CHEMBIO DIAGNOSTICS, INC.
Form S-3
January 08, 2013

As filed with the U.S. Securities and Exchange Commission on January 8, 2013
Registration No. 333-_____

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

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FORM S-3

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REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

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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)

_____

Lawrence A. Siebert
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.
David M. Allred, Esq.
Patton Boggs LLP
1801 California Street, Suite 4900
Denver, Colorado 80202
(303) 830-1776

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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(l)
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		$4,774

(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.

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 January 8, 2013

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 $33,800,000 on January 4, 2013. 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 [ ], 2013.

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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 ind
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," "int
words or phases of similar meaning. We caution that the forward-looking statements are based largely on our expectations and are subject to a number of known and unknown risks and uncertainties that are subject to change based on factors which are, in many instances, beyond our control. Actual results, performance or achievements could differ materially from those contemplated, expressed, or implied by the forward-looking statements.

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

- the strength of the United States economy in general and the strength of the local economies in which the Company conducts operations;

- geopolitical conditions, including acts or threats of terrorism, actions taken by the United States or other governments in response to acts or threats of terrorism and/or military conflicts, which could impact business and economic conditions in the United States and abroad;

- the effects of, and changes in, trade, monetary and fiscal policies and laws, including interest rate policies of the Board of Governors of the Federal Reserve System, or the Federal Reserve Board; inflation, interest rate, market and monetary fluctuations;

- the timely development of competitive new products and services, and the acceptance of these products and services by new and existing customers;

- the willingness of users to substitute competitors' products and services for our products and services;

- the impact of changes in financial services policies, laws and regulations, including laws, regulations and policies concerning taxes, banking, securities and insurance, and the application thereof by regulatory bodies;

- technological changes;

- the effect of acquisitions we may make, including, without limitation, the failure to achieve the expected revenue growth and/or expense savings from such acquisitions;

- the growth and profitability of non-interest or fee income being less than expected;

- changes in consumer spending and savings habits; and

- unanticipated regulatory or judicial proceedings.

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

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. On May 5, 2004, Chembio Diagnostic Systems Inc. completed a merger through which it became a wholly-owned subsidiary of Chembio Diagnostics, Inc., formerly known as Trading Solutions.com, Inc. As a result of this transaction, the management and business of Chembio Diagnostic Systems Inc. became the management and business of Chembio Diagnostics, Inc. 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 four rapid tests for the detection of HIV antibodies, two rapid tests for the detection of syphilis, and a rapid test for the detection of canine leishmaniasis. Three of the HIV 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 and are exclusively distributed by Alere, Inc. ("Alere") in the United States and by Chembio outside the United States. Our fourth rapid HIV test incorporates our patented Dual Path Platform® (DPP®), and does not require in-licensing. The DPP® HIV test, detects antibodies to HIV 1 & 2 in oral fluid samples as well as in all blood matrices. We received United States FDA regulatory approval for this product on December 19, 2012 and we anticipate launching it under Chembio's brand in 2013.

Our new product pipeline, which currently includes rapid tests for Syphilis and Hepatitis-C, as well as a multiplex test that detects HIV and Syphilis specific antibodies, 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 worldwide. With the DPP® proprietary platform, we can participate in the estimated $8-10 billion point-of-care market segment of the estimated nearly $50 billion global in-vitro diagnostic market that has an overall growth rate of approximately 7% per annum. POCTs, by providing prompt and early diagnosis, can reduce patient stays, lower overall costs, improve therapeutic interventions and improve patient outcomes as a result of prompt and early diagnosis. They 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 for example), the utility of a rapid point–of-care 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.

PRODUCTS

Lateral Flow Rapid HIV Tests

All three of our lateral flow rapid HIV tests are qualitative "yes/no" tests for the detection of antibodies to HIV 1 & 2 with visually interpreted results (one line "negative"; two lines "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 (for example directly 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. We believe that this format may be an ideal candidate as an over-the-counter HIV test and we are participating in certain studies that should help to better ascertain this. 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.

Both of the above-described products are marketed exclusively in the United States by Alere as Clearview® Complete HIV 1/2 (the barrel format) and Clearview® HIV 1/2 STAT PAK® (the cassette format), and by Chembio in all other markets under the names Chembio Sure Check® HIV 1/2 and Chembio HIV 1/2 STAT PAK®. Alere has non-exclusive rights to the barrel product outside the United States.

