CHEMBIO DIAGNOSTICS, INC.
Form S-3
March 08, 2016
As filed with the U.S. Securities and Exchange Commission on March 8, 2016

Registration No. 333-_____

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

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FORM S-3

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

_____

CHEMBIO DIAGNOSTICS, INC.
(Exact Name of Registrant as Specified in its Charter)

Nevada	6282	88-0425691
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

3661 Horseblock Road
Medford, New York 11763
(631) 924-1135
(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

_____

Richard J. Larkin
Chembio Diagnostics, Inc.
Chief Financial Officer
3661 Horseblock Road
Medford, New York 11763
(631) 924-1135

(Name, address, including zip code, and telephone number, including area code, of agent for service for Registrant)

_____

with copies to:
Alan L. Talesnick, Esq.
Jamie M. Jackson, Esq.
Haynes and Boone, LLP
1801 Broadway St., Suite 800
Denver, Colorado 80202
(303) 382-6200

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Approximate date of commencement of proposed sale to the public: From time to time after this Registration Statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. £

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with the dividend or interest reinvestment plans, check the following box.

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

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

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment hereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. £

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. £

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

Large accelerated filer £	Accelerated filer £	Non-accelerated filer £ (Do not check if a smaller reporting company)	Smaller reporting company R

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered(2)	Amount to be Registered(3)	Proposed Maximum Price per Unit(4)	Proposed Maximum Aggregate Offering Price(5)	Amount of Registration Fee(1)
Chembio Diagnostics, Inc.:				
Common Stock (6)				
Preferred Stock (6)				
Warrants to purchase Common Stock (7)				
Warrants to purchase Preferred Stock (7)				
Units (8)				
TOTAL:	$35,000,000	$35,000,000		$3,524.50

(1) Estimated in accordance with Rule 457(o) solely for the purpose of calculating the registration fee.

(2) Any securities registered hereunder may be sold separately or together with other securities registered hereunder as units.

(3) Includes such indeterminate number of shares of common stock, shares of preferred stock, warrants to purchase common stock, warrants to purchase preferred stock and units that Chembio Diagnostics, Inc. may sell pursuant to this Registration Statement, which may not exceed the maximum aggregate offering price of $35,000,000. The securities registered hereunder also include such indeterminate number of shares of common stock, preferred stock, warrants or units that may be issued upon conversion, exchange or exercise of any of the securities being registered hereby.

(4) Omitted pursuant to General Instruction II.D of Form S-3. The proposed maximum offering price per class of security will be determined from time to time by Chembio Diagnostics, Inc. in connection with, and at the time of, the issuance by Chembio Diagnostics, Inc. of the securities registered hereunder.

(5) In no event will the aggregate initial offering price of the securities issued under this Registration Statement exceed the amount registered above or the equivalent thereof in one or more foreign currencies or currency units.

(6) Such indeterminate number of shares of common stock or preferred stock, as may be issued from time to time at indeterminate prices.

(7) Warrants will represent rights to purchase common stock or preferred stock registered hereby. Because the warrants will provide a right only to purchase such securities offered hereunder, no additional registration fee is required.

(8) Such indeterminate number of units, which will be comprised of two or more of the securities registered hereby in any combination.

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The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this Registration Statement shall become effective on such date as the Commission, acting pursuant to said

Section 8(a), may determine.

We will amend and complete the information in this prospectus. We may not sell any of these securities or accept your offer to buy any of them until the documentation filed with the SEC relating to these securities has been declared "effective" by the SEC. This prospectus is not an offer to sell these securities or our solicitation of your offer to buy these securities in any State or other jurisdiction where that would not be permitted or legal.

SUBJECT TO COMPLETION, DATED [ ] 2016

PROSPECTUS

$35,000,000

Common Stock, Preferred Stock,
Warrants and Units

We may offer from time to time common stock, 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 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 [ ], 2016.

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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 indicate otherwise.

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," "intend," "plan," or 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:

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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.

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.

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® 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 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 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.

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.

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. 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 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 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 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.

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.

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.

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 approximately155 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 2016. The Company and Mr. Esfandiari currently are discussing terms for renewal of his employment agreement. 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®.

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.

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.

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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 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.

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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 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.

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 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 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.

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

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.

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 2016. The Company and Mr. Esfandiari currently are discussing terms for renewal of his employment agreement. 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 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.

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 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.

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.

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.

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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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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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 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.

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

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.

CHEMBIO DIAGNOSTIC SYSTEMS, INC.

Common Stock
Preferred Stock
Warrants
Units

_____

PROSPECTUS

_____

PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution

The following table sets forth the estimated expenses to be incurred in connection with the issuance and distribution of the securities being registered, other than underwriting discounts and commissions, all of which will be paid by the Company.

SEC Registration fee	3,524.50
Legal fees and expenses	25,000.00
Accounting fees and expenses	10,000.00
Other	1,475.50
Total	$40,000.00

* Estimate

Item 15. Indemnification of Directors and Officers.

