain other clearances may in some cases be longer than that required for United States governmental approvals. On the other hand, the fact that our HIV diagnostic tests are of value in the AIDS epidemic may lead to some government process being expedited. The extent of potentially adverse governmental regulation affecting Chembio that might arise from future legislative or administrative action cannot be predicted.

Environmental Laws

To date, we have not encountered any costs relating to compliance with any environmental laws.

Intellectual Property

Intellectual Property Strategy

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

acquire proprietary positions to reagents and new hardware platforms for the development and manufacture of rapid diagnostic tests.

TABLE OF CONTENTS

The Company has obtained patent coverage on the DPP® technology, including four U.S. patents, and patents in China, Malaysia, Eurasia, Mexico, Singapore, Japan, Australia, Indonesia, Korea and the U.K. Additional patent applications on the DPP® technology are pending in the U.S., as well as in many foreign countries such as Brazil, Canada, the European Union, India, Israel, and South Africa. Patents have also been filed on extensions to the DPP® product line concept, such as 4th generation assays. The four U.S. patents are as follows:

U.S. Patent No.	Issued	Expires	Nature	Type	Description
7,189,522	3/13/2007	3/11/2025	test device	utility	a test device for determining the presence of a ligand in a sample
7,682,801	3/23/2010	3/11/2025	test device and method	utility	a test device and a method for determining the presence of a ligand in a sample
7,879,597	2/1/2011	3/11/2025	test device	utility	a test device for determining multiple ligands in a sample
8,507,259	8/13/2013	3/11/2025	test device	utility	a test device for determining the presence of a ligand in a sample

The Company has also filed for patents and obtained some patents in the U.S. for other inventions, such as its multiple host species veterinary TB test, and patent applications for the other inventions are in various stages from being recently filed and not yet examined, to already examined and allowed but not yet issued. The Company selectively and strategically foreign files its patent applications based on a number of economic and strategic factors related to the invention.

Trademarks

The Company has filed and obtained trademarks for its products, including DPP®, SURE CHECK®, and STAT-PAK® and also for the SampleTainer® used in certain DPP® products. The DPP® trademark is also registered under the European convention (ECT). The Company recently filed a trademark for STAT-VIEW®, to market the barrel product in Europe.

Trade Secrets and Know-How

We believe that we have developed a substantial body of trade secrets and know-how relating to the development and manufacture of lateral flow and DPP®-based diagnostic tests, including but not limited to the sourcing and optimization of materials for such tests, and how to maximize sensitivity, speed-to-result, specificity, stability and reproducibility. The Company possesses proprietary know-how to develop tests for multiple conditions using colored latex. Our buffer formulations enable extremely long shelf lives of our rapid HIV and other tests and we believe that this provides us with an important competitive advantage.

Lateral Flow Technology and Reagent Licenses

As part of the agreements executed in 2006 with Alere for the marketing of our HIV tests, we were granted non-exclusive licenses to certain lateral flow patents for certain products manufactured and marketed by Chembio including but not limited to our lateral flow HIV tests. This license allows us to produce, market and sell assays using lateral flow technologies specifically including our STAT-PAK®, SURE CHECK®, DIPSTICK®, and veterinary product lines. Under this license agreement, prior to February 3, 2015, we paid royalties to Alere ranging from 5% to 8½%, depending upon the country in which the products are sold. Even though the relevant patent has expired in most other jurisdictions, or were never issued in markets where we have sold these products, our manufacture of the products in the United States has required that we pay royalties under this license, which has been a substantial

expense. In 2015 our lateral flow royalty expense to Alere was $30,000, and since 2007 we have incurred a total of $2.87 million in lateral flow royalty expenses. As of February 3, 2015 this royalty expense was no longer payable as the applicable patent expired at that time.

Although we believe our DPP® is outside of the scope of all lateral flow patents of which we are aware, we consult with patent counsel, and seek licenses and/or redesigns of products that we believe to be in the best interests of the Company and our stockholders. Because of the costs and other negative consequences of time-consuming patent litigation, we often attempt to obtain a license on reasonable terms. Nevertheless there is no assurance that the Alere lateral flow patents we have licensed will not be challenged or that other patents containing claims relevant to the Company's lateral flow or DPP® products will not be granted to third parties

TABLE OF CONTENTS

and that licenses to such patents, will be available on reasonable terms, if any. In the past Alere has aggressively enforced its lateral flow intellectual property, although some of the main patents have expired and we are not aware of any patent enforcement litigation that is ongoing with respect to the Alere lateral flow intellectual property.

Regardless, the DPP® technology provides us with our own intellectual property. We believe it provides us with a freedom to operate, and that it also enables tests to be developed with improved sensitivity as compared with comparable tests on lateral flow platforms. The Company has signed and anticipates signing new development projects based upon the DPP® technology that will provide new manufacturing and marketing opportunities. We have filed other patent applications that we believe will strengthen the DPP® intellectual property and have also filed for patent protection for certain other point-of-care technologies or applications thereof.

The peptides used in our rapid HIV tests were patented by Adaltis Inc. and were licensed to us under a 10-year non-exclusive license agreement dated August 30, 2002. However, in connection with Adaltis' bankruptcy, during the third quarter of 2009 we bought out all of our remaining obligations under that agreement. We also have licensed the antigens used in other tests including our Syphilis, Tuberculosis, Leptospirosis, Leishmaniasis and Chagas tests, and we may enter other license agreements. In prior years we concluded license agreements related to intellectual property rights owned by the United States associated with HIV-1, and during the first quarter of 2008 we entered into a sub-license agreement for HIV-2 with Bio-Rad Laboratories N.A., the exclusive licensee of the Pasteur Institute's HIV-2 intellectual property estate.

TABLE OF CONTENTS

RISK FACTORS

You should carefully consider each of the following risk factors and all of the other information provided in this prospectus. The risks described below are those we currently believe may materially affect us. An investment in our Company involves a high degree of risk, and should be considered only by persons who can afford the loss of their entire investment.