Our third lateral flow HIV test, 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; an adhesive backing is provided as a more cost-effective and compact "housing" 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 (now Alere' Clearview® HIV 1/2 STAT-PAK in the United States only) products. Waivers under the Clinical Laboratory Improvement Act (hereinafter "CLIA"; see Governmental Regulations) were granted by the FDA for the two FDA- approved products in 2006 and 2007, respectively. The 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. Our HIV 1/2 STAT-PAK Dipstick, though not FDA-approved, qualifies under FDA export regulations to sell to customers outside the United States subject to any required approval by the importing country.

All three of our lateral flow HIV tests have qualified for procurement under the President's Emergency Plan for AIDS Relief ("PEPFAR"). The STAT PAK (both the cassette and dipstick versions) are also 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 Test

As in the case of our lateral flow HIV tests, our DPP® HIV test is also a qualitative "yes/no" test for the detection of antibodies to HIV 1 & 2, delivers visual results within approximately 15 minutes, is simple to use, has a shelf life of 24 months, and does not require refrigeration. Additionally this product, which is our first 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 tested for multiple conditions. Clinical and laboratory studies, which uniquely included test subjects down to two years of age, have shown this product to have improved performance compared with all of the current FDA-approved CLIA-waived rapid tests, even including our own lateral flow tests.

Regulatory Status: In April 2012 we completed a 3,000 patient clinical study with our DPP® HIV test in the United States which we had begun in 2010. In June 2012 we submitted the third of three modules required for a modular PMA application to the FDA. On December 19, 2012 we received FDA approval of our Pre-Marketing Approval. During the first quarter of 2013, we plan to conduct the additional testing necessary in order to complete a CLIA waiver application for this product. We anticipate that we will be able to complete this testing and complete this application in order to launch the product in the third or fourth quarter of 2013.

The 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 June 2010, ANVISA approved the DPP® HIV test that is being marketed in Brazil through our collaboration with the Oswaldo Cruz Foundation, Brazil's leading public health institute. Given the oral fluid feature, we believe this product can be marketed as a premium-priced product that will address those market segments in the U.S. and globally that express a preference for a less invasive testing experience.

OTHER DPP® PRODUCTS

Our product pipeline current includes a multiplex Syphilis Screen & Confirm test, a rapid test for the detection of Hepatitis-C antibodies and antigens, and a multiplex test for the detection of antibodies to HIV and Syphilis. As mentioned below ("Our Rapid Test Technologies"), we also are considering development of so-called "Fourth Generation" tests that are able to detect disease prior to seroconversion to antibodies. This would allow earlier detection of

diseases at an acute stage. We have completed initial feasibility studies with technologies that complement our DPP® technology and that will further enable even lower limits of analyte detection, which is a capability we believe is essential to have in order to develop new products and markets over the long term.

Our strategy with respect to our DPP® technology has evolved as the Company has evolved. Initially, following the issuance of our DPP® patent in the United States in 2007, our strategy was necessarily limited to developing third-party-funded OEM research and development contracts and grants. This strategy enabled us to conserve capital resources, while at the same time acquiring know-how and experience with the platform and developing third party references and implicit endorsements of the technology. As our capabilities to develop and manufacture DPP® products expanded, and as our financial position has improved, so have our strategic options expanded and improved. While we may continue the strategy of seeking OEM development and manufacturing agreements as a way to participate in markets that we cannot and/or choose not to serve, we believe that we can also develop our own branded line of products, and we plan to do this in the public health area. This brand will be launched with our DPP® HIV Screening Assay in the United States market in 2013, to be followed by our Syphilis test and potentially other related products

Following is a discussion of the DPP® products for which we have completed our development activity pursuant to OEM agreements with FIOCRUZ and Bio-Rad Laboratories, Inc. The statuses of products that are still under development are described in Part II Item 7.

PARTNERS INVOLVED IN MARKETING OUR PRODUCTS

On September 29, 2006, we executed marketing and license agreements with Alere. The marketing agreements (one for each of the two FDA-approved products) provide Alere with a 10-year exclusive right (until September 2016) to market our rapid HIV tests in the United States under Alere's brand. The agreements provide Chembio a non-exclusive license to certain Alere lateral flow patents that may be applicable to our lateral flow products, principally including our lateral flow HIV tests that we have continued to market outside the United States. 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). As a result, 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.

