

CHEMBIO DIAGNOSTICS, INC.
Form S-8
April 24, 2015
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-8
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Chembio Diagnostics, Inc.
(Exact Name of Registrant as Specified in its Charter)

Nevada 88-0425691
(State or Other Jurisdiction of (I.R.S. Employer
Incorporation or Organization) Identification Number)

3661 Horseblock Road
Medford, New York 11763
(631) 924-1135
(Address of Principal Executive Office, including zip code)

Chembio Diagnostics, Inc. 2014 Stock Incentive Plan

Employment Agreement by and between Chembio Diagnostics, Inc. and
John Sperzel effective March 13, 2014
(Full Name of Plans)

Richard J. Larkin
Chembio Diagnostics, Inc.
Chief Financial Officer
3661 Horseblock Road
Medford, New York 11763
(631) 924-1135
(Name, address, including zip code, and telephone number, including area code, of Agent for Service)

Copy to:
Alan Talesnick, Esq.
Haynes and Boone, LLP
1580 Lincoln Street, Suite 1280
Denver, Colorado 80203
(303) 893-2005

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.

Large accelerated filer Accelerated
filer
Non-accelerated filer Smaller reporting
company

(Do not check if a smaller reporting company)

CALCULATION OF REGISTRATION FEE

| Title of Securities To be Registered | Amount to be Registered ⁽³⁾ | Proposed Maximum Offering Price Per share ⁽⁴⁾ | Proposed Maximum Aggregate Offering Price ⁽⁴⁾⁽⁵⁾ | Amount of Registration Fee |
|--|--|--|---|----------------------------|
| Common stock, par value \$0.01 per share | 800,000 ⁽¹⁾ | \$ 4.41 | 3,528,000 | \$ 409.95 |
| Common stock, par value \$0.01 per share | 206,868 ⁽²⁾ | \$ 4.41 | \$912,288 | \$ 106.01 |
| Total | 1,006,868 | \$ 4.41 | \$4,440,288 | \$ 515.96 |

⁽¹⁾ Covers 800,000 shares of the registrant's (the "Registrant's") common stock, par value \$0.01 per share (the "Common Stock"), approved for issuance under the Chembio Diagnostics, Inc. 2014 Stock Incentive Plan.

⁽²⁾ Covers 206,868 shares of the Registrant's Common Stock approved for issuance pursuant to the exercise of options under the Employment Agreement by and between the Company and John Sperzel effective as of March 13, 2014 and, pursuant to Rule 416 under the Securities Act.

⁽³⁾ Pursuant to Rule 416 under the Securities Act of 1933, we also are registering an indeterminable number of shares of common stock that may be issued in connection with stock splits, stock dividends, recapitalizations or other similar transactions effected without consideration.

⁽⁴⁾ Solely for the purpose of calculating the registration fee, the offering price per share and the aggregate offering price have been calculated pursuant to Rules 457(c) and 457(h) of the Securities Act based on the average high and low sales price of the Common Stock as reported on the NASDAQ on April 9, 2015 which is a date within five business date of the date that this Registration Statement was filed.

⁽⁵⁾ Estimated solely for the purpose of determining the registration fee in accordance with Rule 457(h).

EXPLANATORY NOTE

Chembio Diagnostics, Inc. (the "Company" or "Chembio") is registering under this Registration Statement on Form S-8 (the "Registration Statement") (i) 800,000 shares of its common stock, par value \$0.01 per share (the "Common Stock") that are issuable pursuant to the Chembio Diagnostics, Inc. 2014 Stock Incentive Plan (the "Plan"), which was approved by the Company's stockholders on June 19, 2014, and (ii) 206,868 shares of its Common Stock that are issuable upon the exercise of stock options granted pursuant to the Employment Agreement by and between the Company and John Sperzel effective as of March 13, 2014 (the "Employment Agreement"). The shares issuable pursuant to the Plan consist of (i) 129,750 shares issuable upon the exercise of options that have been granted pursuant to the Plan; and (ii) 670,250 other shares available to be issued under the Plan.

This Registration Statement also includes a prospectus (the "Prospectus") prepared in accordance with General Instruction C of Form S-8 and in accordance with the requirements of Part I of Form S-3, prepared in accordance with Part I of Form S-3, in accordance with General Instruction C of Form S-8 (the "Prospectus"). The Prospectus permits reoffers and resales of those shares referred to above that may be deemed to be "restricted securities" or "control securities", under the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder (the "Securities Act"). These are shares that were or may be acquired by our officers, directors, and affiliates, or that were acquired by our employees or consultants, under an employee benefit plan. To the extent, at this time, they hold restricted or control securities covered by the Registration Statement, such officers, directors, affiliates, employees, and consultants are the selling stockholders identified in the Prospectus.

PART I

INFORMATION REQUIRED IN THE SECTION 10(a) PROSPECTUS

The documents containing the information specified in Part I of this Registration Statement will be sent or given to our employees, officers and directors, as specified by Rule 428(b)(1) under the Securities Act. Those documents do not need to be filed with the Securities and Exchange Commission (the "Commission") either as part of this Registration Statement or as prospectuses or prospectus supplements pursuant to Rule 424 under the Securities Act. These documents and the documents incorporated by reference in this Registration Statement pursuant to Item 3 of Part II of this Registration Statement, taken together, constitute a prospectus that meets the requirement of Section 10(a) of the Securities Act. The Company will provide without charge to any person, upon written or oral request of such person, a copy of each document incorporated by reference in Item 3 of Part II of this Registration Statement, other than exhibits to such documents that are not specifically incorporated by reference, the other documents required to be delivered to eligible employees pursuant to Rule 428(b) under the Securities Act and additional information about the Plan. Requests should be directed to the Company's Secretary at 3661 Horseblock Road, Medford, New York 11763.