Risks related to our industry, business and strategy

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

All of our proposed and existing products are subject to regulation in the U.S. by the U.S. Food and Drug Administration, 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. 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 in government regulations 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.

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 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 USDA as well as by non-governmental organizations such as the ISO and WHO. We have implemented a quality system that is intended to comply with applicable regulations. Although FDA approval is not required for the export of our products, there are export regulations promulgated by the FDA that specifically relate to the export of our products that require compliance with FDA quality system regulation (QSRs) and that also require meeting certain documentary requirements regarding the approval of the product in export markets. Although we believe that we meet the regulatory standards required for the export of our products, these regulations could change in a manner that could adversely impact our ability to export our products.

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

The diagnostic industry is focused on the testing of biological specimens in a laboratory or at the point-of-care and is highly competitive and rapidly changing. Some of our principal competitors may have considerably greater financial, technical and marketing resources than we do. Several companies produce diagnostic tests that compete directly with our testing product line, including but not limited to, OraSure Technologies, Alere and Trinity Biotech. Furthermore these and/or other companies have or may have

TABLE OF CONTENTS

products incorporating molecular and/or other advanced technologies that over time could directly compete with our testing product line. As new products incorporating new technologies enter the market, our products may become obsolete or a competitor's products may be more effective or more effectively marketed and sold.

There are competing products that could significantly reduce our U.S. sales of rapid HIV tests.

In 2006 Alere, Inc. acquired a division from Abbott Diagnostic located in Japan that manufactured and marketed a rapid HIV test product line called Determine®. The Determine® format was developed for the developing world and remote settings and, central to the needs of that market. The format is essentially a test strip that is integrated into a thin foil wrapper. When opened, the underside of the wrapper serves as the test surface for applying the blood sample and performing the test. This design reduces costs and shipping weights and volumes and provides an advantage for the developing world markets it serves. Some of the disadvantages of the platform are the amount of blood sample that is needed (50 microliters versus 2.5, 5 and 10 for our lateral flow barrel, lateral flow cassette, and DPP® products respectively), the open nature of the test surface, and the absence of a true control that differentiates biological from other kinds of samples.

The so-called "3rd generation" version of this product has been marketed for many years and is the leading rapid HIV test that is used in a large majority of the national algorithms of countries funded by PEPFAR and the Global Fund, as well as many other countries in the world. That product is not FDA-approved though it is CE marked. The newest Determine® HIV version, which was developed and manufactured by Alere's subsidiary in Israel, Orgenics, is the so-called "4th Generation" version Determine® test. According to its claims, this product detects HIV antibodies and P24 HIV antigens. Because the P24 antigen is known to occur in HIV-positive individuals' blood samples before antibodies do, the 4th generation Determine® test is designed to detect HIV infection earlier than tests that solely rely on antibody detection. Chembio's tests, as well as all of the other currently FDA-approved rapid HIV tests, only detect antibodies. There are however laboratory tests that are FDA-approved that are "4th generation" tests, but they are of course neither rapid nor point-of-care.

The initial "4th generation" Alere Determine® rapid test product that was also CE marked and that Alere launched internationally some years ago has not been successfully commercialized to the best of our knowledge and at least certain published studies were not favorable for this product. However the 4th generation product that is now FDA-approved was apparently modified as compared to the initial international version, and it may perform more satisfactorily. Alere received FDA approval of this modified product in August 2013 and CLIA waiver for it in December 2014. Alere is also aggressively pursuing development of the market for this product. Moreover there is support by a number of key opinion leaders for the public health value of such 4th generation tests, and this product represents a significant competitive threat to Chembio as well as to each of the other rapid HIV test manufacturers (OraSure and Trinity primarily).

During 2011, Biolytical, Inc. of Vancouver, Canada received FDA approval and in 2012 received CLIA waiver of a flow-through rapid HIV test called "INSTI". The flow-through technology used in the INSTI test is older than lateral flow, and requires handling of multiple components (3 vials of solution) to perform the test in multiple steps. However, these steps can be accomplished in less than ten minutes, and the actual test results occur in only one minute after those steps are completed. Therefore sample-to-result time is shorter than any of the competitive products. The product also has good performance claims. There are settings where that reduced total test time, despite the multiple steps required, may be a distinct advantage, and we believe Biolytical has made some progress in penetrating certain public health markets.

Our products may not be able to compete with new diagnosticproducts or existing products developed by well-estab

Therefore, even though our lateral flow products currently enjoy a substantial market share in the U.S. rapid HIV test market, and we have an additional rapid HIV test, the DPP® HIV 1/2 Assay, there a number of risks and uncertainties concerning current and anticipated developments in this market. Although we have no specific knowledge of any other new product that is a significant competitive threat to our products, or that will render our products obsolete, if we fail to maintain and enhance our competitive position or fail to introduce new products and product features, our customers may decide to use products developed by our competitors, which could result in a loss of revenues and cash flow.

More generally, the point-of-care diagnostics industry is undergoing rapid technological changes, with frequent introductions of new technology-driven products and services. As new technologies become introduced into the point-of-care diagnostic testing market, we may be required to commit considerable

TABLE OF CONTENTS

additional efforts, time and resources to enhance our current product portfolio or develop new products. We may not have the available time and resources to accomplish this, and many of our competitors have substantially greater financial and other resources to invest in technological improvements. We may not be able to effectively implement new technology-driven products and services or be successful in marketing these products and services to our customers, which would materially harm our operating results.

Although we own our DPP® patent, lateral flow technology is still a competitive platform to DPP®, and lateral flow technology has a lower cost of manufacture than DPP® products. Although the DPP® platform has shown improved sensitivity as compared with conventional lateral flow platforms in a number of studies, several factors go into the development and performance attributes of products. Therefore the ability of our products to successfully compete will depend on several other factors, including but not limited to our having a patented rapid test platform technology that differentiates DPP® from lateral flow as well as from other diagnostic platform technologies.