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 and Asia, 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 in periods of relatively lower demand, based on the variations associated with this kind of demand.

Our DPP® HIV test was approved by ANVISA in June 2010. This approval was granted to our Brazilian partner, the Oswaldo Cruz Foundation ("FIOCRUZ"), pursuant to one of five technology transfer, supply and license agreements that we entered into with this public health organization in 2008 and 2010. See "OEM DPP® Products," below.

OEM DPP® Products

Oswaldo Cruz Foundation OEM DPP® Agreements

During 2008-2010 we signed five agreements with the Oswaldo Cruz Foundation (FIOCRUZ) in Brazil relating to 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 diagnostic products.

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. As a result, during 2011, we shipped approximately $4.25 million of products to FIOCRUZ pursuant to the agreements, and we expect that number to substantially exceed $9 million for

fiscal year 2012. 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 under agreement with FIOCRUZ are for DPP® products for HIV screening, HIV confirmatory, Leishmaniasis, Leptospirosis and Syphilis. All of the agreements with FIOCRUZ contemplate a technology transfer and license to FIOCRUZ for the manufacture of the subject products over stipulated periods of time. These technology transfers, and the provision by Chembio of the information and training that is required for this to occur, are subject to Chembio receiving orders from FIOCRUZ for a minimum amount of products for manufacture by Chembio, which is approximately $23 million in the aggregate under the five agreements. The actual demand for these products may be more or less than this amount. The actual amount will depend on the actual demand for the products by the specific programs for each product funded by the Brazilian Ministry of Health as well as whether and when FIOCRUZ is able to implement the technology transfer steps including, for example, the readiness of new production facilities currently under construction that are scheduled to be completed in mid-2013; thereafter Chembio may receive royalty payments under some of the agreements for a defined period based on product sold by FIOCRUZ to the public health programs in Brazil.

Bio-Rad Laboratories OEM DPP® Agreement- On April 6, 2008, we entered a milestone-based development agreement with Bio-Rad Laboratories N.A., a division of Bio-Rad Laboratories Inc. (NYSE:BIO), a leading in-vitro diagnostic and life science company. The agreement with Bio-Rad was for the development of a six-band multiplex product on our DPP®. Based on achieving the proof of concept for this product during 2008, in January 2009 we entered a limited exclusive license agreement with Bio-Rad related to the field of use for this application, and we continued the development work during all of 2009 and until Bio-Rad confirmed that the product specifications were met in the second quarter of 2010. In June 2010, Bio-Rad exercised its option to have Chembio transfer the manufacturing of this product to Bio-Rad subject to a royalty payment payable to Chembio pursuant to a license agreement with Bio-Rad based on Bio-Rad's net sales of the licensed product, which process was completed in October 2010. Chembio believes that Bio-Rad is proceeding with the regulatory approvals of this product, with CE Mark likely by the end of 2012 or early 2013, although there can be no assurance of this. We further believe that Bio-Rad has begun discussions with the FDA with respect to this product, its proposed performance claims and the intended clinical protocol to support its regulatory submission.

During 2008 to 2010, Chembio earned approximately $460,000 for product development work rendered to Bio-Rad under this agreement, plus an additional $490,000 in license and other fees related to the manufacturing transfer.

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 and are 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.

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. Also, because of the usage in DPP® of a separately connected sample strip, the control and delivery of sample material is substantially improved. This 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. The HIV confirmatory test we developed for Bio-Rad employs six different markers. We have a contract development program that involved the use of eight bands. Our intellectual property also extends to the use of multiple test membranes that through a common sample strip utilize a single sample. Employing this feature we can develop so-called "Fourth Generation" tests that are able to detect antigens prior to seroconversion to antibodies, as well as antibodies. This would allow earlier detection of diseases at an acute stage, which improves outcomes. We have completed initial feasibility studies with technologies that uniquely complement our DPP® technology and that will

assist in these efforts by enabling even lower limits of analyte detection. This is a capability which we believe is essential to have in order to develop new products and markets over the long term.

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 if samples have to be sent out to a laboratory which can take at least several days to process. However, 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.