REOFFER PROSPECTUS

CHEMBIO DIAGNOSTICS, INC.

800,000 SHARES OF COMMON STOCK

Acquired or to be Acquired by the Selling Stockholders Under the 2014 Stock Incentive Plan

206,868 SHARES OF COMMON STOCK

Acquired or to be Acquired by John Sperzel Under the Employment Agreement by and between the Company and John Sperzel Effective as of March 13, 2014

This reoffer prospectus (this "Prospectus") relates to (i) 800,000 shares of common stock, par value \$0.01 per share (the "Common Stock"), of Chembio Diagnostics, Inc., a Nevada corporation (the "Company"), consisting of 129,750 shares issuable upon exercise of currently outstanding options, and 670,250 shares issuable under the terms of the Chembio Diagnostics, Inc. 2014 Stock Incentive Plan (the "Plan") either as restricted shares or as shares issuable upon the exercise of options granted under the Plan; and (ii) 206,868 shares of Common Stock issuable upon the exercise of currently outstanding options granted to John Sperzel ("Sperzel") pursuant to the Employment Agreement by and between the Company and Sperzel effective as of March 13, 2014 (the "Employment Agreement"). The term "Selling Stockholders" will be used in this Prospectus to refer collectively to Sperzel and to any (other officers, directors and affiliates of the Company, together with any) other persons, who sell shares pursuant to this Prospectus.

This Prospectus covers the offering for resale of shares to be acquired by the Selling Stockholders upon the exercise of currently outstanding options and shares covered by this Prospectus and that are acquired by Selling Stockholders after the filing of this Registration Statement on Form S-8 of which this Prospectus is a part.

Shares acquired pursuant to the Plan or pursuant to the Employment Agreement prior to the effective date of this Registration Statement are "restricted securities" pursuant to Rule 144, regardless of whether held by affiliates of the Company. This Prospectus has been prepared for the purpose of registering the sale of these restricted securities under the Securities Act to allow for future sales by the Selling Stockholders, on a continuous or delayed basis, to the public without restriction. The Selling Stockholders may offer these shares for resale from time to time.

The Selling Stockholders may sell the shares covered by this Prospectus through various means, including directly or indirectly to purchasers, in one or more transactions on any stock market on which the shares are traded at the time of sale, in privately negotiated transactions, or through a combination of these methods. Each Selling Stockholder that sells any shares pursuant to this Prospectus may be deemed to be an "underwriter" within the meaning of the Securities Act of 1933, as amended (the "Securities Act"). Any commissions received by a broker or dealer in connection with resales of shares may be deemed to be underwriting commissions or discounts under the Securities Act. For additional information on the Selling Stockholders' possible methods of sale, please refer to the section in this Prospectus entitled "Plan of Distribution."

The Company will not receive any proceeds from the sale of the shares being offered by any Selling Stockholder. The Company will pay all of the expenses associated with this Prospectus. Brokerage commissions and similar selling expenses, if any, attributable to the offer or sale of the shares will be borne by each respective Selling Stockholder.

The Company's Common Stock is quoted on the NASDAQ under the symbol "CEMI." On April 9, 2015, the closing bid price of our Common Stock on the NASDAQ was \$4.05 per share.

This investment involves a high degree of risk. Please see "Risk Factors" beginning on page 3 of this Prospectus.

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

The date of this Prospectus is April 24, 2015.

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You may only rely on the information incorporated by reference or provided in this Prospectus or any supplement. The Company has not authorized anyone else to provide different information. The Common Stock is not being offered in any state where the offer is not permitted. Do not assume that the information in this Prospectus or any supplement is accurate as of any date other than the date on the front of this Prospectus.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

The Company, a Nevada corporation, is subject to the information requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and, in accordance therewith, files reports, proxy statements and other information with the Securities and Exchange Commission (the "Commission"). The reports, proxy statements and other information filed by the Company with the Commission can be inspected and copied at the Public Reference Room of the Commission at 100 F Street, N.E., Washington, D.C. 20549. Copies of such material also may be obtained by mail from the Public Reference Room of the Commission, 100 F Street, N.E., Washington, D.C. 20549, at prescribed rates. Information regarding the operation of the Public Reference Room may be obtained by calling the Commission at 1-800-SEC-0330. Additionally, the Commission maintains an Internet site that contains reports, proxy and information statements and other information regarding registrants that file electronically with the Commission and that is located at <http://www.sec.gov>.

This Prospectus constitutes part of the Registration Statement filed on the date hereof by the Company with the Commission under the Securities Act. This Prospectus does not contain all of the information set forth in the Registration Statement, certain parts of which are omitted in accordance with the rules and regulations of the Commission. For further information with respect to the Company and the Common Stock, reference is hereby made to the Registration Statement. Statements contained herein concerning the provisions of any contract, agreement or other document are not necessarily complete, and in each instance reference is made to the copy of such contract, agreement or other document filed as an exhibit to the Registration Statement or otherwise filed with the Commission. Each such statement is qualified in its entirety by such reference. Copies of the Registration Statement together with exhibits may be inspected at the offices of the Commission as indicated above without charge, and copies thereof may be obtained therefrom upon payment of a prescribed fee.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Prospectus contains forward-looking statements that may be affected by matters outside our control that could cause materially different results.