We believe that our DPP® is outside of the scope of currently issued patents in the field of lateral flow technology, thereby offering the possibility of greater freedom to operate. However there can be no assurance that our patents or our products incorporating the patent claims will not be challenged at some time in the future.

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

A number of our components and critical raw materials are provided by third-party suppliers, some of which may be sole-source suppliers, which impacts our ability to manufacture or sell product if our suppliers cannot or will not deliver those materials in a timely fashion, or at all, due to an interruption in their supply, quality or technical issues, or any other reason. If this occurs, we could incur substantial expense and time to be able to reestablish the appropriate quality, cost, regulatory and market-acceptance circumstances needed for commercial success. Even with the needed expense and time, we may not be able to reestablish any or all of these factors. The absence of any one or more of these factors could prevent us from being able to commercially produce and market the affected product or products.

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

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

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

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

The success of our business depends on, in addition to the market success of our products, our ability to raise additional capital through the sale of debt or equity or through borrowing, and we may not be able to raise capital or borrow funds on attractive terms and/or in amounts necessary to continue our business, or at all.

We were profitable for five consecutive years through 2013. Nevertheless, prior to 2009 we sustained significant operating losses since 2004, and we incurred an operating loss for 2014 and 2015. We estimate that our resources are sufficient to fund our needs through the end of 2016 and beyond. Nevertheless we have already made, and may continue to make, significant financial commitments to invest in our sales and

TABLE OF CONTENTS

marketing organization, regulatory approvals, research and development including new technologies, and production capacity, including expanded facilities.

Our liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenues; (2) the extent to which, if any, that revenue level improves operating cash flows; (3) our investments in research and development, facilities, marketing, regulatory approvals, and other investments we may determine to make; and (4) our investment in capital equipment and the extent to which it improves cash flow through operating efficiencies. There are no assurances that we will generate positive cash flow for 2016 or, in the alternative, be successful in raising sufficient capital to fund our needs after 2016.

Our U.S. market sales are difficult to predict in 2016 given (i) our early June 2014 termination of the agreement with a third party for exclusive distribution of our cassette product in the U.S; and (ii) the impending May 31, 2016 termination of the agreement with a third party for exclusive distribution of our barrel product in the U.S. As a result of these terminations, we expect to continue to experience higher average revenue per unit, and a lower volume of U.S. sales, of the cassette and barrel products. Higher revenue per unit is anticipated because we previously sold these products to the exclusive U.S. distributor at a significantly lower price than the price at which the distributor resold these products to customers (including re-sellers and distributors) in the United States. However at this point with respect to the barrel product, this can occur only after any inventory that the exclusive U.S. distributor has accumulated is consumed, which may take several months. In addition, in marketing these products directly, we are incurring substantial costs associated with developing our sales and marketing organization and channel distribution partners.

We believe that underlying demand for HIV rapid testing in the United States remains strong, and that the restoration of some of the funding cutbacks from sequestration and the implementation of the Affordable Care Act and of the United States Preventive Services Task Force recommendations will have a positive impact on the development of the market. Further, our products are well established and relied upon by a large installed base of customers over many years of use in the U.S. global market, and we believe this is a strong advantage. We also believe that our DPP® HIV 1/2 Assay for which CLIA waiver was obtained in October 2014, for use with oral fluid or bloods samples will be able to serve new customers that were previously unavailable to us with our lateral flow blood tests. However, development of new customers with this product is costly and time-consuming.

We are attempting to increase international sales of our products, and we have invested in additional resources in connection with this effort; but as we have experienced, the nature of international business is such that it can be volatile from period to period, depending on ordering patterns of donor-funded programs.

Furthermore, a number of factors can slow or prevent sales increases or cause sales decreases, or substantially increase the cost of achieving sales assuming they are achieved. These factors include:

economic conditions and the absence of or reduction in available funding sources;
regulatory requirements and customs regulations;
cultural and political differences;
foreign exchange rates, currency fluctuations and tariffs;
dependence on and difficulties in managing international distributors or representatives;
the creditworthiness of foreign entities;
difficulties in foreign accounts receivable collection;
competition;
pricing; and
any inability we may have in maintaining or increasing revenues.

The success of our business depends on, in addition to themarket success of our products, our ability to raise addit

If we are unable to maintain or increase our revenues from domestic and/or international customers, our operating results will be materially harmed.

The success of our business depends on, in addition to themarket success of our products, our ability to raise addit

TABLE OF CONTENTS

Although we have an ethics and anti-corruption policy in place, and have no knowledge or reason to know of any practices by our employees, agents or distributors that could be construed as in violation of such policies, our business includes sales of products to countries where there is or may be widespread corruption.

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

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

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

We seek to protect our proprietary products under trade secret and copyright laws, enter into license agreements for various materials and methods employed in our products, and enter into strategic relationships for distribution of the products. These strategies afford only limited protection. We currently have some foreign patents issued, and we are seeking additional patent protection in several other foreign jurisdictions for our DPP® technology. We have licenses to reagents (antigens and peptides) used in several of our products and products under development. Despite our efforts to protect our proprietary assets, and respect the intellectual property rights of others, we participate in several

markets where intellectual property rights protections are of little or no value. This can place our products and our company at a competitive disadvantage.

Despite the efforts we make to protect our confidential information, such as entering into confidentiality agreements in connection with new business opportunities, unauthorized parties may attempt to copy aspects of our products or to obtain information that we regard as proprietary. We may be required to expend substantial resources in asserting or protecting our intellectual property rights, or in defending suits related to intellectual property rights. Disputes regarding intellectual property rights could substantially delay product development or commercialization activities because some of our available funds would be diverted away from our business activities. Disputes regarding intellectual property rights might include state, federal or foreign court litigation as well as patent interference, patent reexamination, patent reissue, or trademark opposition proceedings in the U.S. Patent and Trademark Office.

We rely on trade secret laws and agreements with our keyemployees and other third parties to protect our proprieta

TABLE OF CONTENTS

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

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 will depend to a large extent upon the skills and experience of our executive officers, management and sales, marketing, operations and scientific staff. We may not be able to attract or retain qualified employees in the future due to the intense competition for qualified personnel among medical products businesses, geographic considerations, our ability to offer competitive compensation, relocation packages, benefits, and/or other reasons.