There are approximately 53,000 new diagnoses of HIV infection in the United States each year, according to the CDC. In time, most of these infections progress to AIDS. The CDC estimates that approximately 1.1 million individuals in the U.S. are living with HIV, with an estimated 250,000 Americans, or more than 20%, unaware that they are infected. It is these 250,000 infected people that are reported to account for 54% of all new infections per year. 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 from samples that have to be sent out to a laboratory and that can take at least several days to process. Making more people aware of their HIV status at the point-of-care will reduce the number of HIV transmissions.

Rapid HIV testing in the United States has now developed into an estimated 7 million test market. This is from zero in 2003 when Orasure Technologies, Inc. received the first FDA approval for a rapid HIV test. We believe that the US professional HIV rapid test market (not including the OTC market) has the potential to increase to 15-18 million tests over the next several years, which would represent 40-50% of all HIV tests done today in the United States for clinical purposes. Assuming an average price to the manufacturers of $8.00 per test, a total potential U.S. market of nearly $120-$150 million is implied.

In 2006, the outlook for HIV testing was given a big boost with the release by the CDC of new guidelines for HIV testing. These new CDC recommendations 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. Adoption of the 2006 CDC recommendations by a number of states continues to have an increasing impact. Most recently, the United States Preventive Services Task Force ("USPSTF") fully embraced these routine HIV testing recommendations of the CDC's after years of still endorsing the older CDC recommendation of a risk-based approach. This USPSTF policy will mandate insurance coverage under the Affordable Care Act (the "ACA") and we expect this to result in an increase in testing in the United States in the coming years. Currently most public health testing in the United States is funded by grants allocated to high prevalence areas by the CDC, but we believe this will shift to an insurance-funded model under the ACA in the years to come.

In the international market, PEPFAR, the large United States funded international AIDS relief program focused on fifteen countries, was reauthorized in 2008 for up to $48 billion for FY2009-2013 (up from $15 billion in 2004-2008). PEPFAR and the Global Fund are the largest of the global initiatives that have helped to make prevention, care and life-saving treatments available to those that need them. For example, PEPFAR has the goal that by 2013 three million infected individuals will be provided treatment and 12 million new cases will be averted. To achieve these goals, more and more people are likely to get tested. As more effective treatments become available at lower costs, there is a clearer reason to be tested.

The U.S. and international economics crisis of the last few years has impacted the growth in funding of these large programs, though private donations have supplemented the governmental and non-governmental programs. Still, accountability, alleged corruption, and the eligibility of lower quality and lower cost products make these markets

challenging. Regardless of these occurrences, we believe that Chembio has remained, and is increasingly recognized as, a reputable and dependable supplier of high quality products that are available at reasonably competitive prices.

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.

There is also now an over-the-counter market for HIV self-testing and we are well positioned to participate in this market, should we believe the investment is justified. So far one company, Orasure Technologies Inc., received FDA approval for an over-the-counter (self-testing) version of its previously professional-market-approved HIV test. The FDA approval was granted in July 2012, the product was launched in October, and we believe that the results during the first several months of 2013 will be instructive as to how rapidly this market can develop.

Based on the fact that FDA has required any over-the-counter HIV test to have first been approved for the professional market, we believe that Chembio is the only other company that can participate in this market opportunity if it chooses to. Although there is a third company, Trinity Biotech, that meets that condition, they have stated that they do not intend to pursue this market. Therefore Chembio is carefully monitoring developments in this market, which may be significant during 2013. Currently we could initiate the over-the-counter approval process with either of our two blood tests. And we have nearly completed a preliminary self-study for one of those products as the final component to our submitting an Investigational Device Exemption ("IDE") application to the FDA during the first quarter of 2013. Provided we submit this application and it is granted, that would enable us to begin clinical trials by the time we gather better information as to how the Orasure product is doing in the market. And now that we have received approval of our pre-marketing application for our DPP® oral fluid HIV test, we could additionally, or alternatively, pursue over-the-counter approval for that product once we receive the CLIA waiver grant for that product. We believe that we are well advised to wait before commencing these clinical trials because (1) 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; (2) Orasure's first six months results will be known relatively soon; and (3) we are well positioned versus any other competitors.

Rapid Syphilis Tests

Recent data indicate that approximately 70,000-100,000 new cases of syphilis are occurring annually in the U.S. Syphilis can be treated with antibiotics, but untreated it can cause pelvic inflammatory disease, infertility, ectopic pregnancy and can infect newborns. Treatment cannot be provided without a confirmed diagnosis of an active case of syphilis. Current testing algorithms in the United States require two different tests (called non-treponemal and treponemal markers), each requiring trained personnel in laboratory settings and several days to receive back results, in order to confirm an active, previously untreated case. The screening test still employed in the United States is known as RPR; it utilizes an old technology that has a high degree of false positive results.