Some of the information in this Prospectus contains forward-looking statements within the meaning of Section 21E of the Exchange Act and Section 27A of the Securities Act of 1933, as amended (the "Securities Act"). Any statements contained in this report that are not statements of historical fact may be forward-looking statements. These statements express, or are based on, our expectations about future events. Forward-looking statements give our current expectations or forecasts of future events. Forward-looking statements generally can be identified by the use of forward-looking terminology, such as, use the words "intends," "estimates," "predicts," "potential," "continues," "anticipates," "plans," "expects," "believes," "should," "could," "may," "will" or the negative of these terms or other comparable terminology. They include statements regarding our:

- financial position;
- business strategy;
- budgets;
- amount, nature and timing of capital expenditures;
- acquisition risks;
- operating costs and other expenses; and
- cash flow and anticipated liquidity.

Although we believe the expectations and forecasts reflected in these and other forward-looking statements are reasonable, we can give no assurance they will prove to have been correct. They can be affected by inaccurate assumptions or by known or unknown risks and uncertainties. Factors that could cause actual results to differ materially from expected results are described under "Risk Factors" and include:

- general economic conditions;
- currency exchange volatility;
- the risks associated with acquiring and integrating new businesses;
- our ability to generate sufficient cash flows to operate;
- availability of capital;
- the strength and financial resources of our competitors;
- regulatory risks and developments;
- our ability to find and retain skilled personnel; and
- the lack of liquidity of our Common Stock.

Any of the factors listed above and other factors contained in this Prospectus could cause our actual results to differ materially from the results implied by these or any other forward-looking statements made by us or on our behalf. We cannot assure you that our future results will meet our expectations.

When you consider these forward-looking statements, you should keep in mind these risk factors and the other cautionary statements in this Prospectus. Our forward-looking statements speak only as of the date made.

SUMMARY

The following summary is qualified in its entirety by the more detailed information and the financial statements and notes thereto appearing elsewhere in, or incorporated by reference into, this Prospectus. Consequently, this summary does not contain all of the information that you should consider before investing in our Common Stock. You should carefully read the entire Prospectus, including the "Risk Factors" section, and the documents and information incorporated by reference into this Prospectus before making an investment decision.

This Prospectus relates to (i) 800,000 shares of the Common Stock that are issuable pursuant to the Plan, consisting of 129,750 shares issuable upon exercise of currently outstanding options, and 670,250 shares available for issuance under the terms of the Plan; and (ii) 206,868 shares issuable upon exercise of currently outstanding options granted to John Sperzel pursuant to the Employment Agreement. The 1,006,868 shares covered by this Prospectus (the "Covered Shares") may be offered and sold from time to time by the persons acquiring those shares pursuant to the Plan or the Employment Agreement, respectively. Those persons, including both John Sperzel and the persons receiving shares under the Plan, are referred to as "Selling Stockholders" in this Prospectus. The Selling Stockholders will offer the Covered Shares for sale at prevailing market prices on the NASDAQ on the date of such sale. The Company will not receive any proceeds from these sales. The Company is paying the expenses incurred in registering the Covered Shares, but all selling and other expenses incurred by any of the Selling Stockholders will be borne by such Selling Stockholder.

Chembio Diagnostics, Inc.

Our Corporate Information

Chembio Diagnostic Systems Inc. was formed in 1985. Since our 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 the Company, 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 the Company.

On May 30, 2012, Chembio effected a 1-for-8 reverse split of its common stock, and on June 7, 2012 the Company's common stock, which had been traded on the OTCQB market, began trading on the NASDAQ Stock Market. As a result of the stock split, the outstanding 63,967,263 common shares were reduced to 7,995,918 outstanding common shares on May 30, 2012. The effect of the reverse stock split has been retroactively reflected for all periods in the Company's financial statements.

Chembio's 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

We develop, manufacture, market and license rapid point-of-care diagnostic tests ("POCTs") that detect infectious diseases. Our main products presently commercially available are rapid tests for the detection of HIV 1/2 antibodies, and a multiplex rapid test for the detection of HIV and Syphilis antibodies. The HIV 1/2 rapid tests employ in-licensed lateral flow technologies, can be used with all blood matrices as samples, and are manufactured in a standard cassette format, a dipstick format, and a proprietary barrel format. The tests employing the cassette and proprietary barrel formats were approved by the FDA in 2006.