If we are not able to attract and retain the necessary 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 strategic partners in a timely fashion, or to support internal research and development programs. Although we believe we will be successful in attracting and retaining qualified personnel, competition for experienced scientists and other personnel from numerous companies and academic and other research institutions may limit our ability to do so on acceptable terms.

We have entered into employment contracts with our Chief Executive Officer, John Sperzel, our Chief Operating Officer, Sharon Klugewicz, and our Chief Scientist & Technology Officer, Javan Esfandiari. Due to the specific knowledge and experience of these executives regarding the industry, technology and market, the loss of the services of any one of them could have a material adverse effect on the Company. The contract with Mr. Sperzel has a term of three years ending March 2017. The contract with Ms. Klugewicz has a term of two years ending May 2017. The contract with Mr. Esfandiari has a term of three years ending March 2019. The Company has obtained a key man insurance policy on Mr. Esfandiari. The contract with Mr. Sperzel provides that Mr. Sperzel will serve as the Chief Executive Officer and as a Director of the Company through March 13, 2017.

We believe our success depends in part on the continued funding of and our ability to participate in large testing programs in the U.S. and worldwide. Funding of these and or similar programs may be reduced, discontinued and/or we may not be able to participate for other reasons.

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

In December 2013 President Obama signed into law the PEPFAR Stewardship and Oversight Act, which is the most recent reauthorization of PEPFAR. However, unlike the 2008 PEPFAR authorization, which authorized approximately $45 billion in funding, the new law does not authorize a specific dollar amount for funding. Nevertheless it is widely anticipated that PEPFAR will continue to enjoy strong funding; the FY14 budget has $6 billion for global HIV/AIDS assistance, including $4 billion for PEPFAR.

To the extent that we are unable to collect our outstanding accounts receivable, our operating results could be materially harmed.

There may be circumstances and timing that require us to accept payment terms, including delayed payment terms, from distributors or customers, which, if not satisfied, could cause financial losses.

We believe our success depends in part on the continuedfunding of and our ability to participate in large testingprog

TABLE OF CONTENTS

We generally accept payment terms which require us to ship product before the contract price has been paid fully, and there also are circumstances pursuant to which we may accept further delayed payment terms pursuant to which we may continue to deliver product. To the extent that these circumstances result in significant accounts receivables and those accounts receivables are not paid on a timely basis, or are not paid at all, especially if concentrated in one or two customers, we could suffer financial losses.

Although we were profitable from 2009 through 2013, we incurred a net loss for 2014 and 2015 and cannot be certain that we will be able to sustain profitability in the future.

From the inception of Chembio Diagnostic Systems, Inc. in 1985 through the period ended December 31, 2008, we incurred net losses. We were then profitable each year from 2009 through 2013. In 2014 and 2015, we made substantial expenditures for sales and marketing, regulatory submissions, product development, production and warehouse capacity, and other purposes, and we incurred a net operating loss. Our ability to re-achieve profitability in the future will primarily depend on our ability to increase sales of our products based on having made the aforementioned expenditures to reduce production and other costs, and to successfully introduce new products and enhanced versions of our existing products into the marketplace. If we are unable to increase our revenues at a rate that is sufficient to achieve profitability, or adequately control and reduce our operating costs, our operating results would be materially harmed.

To the extent that we are unable to obtain sufficient product liability insurance or that we incur product liability exposure that is not covered by our product liability insurance, our operating results could be materially harmed.

We may be held liable if any of our products, or any product which is made with the use or incorporation of any of the technologies belonging to us, causes injury of any type or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or use. We have obtained product liability insurance even though we have never received a product liability claim, and have generally not seen product liability claims for screening tests that are accompanied by appropriate disclaimers. Nevertheless, in the event there is a claim, this insurance may not fully cover our potential liabilities. In addition, as we attempt to bring new products to market, we may need to increase our product liability coverage which could be a significant additional expense that we may not be able to afford. If we are unable to obtain sufficient insurance coverage at an acceptable cost to protect us, we may be forced to abandon efforts to commercialize our products or those of our strategic partners, which would reduce our revenues.

Risks related to our Common Stock

Our Common Stock continues to be illiquid, so investors may not be able to sell as much stock as they want at prevailing market prices.

To the extent that we are unable to collect our outstandingaccounts receivable, our operating results could be mate

The average daily trading volume of our Common Stock on the NASDAQ market was approximately 21,600 shares per day over the three months ended December 31, 2015 as compared with approximately 109,000 shares per day over the three months ended December 31, 2014. The liquidity of our stock depends on several factors, including but not limited to the financial results of the Company 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 the Company.

Our Common Stock continues to be illiquid, so investors maynot be able to sell as much stock as they want at preva

TABLE OF CONTENTS

Our management and larger stockholders exercise significant control over the Company.

As of December 31, 2015, our named executive officers, directors and 5% stockholders beneficially owned approximately 24.0% of our voting power, which includes two large investors that beneficially owns approximately 11.4% and 9.2%, respectively of the outstanding stock. For the foreseeable future, and assuming these ownership percentages continue to apply, to the extent that these parties vote similarly, they may be able to exercise significant control over many matters requiring approval by the board of directors or our stockholders. As a result, they may be able to:

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

TABLE OF CONTENTS

USE OF PROCEEDS

Unless otherwise specified in the applicable prospectus supplement, we will use the proceeds from the sale of the securities described in this prospectus for product development, the acquisition or license of new and/or complementary technologies, other intellectual property, operational expansion or improvements, FDA submission-related activities, strategic acquisitions of products, businesses or companies, sales and marketing, general corporate purposes, and working capital. Pending such use, we may temporarily invest the proceeds or use them to reduce short-term indebtedness. The applicable prospectus supplement will provide more details on the use of proceeds of any specific offering.