Development of the POC market for syphilis testing is expected to be comparable to the development of the POC market for HIV testing, as there is a significant public health value to being able to provide results at the point-of-care. There are several ways to assess the market opportunity for this unique rapid test, although we believe the U.S. rapid test market opportunity may exceed 8 million tests, which is approximately 20% of the total number of syphilis tests performed in the United States for clinical use today. Unlike HIV testing, where a positive result first requires a confirmatory test, and then further tests to measure viral load before expensive treatment decisions are made, an individual with a confirmed active case of syphilis can be prescribed antibiotics immediately.

Marketing Strategy

Our marketing strategy is to:

- Support, review and assess the marketing and distribution efforts of our rapid HIV tests by Alere. Alere, which is a leading marketer of point-of-care diagnostic products, has significantly expanded its distribution footprint since we signed our agreement with them, and although we believe that this will enhance opportunities for Alere to market our rapid HIV tests, the product line is a very small one for them, notwithstanding the strong growth they have enjoyed with respect to our products.

- Leverage our DPP® intellectual property and regulated 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 long-term creation of shareholder value.

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 dual path platform® technology, particularly for the development and manufacture of tests for the detection of antibodies to infectious diseases such as HIV, are very strong.

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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 Dual Path Platform® (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 Dual Path Platform® (DPP®) 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.

Research and Development

During 2011 and 2010, $4.9 million and $4.1 million ($2.6 million, net of Qualified Therapeutic Discovery Project ("QTDP") grants), respectively, were spent on research and development (including regulatory activities). These expenses were in part underwritten by funding from R&D and milestones revenues of $1.8 million in 2011 and $2.8 million in 2010. All of our new product development activities involve employment of our Dual Path Platform® (DPP®) technology. These activities include completing development of certain products and making significant progress toward the development of additional products.

Employees

At September 30, 2012, we employed 172 people. We have entered into employment contracts with our President, Lawrence Siebert, and our Senior Vice President of Research and Development, Javan Esfandiari. Due to the specific knowledge and experience of these executives regarding the industry, technology and market, the loss of the services of either one of them would likely have a material adverse effect on the Company. The contract with Mr. Siebert provides that Mr. Siebert will serve as the Chief Executive Officer and President of the Company through May 11, 2013. The contract with Mr. Esfandiari has a term of three years ending March 2013. We have obtained a key man insurance policy for Mr. Esfandiari.

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 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 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 rapid HIV tests now marketed by Alere Medical as Clearview® Complete HIV 1/2 and Clearview® HIV 1/2 STAT PAK®. 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. Given the low prevalence of HIV, the FDA will require 30 new HIV cases to be identified, supplemented by additional data and this is the study the Company will perform during 2013.

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.

One or more of the Company's rapid HIV tests are also approved or pending approval for marketing in several foreign jurisdictions, including but not limited to Brazil, Mexico, and a number of other nations in the developing world.

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 Dual Path Platform® 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 three U.S. patents, and patents in China, Malaysia, Eurasia, Mexico, Singapore, Japan and the U.K. Additional patent applications on the DPP® product line are pending in the U.S., as well as in many foreign countries such as Australia, Brazil, Canada, the European Union, India, Indonesia, Israel, Korea, and South Africa. Patents have also been filed on extensions to the DPP® product line concept such as 4th generation assays.

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®. The DPP® trademark is also registered under the European convention (ECT).

Trade Secrets and Know-How

We believe that we have developed a substantial body of trade secrets and know-how relating to the development 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 our agreements in 2006 with Alere for the marketing of our HIV tests, we were granted non-exclusive licenses to certain lateral flow technology for certain products manufactured and marketed by Chembio including but not limited to our HIV tests. 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 will expire within the next couple of years 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 patents 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.

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

If we are not able to obtain or maintain the necessary regulatory approvals for our laboratories, our manufacturing facilities or some of our products, we may not be able to generate revenues in the amounts necessary to sustain, continue or grow our business.

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 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. 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. Our principal competitors often 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 Medical and Trinity Biotech. As new products enter the market, our products may become obsolete or a competitor's products may be more effective or more effectively marketed and sold than ours.