The barrel format is exclusively distributed by a distributor in the United States and by Chembio and its designated distributors outside the United States. The Cassette format is distributed by Chembio and its designated distributors worldwide. Our latest generation HIV 1/2 rapid antibody detection test incorporates our patented Dual Path Platform[®] (DPP[®] POCT technology, and this POCT platform does not require in-licensing. The DPP[®] HIV 1/2 Assay detects antibodies to HIV 1 & 2 in oral fluid samples as well as in all blood matrices. We have sold this product in Brazil since 2009 where it was approved by ANVISA, through our agreement with the Oswaldo Cruz Foundation ("FIOCRUZ"), and we received United States FDA regulatory approval for this product in December 2012 and CLIA waiver in October 2014. We launched it in the United States under Chembio's brand in the fourth quarter of 2014. Our product pipeline, which currently includes a multiplex rapid test for earlier detection of HIV by detecting P-24 antigen as well as antibodies, a test for Hepatitis-C, and a multiplex test that detects HIV and Syphilis specific antibodies (which we are already selling internationally), is based on this DPP[®] technology for which we were issued a United States patent in 2007 and for which additional patent protection has been issued or is pending in a number of other countries. With the patented DPP[®] and the lateral flow platform, we participate in the estimated \$8 billion point-of-care market segment of the estimated nearly \$50 billion global in-vitro diagnostic market that has an overall growth rate exceeding 3% per annum. POCTs, by providing prompt and early diagnosis, can reduce patient stays, lower overall costs, improve therapeutic interventions and improve patient outcomes. POCTs also can 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 disease (such as HIV and syphilis), the utility of a rapid point-of-care (POC) test, particularly in identifying patients unaware of their disease status, has been well established. Large and growing markets have been established for these kinds of tests, initially in high prevalence regions where they are indispensable for large scale prevention and treatment programs. More recently introduced in the United States in 2004, rapid HIV tests now also present a significant segment of the U.S. market for HIV clinical testing, which is still dominated by laboratory tests. We have focused our product development activity within areas where the availability of rapid, point-of-care screening diagnostic, or confirmatory results can improve health outcomes. More generally we believe there is and will continue to be a growing demand for diagnostic products that can provide accurate, actionable diagnostic information in a rapid, cost-effective manner at the point of care.

RISK FACTORS

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

Risks related to our industry, business and strategy

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

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

The time taken to obtain approval or clearance varies depending on the nature of the application and may result in the passage of a significant period of time from the date of submission of the application. Delays in the approval or clearance processes increase the risk that we will not succeed in introducing or selling the subject products, and we may determine to devote our resources to different products.

Changes in government regulations could increase our costs and could require us to undergo additional trials or procedures, or could make it impractical or impossible for us to market our products for certain uses, in certain markets, or at all.

Changes in government regulations may adversely affect our financial condition and results of operations because we may have to incur additional expenses if we are required to change or implement new testing, manufacturing and control procedures. If we are required to devote resources to develop such new procedures, we may not have sufficient resources to devote to research and development, marketing, or other activities that are critical to our business.

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

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

The diagnostic industry is focused on the testing of biological specimens in a laboratory or at the point-of-care and is highly competitive and rapidly changing. Some of our principal competitors may have considerably greater financial, technical and marketing resources than we do. Several companies produce diagnostic tests that compete directly with our testing product line, including but not limited to, Orasure Technologies, Alere and Trinity Biotech. Furthermore these and/or other companies have or may have products incorporating molecular and/or other advanced technologies that over time could directly compete with our testing product line. As new products incorporating new technologies enter the market, our products may become obsolete or a competitor's products may be more effective or more effectively marketed and sold.

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

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

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

The initial "4th generation" Alere Determine® rapid test product that was also CE marked and that Alere launched internationally some years ago has not been successfully commercialized to the best of our knowledge and at least certain published studies were not favorable for this product. However the 4th generation product that is now FDA-approved was apparently modified as compared to the initial international version, and it may perform more satisfactorily. Alere received FDA approval of this modified product in August 2013 and is seeking CLIA waiver for it. Alere is also aggressively pursuing development of the market for this product in anticipation of receiving CLIA waiver. Although the product can now be sold to moderate complexity certified laboratories, there is very limited supply of the product thus far, and there is no assessment thus far concerning the actual performance of this product in the hands of customers. We believe the price that Alere is charging for this product is substantially higher than our antibody tests, as well as those of our competitors, as the antigen claim provides some customers of an additional reimbursement code. Moreover there is support by a number of key opinion leaders for the public health value of such 4th generation tests, and if Alere is able to successfully launch this product, it represents a significant competitive threat to Chembio as well as to each of the other rapid HIV test manufacturers (Orasure and Trinity primarily).

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

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

More generally, the point-of-care diagnostics industry is undergoing rapid technological changes, with frequent introductions of new technology-driven products and services. As new technologies become introduced into the

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

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

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

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

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

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

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

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

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

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

We were profitable for five consecutive years through 2013. Nevertheless, prior to 2009 we sustained significant operating losses since 2004, and we incurred an operating loss for 2014. As of December 31, 2014, we had a stockholders' equity of \$19.7 million and a working capital surplus of \$12.4 million. We estimate that our resources are sufficient to fund our needs through the end of 2015 and beyond. Nevertheless we have already made, and may continue to make, significant financial commitments to invest in our sales and marketing organization, regulatory approvals, research and development including new technologies, and production capacity, including expanded facilities.

Our liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenues; (2) the extent to which, if any, that revenue level improves operating cash flows; (3) our investments in research and development, facilities, marketing, regulatory approvals, and other investments it may determine to make; and (4) our investment in capital equipment and the extent to which it improves cash flow through operating efficiencies. There are no assurances that we will generate positive cash flow for 2015 or, in the alternative, be successful in raising sufficient capital to fund our needs after 2015.