DESCRIPTION OF SECURITIES WE MAY OFFER

This prospectus contains summary descriptions of our common stock, preferred stock, warrants and units that we may offer from time to time. These summary descriptions are not meant to be complete descriptions of each security. The particular terms of any security will be described in the accompanying prospectus supplement and other offering material. The accompanying prospectus supplement may add, update or change the terms and conditions of the securities as described in this prospectus.

TABLE OF CONTENTS

DESCRIPTION OF COMMON STOCK

General

This section of the prospectus describes the material terms and provisions of our common stock. When we offer to sell or otherwise issue shares of our common stock, we will describe the specific terms of the offering and the shares in a supplement to this prospectus. This summary does not purport to be exhaustive and is qualified in its entirety by reference to our articles of incorporation, as amended, our bylaws, as amended, and the applicable provisions of Nevada law.

Our authorized capital stock consists of 100,000,000 shares of our common stock, par value $0.01 per share. Our authorized capital stock may be increased and altered from time to time in the manner prescribed by Nevada law upon the vote of at least a majority of the shares entitled to vote on the matter. Our shares of common stock are traded on the NASDAQ trading market under the symbol CEMI.

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

The holders of common stock have no preemptive or conversion rights and are not subject to further calls or assessments. There are no redemption or sinking fund provisions applicable to the common stock. Under our corporate documents and Nevada law, the election of directors requires a plurality of the votes cast by holders of our outstanding common stock at the annual meeting while other fundamental corporate actions, such as mergers and sales of substantial assets, or amendments or our articles of incorporation require the approval of the holders of a majority of our outstanding common stock. There exists no provision in our articles of incorporation or our bylaws that would delay, defer or prevent a change in control of the Company.

Transactions with Interested Persons

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

the fact of the common directorship, office or financial interest is known to the board of directors or a committee of the board of directors and a majority of disinterested directors on the board of directors (or on the committee) authorized, approved or ratified the transaction;
the fact of the common directorship, office or financial interest is known to the stockholders and disinterested stockholders holding a majority of the shares held by disinterested stockholders authorized, approved or ratified the transaction;

the fact of the common directorship, office or financial interest is not known to the director or officer at the time the transaction is brought to the board of directors for action; or

the transaction was fair to the Company at the time it is authorized or approved.

Control Share Acquisition Provisions

Nevada law precludes an acquirer of the shares of a Nevada corporation who crosses one of three ownership thresholds (20%, 33 1/3% or 50%) from obtaining voting rights with respect to those shares unless the disinterested holders of a majority of the shares of the Company held by disinterested stockholders vote to accord voting power to those shares.

TABLE OF CONTENTS

Combinations with Interested Stockholders

Under the NRS, except under certain circumstances, a corporation is not permitted to engage in a business combination with any interested stockholder for a period of two years following the date such stockholder became an interested stockholder. An interested stockholder is a person or entity who owns 10% or more of the outstanding shares of voting stock. Nevada permits a corporation to opt out of the application of these business combination provisions by so providing in the articles of incorporation. The Company did not opt out of the application of these business combination provisions in its articles of incorporation, as amended.

Stockholder Rights Agreement

On March 8, 2016, the Company entered into a Rights Agreement (the Rights Agreement) between the Company and Action Stock Transfer Corp., as Rights Agent. Pursuant to the Rights Agreement, the Company declared a dividend distribution of one Preferred Share Purchase Right (a Right) for each outstanding share of common stock, par value $0.01 (the Common Stock), of the Company, in the manner described below. The Board of Directors set the payment date for the distribution of the Rights as March 8, 2016, and the Rights were distributed to the Company's shareholders of record on that date. The description and terms of the Rights are set forth in the Rights Agreement.

Rights Initially Not Exercisable. The Rights are not exercisable until a Distribution Date. Until a Right is exercised, the holder thereof, as such, has no rights as a shareholder of the Company, including, without limitation, the right to vote or to receive dividends.

Separation and Distribution of Rights. The Rights are to be evidenced by the certificates for shares of Common Stock registered in the names of the holders thereof, and not by separate rights certificates until the earlier to occur of (i) the close of business on the tenth business day following a public announcement that an Acquiring Person (as defined in the Rights Agreement) has acquired a Combined Ownership (as defined in the Rights Agreement) of 20% or more of the outstanding shares of the Common Stock (the Shares Acquisition Date) or (ii) the later of (A) the close of business on the tenth business day (or such later date as may be determined by action of the Board of Directors prior to such time as any person or group of affiliated or associated persons becomes an Acquiring Person) after the date that a tender or exchange offer or intention to commence a tender or exchange offer by any person is first published, announced, sent or given within the meaning of Rule 14d-4(A) under the Securities Exchange Act of 1934, as amended, the consummation of which would result in any person having Combined Ownership of 20% or more of the outstanding shares of the Common Stock, or (B) if such a tender or exchange offer has been published, announced, sent or given before the date of the Rights Agreement, then the close of business on the tenth business day after the date the Rights Agreement was entered into (or such later date as may be determined by action of the Board of Directors prior to such time as any person becomes an Acquiring Person); (the earlier of such dates referred to in (i) and (ii), which date may include any such date that is after the date of the Rights Agreement but prior to the issuance of the Rights, being called the Distribution Date).

Transfer Agent

The transfer agent and registrar for the Company's common stock is Action Stock Transfer.

TABLE OF CONTENTS

DESCRIPTION OF PREFERRED STOCK

General

This section of the prospectus describes the material terms and provisions of our preferred stock. When we offer to sell or otherwise issue shares of our preferred stock, we will describe the specific terms of the offering and the shares in a supplement to this prospectus. The prospectus supplement will also indicate whether the terms and provisions described in this prospectus apply to the particular series of preferred stock. This summary does not purport to be exhaustive and is qualified in its entirety by reference to our articles of incorporation, as amended, our bylaws, as amended, and the applicable provisions of Nevada law.