We have granted Alere exclusive rights to market our SURE CHECK® HIV 1/2 in the United States and non-exclusive rights in the rest of the world and exclusive rights to market our HIV 1/2 STAT PAK® in the U.S. only. Alere has no rapid HIV tests that are approved for marketing in the U.S. and Alere is obligated to inform us of any such products within certain time frames. We believe that Alere is committed to successfully marketing our products in the U.S. Alere may however choose to develop or acquire competing products for marketing in the U.S. and such an action could have at least a temporary material adverse effect on the marketing of these products until such time as alternative marketing arrangements could be implemented. In particular Alere manufactures and markets a rapid HIV test product called Determine® that, with its 3rd generation test, is the leading product used in the developing world. The Determine HIV test product line, which was until 2006 a division of Abbott Diagnostics in Japan that was then sold to Alere, has had at least a few versions, the newest of which is the so called "4th Generation" Determine test which, according to its claims, detects HIV antibodies and HIV antigen. The claim of such a 4th generation product is that it detects infection earlier than tests that solely rely on antibody detection, which required immune response before detection can occur. Alere has made statements that it is or will be seeking FDA approval of this product which, if approval is granted, could potentially be a competitive product to the Chembio products that Alere markets as Clearview® Complete (barrel) and Clearview HIV ½ STAT PAK® (cassette). Under our agreements, Alere is in fact expressly permitted to "exploit" such a product in the United States without breaching the agreement, though there are defined consequences in such case: for the cassette product, Chembio may either terminate Alere or make the agreement with Alere non-exclusive, and for the barrel product, Chembio and StatSure Diagnostics (the other party to the Alere 3-way agreement pertaining to the barrel product) can jointly agree to either continue the agreement with Alere or to also make the barrel agreement non-exclusive. As part of any decision by Chembio to market either product, Alere would expand the lateral flow license granted to allow Chembio to market the product under Chembio brands.

Although we have no specific knowledge of any other competitor's product 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.

We have developed an oral fluid rapid HIV test as well as other applications utilizing our Dual Path Platform® technology, which we believe will enhance our competitive position in HIV rapid testing and other fields. During 2011 we made significant progress toward the commercialization of this product. However we still have technical, manufacturing, regulatory and marketing challenges to meet before we will know whether we can successfully commercialize products incorporating this technology. There can be no assurance that we will overcome these challenges.

We plan to introduce our DPP® oral fluid HIV test, which test also can be used with blood samples, in the U.S. market under a Chembio brand once it is FDA approved, currently anticipated in 2013, but for which there can be no assurance. Under our 2006 Agreement with Alere, Alere has a right of first negotiation for the right to market any new rapid HIV antibody detection test that we develop. In accordance with this provision in our agreement, we presented this product to Alere in 2007, and in 2007 Alere waived its right of first negotiation under the agreement. While such waiver does not prevent Alere from reconsidering the marketing of this product, we have no reason to believe that they will. Also, although we believe that the primary market opportunity for the DPP® HIV product is for those customers that have a clear preference for an oral fluid HIV test, the product is also likely to compete to some extent with our FDA-approved rapid HIV tests being marketed by Alere. Therefore this could have a material and adverse effect on our business with Alere.

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, we own no issued patents covering lateral flow technology, and the field of lateral flow technology is complex and characterized by a substantial amount of litigation, so the risk of potential patent challenges is ongoing for us in spite of our DPP® patent. Moreover, we believe that certain lateral flow patents are going to expire in the next couple of years which may materially impact the competitive landscape.

Although we have been granted non-exclusive licenses to the lateral flow patents owned by Alere, there is no assurance that its lateral flow patents will not be challenged or that licenses from other parties may not be required, if available at all. In addition, certain of the Alere patents will expire in the next couple of years which expiration could open the market to certain competitors. In the event that it is determined that a license is required and it is not possible to negotiate a license agreement under a necessary patent, we may be able to modify our HIV rapid test products and other products such that a license would not be necessary. However, there is no assurance that we would be able to do so, and even if accomplished, this alternative could delay or limit our ability to sell these products in the U.S. and other markets, which would adversely affect our results of operations, cash flows and business.