Our U.S. market sales are difficult to predict in 2015 given (i) the introduction of a new rapid test by Alere, and the uncertainty as to whether or to what extent it will be successful in taking away sales of our products; and (ii) our early June 2014 termination of the agreement with a third party for exclusive distribution of our cassette product in the U.S. As a result of this termination, we expect to continue to experience higher average revenue per unit, and a lower volume of U.S. sales, of the cassette product. Higher revenue per unit is anticipated because we previously sold the cassette product to the exclusive U.S. distributor at a significantly lower price than the price at which the distributor resold the product to customers (including re-sellers and distributors) in the United States. However this could occur only after any inventory that the exclusive U.S. distributor had accumulated of our product was consumed, which has taken several months. In addition, in marketing this product directly, we are incurring substantial costs associated with establishing a sales and marketing organization and in establishing channel distribution partners.

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

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

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

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

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

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

Chembio has a policy in place prohibiting its employees, distributors and agents from engaging in corrupt business practices, including activities prohibited by the United States Foreign Corrupt Practices Act (the "FCPA").

Nevertheless, because we work through independent sales agents and distributors (and do not have any employees or subsidiaries) outside the United States, we do not have control over the day-to-day activities of such independent agents and distributors. In addition, in the donor-funded markets in Africa where we sell our products, there is significant oversight from PEPFAR, the Global Fund, and advisory committees comprised of technical experts concerning the development and establishment of national testing protocols. This is a process that includes an overall assessment of a product which includes extensive product performance evaluations including five active collaborations and manufacturer's quality systems, as well as price and delivery. In Brazil, where we have had a total of six product collaborations with FIOCRUZ, the programs through which our products may be deployed are all funded by the Brazilian Ministry of Health. Although FIOCRUZ is affiliated with the Brazilian Ministry of Health, and is its sole customer, FIOCRUZ is not the exclusive supplier for the Ministry of Health. However, because each of our collaborations with FIOCRUZ incorporates a technology transfer aspect, we believe we have a competitive

advantage versus other suppliers to the Brazilian Ministry of Health, assuming other aspects of our product offering through FIOCRUZ are otherwise competitive in comparison. We have no knowledge or reason to know of any activities by our employees, distributors or sales agents of any actions which could be in violation of the FCPA, although there can be no assurance of this.

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

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

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

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

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

Our continued growth depends on retaining our current key employees and attracting additional qualified personnel, and we may not be able to do so.

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

If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will adversely affect our ability to effectively manufacture, sell and market our products to meet the demands of our strategic partners in a timely fashion, or to support internal research and development programs. Although we believe we will be successful in attracting and retaining qualified personnel, competition for experienced scientists and other personnel from numerous companies and academic and other research institutions may limit our ability to do so on acceptable terms.

We have entered into employment contracts with our Chief Executive Officer, John Sperzel, our Chief Operating Officer, Sharon Klugewicz, and our Chief Scientist & Technology Officer, Javan Esfandiari. Due to the specific knowledge and experience of these executives regarding the industry, technology and market, the loss of the services of any one of them could have a material adverse effect on the Company. The contract with Mr. Sperzel has a term of three years ending March 2017. The contract with Ms. Klugewicz has a term of two years ending May 2015. The contract with Mr. Esfandiari has a term of three years ending March 2016. The Company has obtained a key man insurance policy on Mr. Esfandiari. The contract with Mr. Sperzel provides that Mr. Sperzel will serve as the Chief Executive Officer and as a Director of the Company through March 13, 2017.

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

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

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

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

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

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

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

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

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

Risks related to our Common Stock

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

The average daily trading volume of our Common Stock on the NASDAQ market was approximately 109,000 shares per day over the three months ended December 31, 2014 as compared with approximately 40,500 shares per day over the three months ended December 31, 2013. The liquidity of our stock depends on several factors, including but not limited to the financial results of the Company and overall market conditions, so it is not possible to predict whether this level of liquidity will continue, be sustained, or decrease.

Decreased trading volume in our stock would make it more difficult for investors to sell their shares in the public market at any given time at prevailing prices.

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

As of December 31, 2014, our named executive officers, directors and 5% stockholders beneficially owned approximately 23.1% of our voting power, which includes two large investors that beneficially owned approximately 10.9% and 6.4%, respectively, of the outstanding stock. For the foreseeable future, and assuming these ownership percentages continue to apply, to the extent that these parties vote similarly, they may be able to exercise significant control over many matters requiring approval by the board of directors or our stockholders. As a result, they may be able to:

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

USE OF PROCEEDS

The Company will not receive any of the proceeds from the sale of the shares by any of the Selling Stockholders. Each of the Selling Stockholders will pay any underwriting discounts, commissions and expenses for brokerage, or any other expenses that they, respectively, incur in disposing of the shares. The Company will bear all other costs, fees and expenses incurred in effecting the registration of the shares covered by this Prospectus.

SELLING STOCKHOLDERS

This Prospectus relates to shares that are being registered for reoffers and resales by Selling Stockholders who have acquired, or may acquire, shares pursuant to the Plan and the Employment Agreement, respectively. Selling Stockholders holding shares issued under the Plan and who are not named below may use this Prospectus for the offer or sale of those shares.

Beneficial ownership is determined in accordance with the rules of the Commission and is based upon 9,627,24 shares outstanding as of March 9, 2015, and generally includes voting or investment power with respect to securities.

Options to purchase 275,923 shares of Common Stock that are currently exercisable or exercisable within 60 days of March 9, 2015 are deemed to be outstanding and to be beneficially owned by the person holding such options for the purpose of computing the percentage ownership of such person but are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Information regarding any of the Selling Stockholders, including the number of shares offered for sale, will be set forth in a prospectus supplement to the extent required.