Our authorized capital stock consists of 10,000,000 shares of our preferred stock, par value $0.01 per share. Under our Articles of Incorporation, as amended, we may issue shares of preferred stock in one or more series, as may be determined by our Board of Directors or a duly authorized committee. Our Board of Directors or a committee thereof also may establish, from time to time, the number of shares to be included in each series and may fix the designation, powers, preferences and rights of the shares of each such series and any qualifications, limitations or restrictions thereof, and may increase or decrease the number of shares of any series without any further vote or action by the stockholders. Any preferred stock we may issue will rank senior to our common stock with respect to the payment of dividends or amounts paid upon liquidation, dissolution or winding up of our Company, or both. In addition, any shares of our preferred stock may have class or series voting rights.

Our Board of Directors is authorized to determine or fix from time to time by resolution the following terms for each series of preferred stock, which will be described in a prospectus supplement:

the distinctive serial designation of such series and the number of shares to constitute such series;
the voting rights, if any;
the dividend rate;
whether dividends are cumulative and, if so, the date from which dividends cumulate;
the payment date for dividends;
redemption rights, the applicable redemption prices and such other conditions of redemption;
amounts payable to holders on our liquidation, dissolution or winding up;
the amount of the sinking fund, if any;
whether the shares will be convertible or exchangeable into equity, and, if so, the prices and terms of conversion and such other terms and conditions of such conversion or exchange; and
any other voting powers, designations, preferences, limitations, restrictions, and relative rights.

The preferred stock will be, when issued, fully paid and non-assessable. Holders of preferred stock will not have any preemptive or subscription rights to acquire more stock of the Company.

The transfer agent, registrar, dividend disbursing agent and redemption agent for shares of each series of preferred stock will be named in the prospectus supplement relating to such series.

The rights of holders of the preferred stock offered may be adversely affected by the rights of holders of any shares of preferred stock that may be issued in the future. The Board of Directors may cause shares of preferred stock to be issued in public or private transactions for any proper corporate purpose. Examples of proper corporate purposes include issuances to obtain additional financing in connection with acquisitions or otherwise, and issuances to our officers, directors and employees and our subsidiaries pursuant to benefit plans or otherwise.

Rank

Unless otherwise specified in the prospectus supplement relating to the shares of any series of preferred stock, such shares will rank on an equal basis with each other series of preferred stock and prior to the common stock as to dividends and distributions of assets.

TABLE OF CONTENTS

Dividends

The holders of each series of preferred stock will be entitled to receive cash dividends if declared by our board of directors out of funds we can legally use for payment. The prospectus supplement will indicate the dividend rates and the dates on which we will pay dividends as to each series of preferred stock The rates may be fixed or variable or both. If the dividend rate is variable, the formula used to determine the dividend rate will be described in the prospectus supplement. We will pay dividends to the holders of record of each series of preferred stock as they appear on the record dates fixed by our Board of Directors.

Conversion or Exchange

The applicable prospectus supplement for any series of preferred stock will state the terms, if any, on which shares of that series are convertible or exchangeable into shares of our common stock or another series of our preferred stock. The terms of any such conversion or exchange and any such preferred stock will be described in the prospectus supplement relating to such series of preferred stock.

Redemption

If so specified in the applicable prospectus supplement, a series of preferred stock may be redeemable at any time, in whole or in part, at our option or at the option of the holder thereof. It also may be mandatorily redeemed subject to a mandatory redemption.

Any partial redemptions of preferred stock will be made in a way that our board of directors decides is equitable.

Unless we default in the payment of the redemption price, dividends will cease to accrue after the redemption date on shares of preferred stock called for redemption and all rights of holders of such shares will terminate, except for the right to receive the redemption price.

Liquidation Preference

Upon any voluntary or involuntary liquidation, dissolution or winding up of the Company, holders of each series of preferred stock will be entitled to receive distributions upon liquidation in the amount set forth in the prospectus supplement relating to such series of preferred stock. Such distributions will be made before any distribution is made on common stock or on any other securities ranking junior to the preferred stock with respect to liquidation.

If the liquidation amounts payable relating to the preferred stock of any series and any other securities ranking on a parity regarding liquidation rights are not paid in full, the holders of the preferred stock of such series and such other securities will share in any such distribution of our available assets on a ratable basis in proportion to the full liquidation preferences. Holders of such series of preferred stock will not be entitled to any other amounts from us after they have received their full liquidation preference.

Voting rights

The holders of shares of preferred stock will have no voting rights, except as otherwise stated in the prospectus supplement, as otherwise stated in the certificate of designation establishing such series, or as required by applicable

law.

TABLE OF CONTENTS

DESCRIPTION OF WARRANTS

In this section, we describe the general terms and provisions of the warrants for the purchase of preferred stock or common stock that we may issue. Warrants issued pursuant to this prospectus may be issued independently or together with any preferred stock or common stock. Warrants sold with other securities may be attached to or separate from the other securities. Each series of warrants will be issued under a separate warrant agreement to be entered into between us and a warrant agent who will be specified in the warrant agreement and in the prospectus supplement. The warrant agent will act solely as our agent in connection with the warrants of that series and will not assume any obligation or relationship of agency or trust for or with any holders or beneficial owners of warrants.

This summary of some of the terms and other provisions of the warrants that may be issued is not complete and is qualified in its entirety by reference to the applicable warrant agreement and related warrant certificate and the prospectus supplement, which both will be filed with the SEC. You should refer to this prospectus, the prospectus supplement, the warrant agreement, including the forms of securities warrant certificate representing the securities warrants, relating to the specific warrants that we may offer for the complete terms of the warrant agreement and the warrants. For more information on how you can obtain copies of the applicable warrant agreement, if we offer warrants, see Where You Can Find More Information. We urge you to read the applicable warrant agreement and the applicable prospectus supplement and any other offering material in their entirety.