On March 13, 2007, our Dual Path Platform® Immunoassay Device patent application was issued as United States patent no. 7,189,522. Additional protection for this intellectual property is pending in a number of other countries. This platform has shown improved sensitivity as compared with conventional platforms in a number of studies. We believe that this new platform is outside of the scope of currently issued patents in the field of lateral flow technology, thereby offering the possibility of a 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.

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 or our contract partners, sales agents, 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. If we are not able to raise capital or borrow funds on attractive terms and/or in amounts necessary to continue our business, our business may not be able to develop, manufacture, obtain regulatory approval or sell our products in the manner and according to the timetable that is desirable for the Company.

Our revenues and gross margins have increased significantly in recent periods, and we have been profitable for three consecutive years. Nevertheless, prior to 2009 we sustained significant operating losses since 2004. At December 31, 2011, we had a stockholders' equity of $12.5 million and a working capital surplus of $6.1 million. The Company's 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) the Company's investments in research

and development, facilities, marketing, regulatory approvals, and other investments it may determine to make; and (4) the Company's investment in capital equipment and the extent to which it improves cash flow through operating efficiencies. There are no assurances that the Company will remain profitable or generate positive cash flow in 2013 or, in the alternative, be successful in raising sufficient capital to fund its needs through 2013 and thereafter.

Continued revenues from Alere from the U.S. rapid HIV test market and increased sales to developing world markets are critical for us to continue to maintain and increase our profitability while funding our new product regulatory approval and commercialization programs. If we fail to meet any of these objectives, our lower cash flow, profitability and research and development will have a material negative effect on our business and on our ability to meet our operating expenses and other costs, amounts necessary to maintain and increase our profitability and/or to fund our planned research, development, regulatory, selling, general and administrative expenses in 2012.

We intend to attempt to increase international sales of our products, despite the fact that our current contracts in Brazil provide for a decline in revenue over the next few years. A number of factors can slow or prevent international sales, or substantially increase the cost of international sales, including:

- 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
- economic conditions and the absence of available funding sources.

If we are unable to increase our revenues from international sales, 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. If these policies were violated, our business and our Company could be materially and negatively affected.

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 (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, those programs that our products are or may be deployed in are all funded by the Brazilian Ministry of Health. Although FIOCRUZ is affiliated with the Brazilian Ministry of Health, it is not its exclusive supplier. However because each of our 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.

If our patents and licenses, together with trade secret laws and agreements with our key employees and other third parties, are not adhered to or otherwise are not adequate to protect our proprietary rights, then our business will be increasingly damaged by competitors.

We believe that factors such as the technological and creative skills of our personnel, strategic relationships, new product developments, frequent product enhancements and name recognition are essential to our success. All our management and technological 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 efforts we make to protect our confidential information, such as entering 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.

Failure to retain our current key employees and to attract additional qualified personnel could adversely affect our ability to create, develop, manufacture, sell and/or market our products.

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 for new or advanced products. 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 and President, Lawrence Siebert, and our Senior Vice President of Research and Development, Javan Esfandiari. Due to the specific knowledge and experience of these executives regarding the industry, technology and market, the loss of the services of either one of them would likely have a material adverse effect on the Company. The contract with Mr. Siebert provides that Mr. Siebert will serve as the Chief Executive Officer and President of the Company through May 11, 2013. The contract with Mr. Esfandiari has a term of three years ending March 2013. We have obtained a key man insurance policy for Mr. Esfandiari.

We may not be able to participate in large testing programs in the U.S. and worldwide, and failure to do so may inhibit our future growth and success.

We believe it to be in our best interests to meaningfully participate in large testing programs. Participation in these programs 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.

Although we were profitable in 2009, 2010, 2011, and the first nine months of 2012, we cannot be certain that we will be able to sustain profitability in the future; the lack of profitability could have a negative impact on our stock price and our costs of obtaining financing.

From the inception of Chembio Diagnostic Systems, Inc. in 1985 through the period ended December 31, 2008, we incurred net losses and we have only become profitable during the last three years. While we anticipate growth in our product revenues in 2012 as compared with 2011, there can be no assurance of this. Moreover in 2012 we expect to make substantial expenditures for regulatory submissions, product development and other purposes which may impact profitability. Our ability to continue profitability in the future will primarily depend on our ability to increase sales of our products, 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 usage. We have obtained product liability insurance 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 would 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

In the past, our Common Stock has been illiquid, resulting in a risk that investors may not be able to sell as much stock as they want at prevailing market prices.