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

Indemnification of directors and officers.

(1) A corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding whether civil, criminal, administrative or investigative, except an action by or in the right of the corporation, by reason of the fact that he is or was a director or officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director or officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses including attorneys' fees, judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with such action, suit or proceeding if he: (a) is not liable pursuant to NRS 78.138 or (b) acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere, or its equivalent, does not, of itself, create a presumption that the person is liable pursuant to NRS 78.138 or did not act in good faith and in a manner which he reasonable believed to be in or not opposed to the bests interests of the corporation, or that, with respect to any criminal action or proceedings, he had reasonable cause to believe that his conduct was unlawful.

(2) A corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that he is or was a director or officer, employee or agent of the corporation, or is or was serving at the request of the corporation, or is or was serving at the request of the corporation as a director or officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses including amounts paid in settlement and attorneys' fees actually and reasonably incurred by him in connection with the defense or settlement of the action or suit if he (a) is not liable pursuant to NRS 78.138 or (b) acted in good faith and in a manner which he reasonably believed to be in or not, opposed to the best interests of the corporation. Indemnification may not be made for any claim, issue or matter as to which such a person shall have been adjudged by a court of competent jurisdiction, after exhaustion of all appeals therefrom, to be liable for negligence or

misconduct in the performance of his duty to the corporation or for amounts paid in settlement to the corporation, unless and only to the extent that the court in which such action or suit was brought or other court of competent jurisdiction determines upon application that in view of all the circumstances of the case, the person is fairly and reasonably entitled to indemnity for such expenses which the court shall deem proper.

(3) To the extent that a director or officer of a corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding referred to in subsections (1) or (2) of this section, or in the defense of any claim, issue or matter therein, the corporation shall indemnify him against expenses, including attorneys' fees, actually and reasonably incurred by him in connection therewith.

The Registrant's bylaws provide that it will indemnify any of its directors or officers against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, relating to service for or at the request of the Registrant. The Registrant will not indemnify a director or officer if in relation to matters such director or officer is adjudged in the action, suit or proceeding to be liable for negligence or misconduct in the performance of their duties.

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

Item 16. Exhibits

EXHIBIT INDEX

Exhibit No.	Description
1.1	Form of Underwriting Agreement*
4.1	Form of certificate of designation of series of preferred stock*
4.2	Form of securities and warrant agreement*
5.1	Opinion of Ballard Spahr LLP
8.0	Opinion as to certain federal income tax matters*
23.1	Consent of BDO USA, LLP
23.2	Consent of Ballard Spahr LLP (included in Exhibit 5.1)
24	Power of Attorney of certain officers and directors (located on the signature page to the Registration Statement)

* To be filed, as applicable, by amendment or as an exhibit to a document incorporated by reference herein for the specific offering of securities, if any, to which it relates.

Item 17. Undertakings

The undersigned Registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) to include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

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

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(A) Each prospectus filed by a Registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which the prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof; provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(5) That, for the purpose of determining liability of a Registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, each undersigned Registrant undertakes that in a primary offering of securities of an undersigned Registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned Registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of an undersigned Registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of an undersigned Registrant or used or referred to by an undersigned Registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about an undersigned Registrant or its securities provided by or on behalf of an undersigned Registrant; and

(iv) Any other communication that is an offer in the offering made by an undersigned Registrant to the purchaser.

(6) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the Registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of each Registrant pursuant to the foregoing provisions, or otherwise, each Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by a Registrant of expenses incurred or paid by a director, officer or controlling person of a Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, that Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the state of New York, on March 8, 2016.

CHEMBIO DIAGNOSTICS, INC.

By: /s/ John J. Sperzel III
John J. Sperzel III
President, Chief Executive Officer and
Chairman of the Board

POWER OF ATTORNEY

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the date indicated. Each person whose signature appears below, hereby makes, constitutes and appoints John J. Sperzel III or their respective true and lawful attorney, with full power to sign for such person and in such person's name and capacity indicated below, and with full power of substitution, any and all amendments, including post-effective amendments, to this Registration Statement, hereby ratifying and confirming such person's signature as it may be signed by said attorney to any and all amendments.

Name	Title	Date
/s/ John J. Sperzel III John J. Sperzel III	Chief Executive Officer, President and Chairman of the Board (principal executive officer)	March 8, 2016
/s/ Richard J. Larkin Richard J. Larkin	Chief Financial Officer (principal financial officer & accounting officer)	March 8, 2016
/s/ Gary Meller Dr. Gary Meller	Director	March 8, 2016
/s/ Katherine L. Davis Katherine L. Davis	Director	March 8, 2016
/s/ Pete Kissinger Pete Kissinger	Director	March 8, 2016

/s/ Barbara DeBuono Barbara DeBuono 39	Director	March 8, 2016

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