The applicable prospectus supplement related to an issuance of warrants will describe the following terms, where applicable, of the warrants in respect of which this prospectus is being delivered:

the title of the warrants;
the aggregate number of the warrants;
the price or prices at which the warrants will be issued;
the currency or currencies (including composite currencies) in which the price or prices of the warrants may be payable;
the designation, amount and terms of the offered securities purchasable upon exercise of the warrants;
if applicable, the date on and after which the warrants and the offered securities purchasable upon exercise of the warrants will be separately transferable;
the terms of the securities purchasable upon exercise of such warrants and the procedures and conditions relating to the exercise of such warrants;
any provisions for adjustment of the number or amount of securities receivable upon exercise of the warrants or the exercise price of the warrants;
the price or prices at which and currency or currencies in which the offered securities purchasable upon exercise of the warrants may be purchased;
the date on which the right to exercise the warrants shall commence and the date on which the right shall expire;
if applicable, the minimum or maximum amount of the warrants that may be exercised at any one time;
information with respect to book-entry procedures, if any; and
any other material terms of the warrants, including terms, procedures and limitations relating to the exchange and exercise of the warrants.

The prospectus supplement relating to any warrants to purchase equity securities may also include, if applicable, a discussion of certain U.S. federal income tax and ERISA considerations.

TABLE OF CONTENTS

Warrants for the purchase of preferred stock and common stock will be offered and will be exercisable for U.S. dollars only. Warrants will be issued in registered form only.

Each warrant will entitle its holder to purchase the number of shares of preferred stock or common stock at the exercise price set forth in, or calculable as set forth in, the applicable prospectus supplement and warrant agreement.

After the close of business on the expiration date, unexercised warrants will become void. We will specify the place or places where, and the manner in which, warrants may be exercised in the applicable prospectus supplement.

Upon receipt of payment and the warrant certificate properly completed and duly executed at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement, we will, as soon as practicable, forward the purchased securities. If less than all of the warrants represented by the warrant certificate are exercised, a new warrant certificate will be issued for the remaining warrants.

Prior to the exercise of any warrants to purchase preferred stock or common stock, holders of the warrants will not have any of the rights of holders of the preferred stock or common stock purchasable upon exercise, including, the right to vote or to receive any payments of dividends on the preferred stock or common stock purchasable upon exercise.

TABLE OF CONTENTS

DESCRIPTION OF UNITS

In this section, we describe the general terms and provisions of the units that we may offer. We may issue units consisting of one or more of the securities described in this prospectus in any combination. Each unit will be issued so that the holder of the unit also is the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately at any time or at any time before a specified date.

The applicable prospectus supplement will specify the following terms of any units in respect of which this prospectus is being delivered:

the terms of the units and of any of the common stock, preferred stock and warrants comprising the units, including whether and under what circumstances the units may be traded separately;

a description of the terms of any unit agreement governing the units;

a description of the provisions for the payment, settlement, transfer or exchange of the units or the securities comprising those units; and

whether the units will be issued fully registered or in global form.

The description in the applicable prospectus supplement and other offering material of any units we offer will not necessarily be complete and will be qualified in its entirety by reference to the applicable unit agreement, which will be filed with the SEC if we offer units. For more information on how you can obtain copies of the applicable unit agreement if we offer units, see Where You Can Find More Information. We urge you to read the applicable unit agreement and the applicable prospectus supplement and any other offering material in their entirety.

TABLE OF CONTENTS

PLAN OF DISTRIBUTION

We may sell the securities described in this prospectus to or through one or more agents, underwriters, dealers or directly to purchasers on a continuous or delayed basis.

The distribution of the securities may be effected from time to time in one or more transactions at a fixed price or prices, which may be changed from time to time, at market prices prevailing at the times of sale, at prices related to such prevailing market prices or at negotiated prices.

Each time that we use this prospectus to sell our securities, we will also provide a prospectus supplement. For each series of securities, the applicable prospectus supplement will set forth the terms of the offering including:

the public offering price;
the name or names of any underwriters, dealers or agents;
the purchase price of the securities;
the proceeds from the sale of the securities to us;
any underwriting discounts, agency fees, or other compensation payable to underwriters or agents;
any discounts or concessions allowed or reallowed or repaid to dealers; and
the securities exchanges on which the securities will be listed, if any.

If we use underwriters in the sale of securities, the securities will be acquired by the underwriters for their own account. The underwriters may then resell the securities in one or more transactions at a fixed public offering price or at varying prices determined at the time of sale or thereafter. The securities may be either offered to the public through underwriting syndicates represented by managing underwriters, or directly by underwriters. The obligations of the underwriters to purchase the securities will be subject to certain conditions. The underwriters will be obligated to purchase all the securities offered if they purchase any securities. The public offering price and any discounts or concessions allowed or re-allowed or paid to dealers may be changed from time to time.

If we use dealers in the sale of securities, we will sell securities to such dealers as principals. The dealers may then resell the securities to the public at varying prices to be determined by such dealers at the time of resale. We may solicit offers to purchase the securities directly, and we may sell the securities directly to institutional or other investors, who may be deemed underwriters within the meaning of the Securities Act with respect to any resales of those securities. The terms of these sales will be described in the applicable prospectus supplement. If we use agents in the sale of securities, unless otherwise indicated in the prospectus supplement, they will use their reasonable best efforts to solicit purchases for the period of their appointment. Unless otherwise indicated in a prospectus supplement, if we sell directly, no underwriters, dealers or agents would be involved. We will not make an offer of securities in any jurisdiction that does not permit such an offer.

We may grant underwriters who participate in the distribution of securities an option to purchase additional securities to cover overallotments, if any, in connection with the distribution. Any underwriter may engage in overallotment, stabilizing transactions, short covering transactions and penalty bids in accordance with SEC orders, rules and regulations and applicable law. To the extent permitted by applicable law and SEC orders, rules and regulations, an overallotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. To the extent permitted by applicable law and SEC orders, rules and regulations, short covering transactions involve purchases of the common stock in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the common stock originally sold by the dealer is purchased in a covering transaction to cover short positions. Those activities may cause the price of the

common stock to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time.