Of the 1,006,868 Covered Shares listed below as covered by this Prospectus, 800,000 shares are issuable pursuant to the Plan, and 206,868 shares are issuable upon exercise of outstanding options issued pursuant to the Employment Agreement. All of these shares are being registered for reoffers and resales by current and future Selling Stockholders. The current Selling Stockholders are named in the table below. The Selling Stockholders, including future Selling Stockholders, who do not currently own any Covered Shares, may resell all, a portion, or none of the shares pursuant to this Prospectus from time to time.

The address of each stockholder listed below is care of Chembio Diagnostics, Inc., 3661 Horseblock Road, Medford, New York 11763. The following table sets forth the name and relationship to the Company of each current Selling Stockholder and: (1) the number of shares of Common Stock which each Selling Stockholder beneficially owned as of March 9, 2015; (2) the number of shares of Common Stock which each Selling Stockholder may offer pursuant to this Reoffer Prospectus; and (3) (if one percent or more) the percentage of the class to be beneficially owned by such stockholder assuming the sale of all shares offered pursuant to this Prospectus.

| Selling Stockholder | Position | Shares Beneficially Owned | Shares Covered Under this Prospectus | Shares Beneficially Owned After the Resale |
|---------------------|---------------------------|---------------------------|--------------------------------------|--|
| Sperzel, John | Chief Executive Officer | -0- | 206,868 | n/a |
| Davis, Katherine | Board Chair | 67,671 | 46,875 | n/a |
| Meller, Gary | Director | 114,375 | 46,875 | 1.19% |
| Paul Lambotte | VP of Product Development | -0- | 36,000 | n/a |

PLAN OF DISTRIBUTION

The Covered Shares are being registered by us for the account of the respective Selling Stockholders.

The Covered Shares may be sold from time to time directly by or on behalf of any of the Selling Stockholders in one or more transactions on the NASDAQ or on any stock exchange on which the Common Stock may be listed at the time of sale, in privately negotiated transactions, or through a combination of these methods. Each of the Selling Stockholders may sell shares through one or more agents, brokers or dealers or directly to purchasers. These brokers or dealers may receive compensation in the form of commissions, discounts or concessions from any of the Selling Stockholders and/or purchasers of the shares, or both. Compensation as to a particular broker or dealer may be in excess of customary commissions. Each of the Selling Stockholders will act independently of the Company in making decisions with respect to the timing, manner and size of each sale or non-sale related transfer. If a Selling Stockholder is an employee, officer or director of the Company, he or she will be subject to the Company's policies concerning trading and other transactions in the Company's securities.

Each of the Selling Stockholders and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their Covered Shares on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. Each Selling Stockholder may use any one or more of the following methods when selling the shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the date of this Prospectus;
- broker-dealers may agree with the Selling Stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise; or
- any other method permitted pursuant to applicable law.

Each of the Selling Stockholders may also sell Covered Shares under Rule 144 under the Securities Act, if available, rather than under this Prospectus. There is no assurance that any of the Selling Stockholders will sell all or a portion of the Covered Shares.

In connection with the sale of shares, each of the Selling Stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the shares in the course of hedging the positions they assume. Each of the Selling Stockholders may also sell the shares short and deliver these shares to close out short positions, or loan or pledge the shares to broker-dealers or other financial institutions that in turn may sell these shares. Each of the Selling Stockholders may also enter into option or other transactions with broker-dealers or other financial institutions that require the delivery to the broker-dealer or other financial institution of the shares, which the broker-dealer or other financial institution may resell pursuant to this Prospectus, or enter into transactions in which a broker-dealer makes purchases as a principal for resale for its own account or through other types of transactions.

In connection with the sales, each of the Selling Stockholders and any participating broker or dealer may be deemed to be an "underwriter" within the meaning of the Securities Act, and any commissions they receive and the proceeds of any sale of shares may be deemed to be underwriting discounts or commissions under the Securities Act. Any Selling Stockholder who is deemed to be an "underwriter" within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act. Each of the Selling Stockholders and any other person participating in such distribution will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including, without limitation, Regulation M. Regulation M may limit the timing of purchases and sales of shares of our Common Stock by any of the Selling Stockholders and any other person. Furthermore, Regulation M may restrict, for a period of up to five business days prior to the commencement of the distribution, the ability of any person engaged in a distribution of shares of our Common Stock to engage in market-making activities with respect to these shares. All of the foregoing may affect the marketability of shares of our Common Stock and the ability of any person or entity to engage in market-making activities with respect to shares of our Common Stock.

To the extent required, the shares to be sold, the names of the persons selling the shares, the respective purchase prices and public offering prices, the names of any agent, dealer or underwriter and any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement of which this Prospectus is a part.

The Company is bearing all of the fees and expenses relating to the registration of the Covered Shares. Any underwriting discounts, commissions or other fees payable to broker-dealers or agents in connection with any sale of the Covered Shares will be borne by each respective Selling Stockholder. In order to comply with certain states' securities laws, if applicable, the Covered Shares may be sold in such jurisdictions only through registered or licensed brokers or dealers. In certain states, the Covered Shares may not be sold unless they have been registered or qualified for sale in such state, or unless an exemption from registration or qualification is available and is obtained and complied with. Sales of the Covered Shares made by any of the Selling Stockholders must be made in compliance with all other applicable state securities laws and regulations.