In the past, trading in our Common Stock has been illiquid. In early July 2012, our common stock began trading on NASDAQ, and the volume has increased. Nevertheless, even at current levels, the market for our common stock is not highly liquid, and there is no assurance that the trading volume will be sufficient to result in a liquid trading market. Without a sufficient liquid trading market, stockholders may not be able to sell as much stock as they desire at a given time without incurring a significant decrease in the market value of the stock.

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

As of March 6, 2012, our named executive officers, directors and 5% stockholders beneficially owned approximately 24.3% of our voting power. For the foreseeable future, 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 be different 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 50,000,000 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.

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.

We have adopted a Shareholder Rights Agreement, which under certain circumstances would significantly impair the ability of third parties to acquire control of us without prior approval of our Board of Directors thereby discouraging unsolicited takeover proposals. The preferred stock issued under the Shareholder Rights Agreement would cause substantial dilution to a person or group that attempts to acquire us on terms not approved in advance by our Board of Directors. No shares of preferred stock are currently outstanding. Each series of preferred stock will be issued under a Certificate of Designation, which will be filed with the SEC as an exhibit to a document incorporated by reference in this prospectus concurrently with the offering of such preferred stock. It is also subject to our Articles of Incorporation, as amended, which is incorporated by reference as an exhibit to this registration statement.

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

Patton Boggs LLP, Washington, D.C., will pass upon certain legal matters with respect to the securities offered by us from time to time pursuant to this prospectus, unless we indicate otherwise in a prospectus supplement. Attorneys in

that firm own approximately 29,497 shares of our 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 incorporated in this prospectus by reference from Chembio Diagnostics, Inc.'s Annual Report on Form 10-K for the period ended December 31, 2011 have been audited by BDO USA, LLP, independent registered public accounting firm, and for the year ended December 31, 2010 have been audited by ParenteBeard LLC, independent registered public accounting firm, as stated in their respective reports, which are incorporated herein by reference, and have been so incorporated in reliance upon such reports of such firms given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

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

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

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

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

(a) Our Annual Report on Form 10-K for the year ended December 31, 2011, filed on March 8, 2012.

(b) Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, filed on May 8, 2012; our Quarterly Report on Form 10-Q for the quarter ended June 30, 2012, filed on August 9, 2012; and our Quarterly Report on Form 10-Q, including Amendment No. 1 thereto, for the quarter ended September 30, 2012, both filed on November 13, 2012.

(c) Our Current Reports on Form 8-K filed on January 6, 2012, January 9, 2012, February 22, 2012, March 1, 2012, March 8, 2012, April 18, 2012, April 24, 2012, April 30, 2012, May 8, 2012, May 21, 2012, May 25, 2012, May 29, 2012, June 11, 2012, June 19, 2012, July 18, 2012, July 26, 2012, August 9, 2012, August 14, 2012, August 23, 2012, September 21, 2012, September 27, 2012, November 1, 2012, November 13, 2012, November 28, 2012, November 30, 2012, December 5, 2012, December 11, 2012, December 18, 2012, and December 27, 2012.

(d) Portions of our Proxy Statement for the Annual Meeting of Stockholders, held on September 19, 2012, that have been incorporated by reference in our 2012 Annual Report on Form 10-K.

(e) 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	$4,774
Legal fees and expenses	19,000
Accounting fees and expenses	16,000
Other	226
Total	$40,000

* 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 Patton Boggs LLP
8.0	Opinion as to certain federal income tax matters*
23.1	Consent of BDO USA, LLP
23.2	Consent of ParenteBeard LLC
23.3	Consent of Patton Boggs 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 January 8, 2013.

CHEMBIO DIAGNOSTICS, INC.

By: /s/ Lawrence A. Siebert
Lawrence A. Siebert
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 Lawrence A. Siebert 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/ Lawrence A. Siebert Lawrence A. Siebert	Chief Executive Officer, President and Chairman of the Board (principal executive officer)	January 8, 2013
/s/ Richard J. Larkin Richard J. Larkin	Chief Financial Officer (principal financial officer & accounting officer)	January 8, 2013
Dr. Gary Meller	Director	
/s/ Katherine L. Davis Katherine L. Davis	Director	January 8, 2013
/s/ Peter T. Kissinger Peter T. Kissinger	Director	January 8, 2013
/s/ Barbara DeBuono Barbara DeBuono	Director	January 8, 2013

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*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.