TABLE OF CONTENTS

Any underwriters who are qualified market makers on the NASDAQ trading market may engage in passive market making transactions in the common stock on the NASDAQ trading market in accordance with Rule 103 of Regulation M, during the business day prior to the pricing of the offering, before the commencement of offers or sales of the common stock. Passive market makers must comply with applicable volume and price limitations and must be identified as passive market makers. In general a passive market maker must display its bid at a price not in excess of the highest independent bid for such security; if all independent bids are lowered below the passive market maker's bid, however, the passive market maker's bid must then be lowered when certain purchase limits are exceeded.

Underwriters, dealers and agents that participate in any distribution of securities may be deemed to be underwriters as defined in the Securities Act. Any discounts, commissions or profit they receive when they resell the securities may be treated as underwriting discounts and commissions under the Securities Act of 1933. Only underwriters named in the prospectus supplement are underwriters of the securities offered in the prospectus supplement. We may have agreements with underwriters, dealers and agents to indemnify them against certain civil liabilities, including certain liabilities under the Securities Act, or to contribute with respect to payments that they may be required to make.

We may authorize underwriters, dealers or agents to solicit offers from certain institutions whereby the institution contractually agrees to purchase the securities from us on a future date at a specific price. This type of contract may be made only with institutions that we specifically approve. Such institutions could include banks, insurance companies, pension funds, investment companies and educational and charitable institutions. The underwriters, dealers or agents will not be responsible for the validity or performance of these contracts.

Each series of securities will be a new issue of securities and will have no established trading market, other than our common stock, which is listed on the NASDAQ trading market. Unless otherwise specified in the applicable prospectus supplement, the securities will not be listed on any exchange. It has not presently been established whether the underwriters, if any, of the securities will make a market in the securities. If the underwriters make a market in the securities, such market making may be discontinued at any time without notice. No assurance can be given as to the liquidity of the trading market for the securities.

Agents, dealers and underwriters may be entitled to indemnification by us against certain civil liabilities, including liabilities under the Securities Act, or to contribution with respect to payments which the agents, dealers or underwriters may be required to make in respect thereof. Agents, dealers or underwriters may be customers of, engage in transactions with, or perform services for us and our subsidiaries in the ordinary course of business.

LEGAL MATTERS

The validity of the shares offered hereby has been passed upon for us by Ballard Spahr LLP.

Haynes and Boone, LLP, Denver, Colorado will serve as our counsel. A partner of Haynes and Boone, LLP owns 29,497 shares of Common Stock.

The name of the law firm advising any underwriters or agents with respect to certain issues relating to any offering will be set forth in the applicable prospectus supplement.

EXPERTS

The consolidated financial statements as of December 31, 2015 and 2014 and for each of the two years in the period ended December 31, 2015 incorporated by reference in this Prospectus have been so incorporated in reliance on the report of BDO USA, LLP, an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

TABLE OF CONTENTS

WHERE YOU CAN FIND MORE INFORMATION

This prospectus is a part of a registration statement on Form S-3 filed by us with the SEC under the Securities Act.

This prospectus does not contain all the information set forth in the registration statement, certain parts of which are omitted in accordance with the rules and regulations of the SEC. For further information with respect to us and the securities offered by this prospectus, reference is made to the registration statement. Statements contained in this prospectus concerning the provisions of such documents are necessarily summaries of such documents and each such statement is qualified in its entirety by reference to the copy of the applicable document filed with the SEC.

We file periodic reports, proxy statements and other information with the SEC. Our filings with the SEC are available to the public over the Internet at the SEC's website at *http://www.sec.gov*. Our filings with the SEC are also available to the public on our website at *www.chembio.com*, as well as through document retrieval services. You may read and copy any periodic reports, proxy statements or other information we file at the SEC's public reference room in Washington, D.C., which is located at the following address: Public Reference Room, 100 F Street N.E., Washington, D.C. 20549. You can request copies of these documents, upon payment of a duplicating fee, by writing to the SEC. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the SEC's public reference rooms.

We incorporate by reference into this prospectus the information we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus and information that we file subsequently with the SEC will automatically update this prospectus. We incorporate by reference the documents listed below and any filings we make with the SEC under Sections 13(a), 13(c), 14, or 15(d) of the Exchange Act, after the initial filing of the registration statement that contains this prospectus and prior to the time that we sell all the securities offered by this prospectus, provided, however, that we are not incorporating any information furnished under either Item 2.02 or Item 7.01 of any Current Report on Form 8-K:

(a) Our Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 8, 2016.

(b) Our Current Reports on Form 8-K filed on January 28, 2016; February 23, 2016; February 29, 2016; and two Current Reports filed on March 8, 2016.

(c) Portions of our Proxy Statement for the Annual Meeting of Stockholders, held on June 8, 2015, that have been incorporated by reference in our 2015 Annual Report on Form 10-K.

(d) The description of our common stock contained in our Form 8-A as filed with the SEC on June 6, 2012 pursuant to Sections 12(b) and 12(g) of the Exchange Act.

(f) The description of our Preferred Share Purchase Rights contained in our Form 8-A filed on March 8, 2016, including any amendment to that form that we may file in the future for the purpose of updating the description of our Preferred Share Purchase Rights.

You may request a copy of these filings (other than an exhibit to a filing unless that exhibit is specifically incorporated by reference into that filing) at no cost, by writing to or telephoning us at the following address and telephone number:

Chembio Diagnostic Systems, Inc.
3661 Horseblock Road
Medford, New York 11763
(631) 924-1135
ATTN: Susan Norcott

TABLE OF CONTENTS

You should rely only on the information contained or incorporated by reference in this prospectus and the applicable prospectus supplement. We have not authorized anyone else to provide you with additional or different information. We may only use this prospectus to sell securities if it is accompanied by a prospectus supplement. We are only offering these securities in states where the offer is permitted. You should not assume that the information in this prospectus or the applicable prospectus supplement is accurate as of any date other than the dates on the front of those documents.

TABLE OF CONTENTS

1,783,760 Shares of Common Stock

Chembio Diagnostics, Inc.

$6.75 per share

Prospectus Supplement

Craig-Hallum Capital Group

The date of this prospectus supplement is February 9, 2018