Any of the Selling Stockholders may agree to indemnify any broker-dealer or agent that participates in transactions involving sales of the Covered Shares against certain liabilities in connection with the offering of the shares arising under the Securities Act.

We have notified each of the Selling Stockholders of the need to deliver a copy of this Prospectus in connection with any sale of the Covered Shares.

EXPERTS

Our consolidated financial statements as of December 31, 2014 and December 31, 2013 and for the years ended December 31, 2014 and December 31, 2013, are incorporated by reference in this Prospectus, and the related financial statement schedule incorporated by reference in this Prospectus, have been audited by BDO USA, LLP, a registered independent public accounting firm, as stated in its reports incorporated by reference herein, and are included in reliance upon the reports of such firm given upon its authority as an expert in accounting and auditing. The foregoing financial statements have been incorporated by reference herein in reliance upon such reports given on the authority of such firm as experts in accounting and auditing.

LEGAL MATTERS

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

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

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

We disclose important information to you by referring you to documents that we have previously filed with the Commission or documents we will file with the Commission in the future. We hereby incorporate by reference the following documents into this Prospectus:

the Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed with the Commission on March 5, 2015;

the Current Reports on Form 8-K filed January 8, 2015, January 15, 2015, January 29, 2015, February 23, 2015 and March 5, 2015 (except for Items 7.01 and 9.01 and Exhibits 99.1, 99.2 and 99.3 contained therein); and the current Report on form 8-K filed January 22, 2015 (except for Items 1.01, 2.01, 7.01 and 9.01 and Exhibit 99.1 contained therein); and

the description of the Company's Common Stock set forth in the prospectus filed pursuant to Rule 424(b) of the Securities Act, filed with the Commission on April 2, 2008, and all amendments and reports filed by the Company to update that description.

Additionally, all documents filed by the Company with the Commission under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this Prospectus and before the termination or completion of this offering shall be deemed to be incorporated by reference into this Prospectus from the respective dates of filing of such documents.

Any information that we subsequently file with the Commission that is incorporated by reference as described above will automatically update and supersede any previous information that is part of this Prospectus.

Upon written or oral request, the Company will provide, without charge, a copy of any or all of the documents incorporated by reference, other than exhibits to those documents unless the exhibits are specifically incorporated by reference in the documents. Please send requests to Chembio Diagnostics, Inc., 3661 Horseblock Road, Medford, New York 11763, or call (631) 924-1135.

DISCLOSURE OF COMMISSION POSITION OF INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

The Company's directors and officers are indemnified by our bylaws against amounts actually and necessarily incurred by them in connection with the defense of any action, suit or proceeding in which they are a party by reason of being or having been directors or officers of the Company or its subsidiary. Our articles of incorporation provide that none of our directors or officers shall be personally liable for damages for breach of any fiduciary duty as a director or officer involving any act or omission of any such director or officer. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to such directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

In the event that a claim for indemnification against such liabilities, other than the payment by Chembio of expenses incurred or paid by such director, officer or controlling person 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, we will, unless in the opinion of counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act and we will be governed by the final adjudication.

NO DEALER, SALESMAN OR ANY OTHER PERSON HAS BEEN AUTHORIZED TO GIVE ANY INFORMATION OR TO MAKE ANY REPRESENTATIONS OTHER THAN THOSE CONTAINED IN THIS PROSPECTUS, AND, IF GIVEN OR MADE, SUCH INFORMATION OR REPRESENTATIONS MUST NOT BE RELIED UPON AS HAVING BEEN AUTHORIZED BY THE COMPANY OR ANY SELLING STOCKHOLDER. NEITHER THE DELIVERY OF THIS PROSPECTUS NOR ANY SALE MADE HEREUNDER SHALL, UNDER ANY CIRCUMSTANCES, IMPLY THAT THERE HAS BEEN NO CHANGE IN THE AFFAIRS OF THE COMPANY OR THAT THE INFORMATION HEREIN IS CORRECT AS OF ANY TIME SUBSEQUENT TO THE DATE AS OF WHICH SUCH INFORMATION IS GIVEN. THIS PROSPECTUS DOES NOT CONSTITUTE AN OFFER TO SELL OR THE SOLICITATION OF ANY OFFER TO BUY ANY OF THE SECURITIES OFFERED HEREBY TO ANYONE IN ANY JURISDICTION IN WHICH SUCH OFFER OR SOLICITATION IS NOT AUTHORIZED OR IN WHICH THE PERSON MAKING SUCH OFFER OR SOLICITATION IS NOT QUALIFIED TO DO SO OR TO ANYONE TO WHOM IT IS UNLAWFUL TO MAKE SUCH OFFER OR SOLICITATION.

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CHEMBIO DIAGNOSTICS, INC. HAS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION, WASHINGTON, D.C., A REGISTRATION STATEMENT UNDER THE SECURITIES ACT WITH RESPECT TO THE SHARES OFFERED HEREBY. THIS PROSPECTUS OMITTS CERTAIN INFORMATION CONTAINED IN THE REGISTRATION STATEMENT. THE INFORMATION OMITTED MAY BE OBTAINED FROM THE SECURITIES AND EXCHANGE COMMISSION UPON PAYMENT OF THE REGULAR CHARGE THEREFORE.

800,000 SHARES OF COMMON STOCK

To be Acquired by the Selling Stockholders Under the
2014 Stock Incentive Plan

206,868 SHARES OF COMMON STOCK

To be Acquired by John Sperzel Under the
Employment Agreement by and between the Company and John Sperzel Effective as of March 13, 2014

CHEMBIO DIAGNOSTICS, INC.

COMMON STOCK

REOFFER PROSPECTUS

PART II

INFORMATION REQUIRED IN THE REGISTRATION STATEMENT

ITEM 3. INCORPORATION OF DOCUMENTS BY REFERENCE

The following documents are hereby incorporated by reference into this Registration Statement:

the Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed with the Commission on March 5, 2015;

the Current Reports on Form 8-K filed January 8, 2015, January 15, 2015, January 29, 2015, February 23, 2015 and March 5, 2015 (except for Items 7.01 and 9.01 and Exhibits 99.1, 99.2 and 99.3 contained therein); and the current Report on form 8-K filed January 22, 2015 (except for Items 1.01, 2.01, 7.01 and 9.01 and Exhibit 99.1 contained therein); and

the description of the Company's Common Stock set forth in the prospectus filed pursuant to Rule 424(b) of the Securities Act, filed with the Commission on April 2, 2008, and all amendments and reports filed by the Company to update that description.

All documents filed pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act subsequent to the date hereof and prior to the filing of a post-effective amendment that indicate that all securities offered have been sold or that deregister all securities then remaining unsold shall be deemed to be incorporated by reference into this Registration Statement and to be part hereof from the date of filing of such documents. Any statement contained in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this Registration Statement to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part hereof.

ITEM 4. DESCRIPTION OF SECURITIES

Not applicable.

ITEM 5. INTEREST OF NAMED EXPERTS AND COUNSEL

The validity of the common stock covered by this Registration Statement has been passed upon for us by Ballard Spahr LLP. Haynes and Boone, LLP, Denver, Colorado will serve as our counsel. A partner of Haynes and Boone, LLP owns 29,497 shares of Common Stock.

ITEM 6. INDEMNIFICATION OF DIRECTORS AND OFFICERS

The Company's articles of incorporation provide for the indemnification of the directors, officers, employees and agents of the Company to the fullest extent permitted by the laws of the State of Nevada. Section 78.7502 of the Nevada General Corporation Law permits a corporation to indemnify any of its directors, officers, employees or agents against expenses actually and reasonably incurred by such person in connection with any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (except for an action by or in right of the corporation) by reason of the fact that such person is or was a director, officer, employee or agent of the corporation, provided that it is determined that such person 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 and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful.

Section 78.751 of the Nevada General Corporation Law requires that the determination that indemnification is proper in a specific case must be made by (a) the stockholders, (b) the board of directors by majority vote of a quorum consisting of directors who were not parties to the action, suit or proceeding or (c) independent legal counsel in a written opinion (i) if a majority vote of a quorum consisting of disinterested directors is not possible or (ii) if such an opinion is requested by a quorum consisting of disinterested directors.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

ITEM 7. EXEMPTION FROM REGISTRATION CLAIMED

Not applicable.

ITEM 8. EXHIBITS

The following documents are filed as exhibits to this Registration Statement:

| Exhibit Number | Exhibit |
|----------------|--|
| 4.1 | Chembio Diagnostics, Inc. 2014 Stock Incentive Plan (Incorporated by reference to the Company's definitive proxy statement on Form DEF 14A filed with the Commission on April 29, 2014) |
| 4.2 | Employment Agreement by and between Chembio Diagnostics, Inc. and John Sperzel effective as of March 13, 2014 (Incorporated by reference to the Company's Form 10-Q for the Quarter ended March 31, 2014, filed with the Commission on May 8, 2014). |
| 5.1 | Opinion and Consent of Ballard Spahr LLP |
| 23.1 | Consent of BDO USA, LLP |
| 23.2 | Consent of Ballard Spahr LLP (included in Exhibit 5.1) |
| 24.1 | Power of Attorney (included on signature page hereto) |

ITEM 9. UNDERTAKINGS

The registrant hereby undertakes:

- (a) (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement to:
- (i) Include any prospectus required by Section 10(a)(3) of the Securities Act;
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 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 a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.
- (ii) 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 (a)(1)(i) and (a)(1)(ii) do not apply because this Registration Statement is on Form S-8 and the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or 15(d) of the Exchange Act that are incorporated by reference to the Registration Statement.
- (iii) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment (2) 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.
The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Exchange Act that is (b) 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 may be permitted to the directors, officers and controlling persons of the registrant pursuant to the foregoing provision, or otherwise, the registrant has been advised that in the opinion of the Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (c) (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit, or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act, the registrant certifies that it has reasonable grounds to believe that its meets all of the requirements for filing on Form S-8 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Medford, State of New York, on this 24th day of April 2015.

CHEMBIO DIAGNOSTICS, INC.

By: /s/ John J. Sperzel III

Richard J. Larkin

John J. Sperzel III

Chief Executive Officer and Chief Financial Officer and
Principal Executive Officer Principal Accounting Officer

By: /s/

Richard J. Larkin

Each person whose signature appears below appoints each of John J. Sperzel III and/or Richard J. Larkin, or either of them individually, as true and lawful attorney-in fact and agent, with full power of substitution to sign any amendments (including post-effective amendments) to this Registration Statement and to each registration statement amended hereby, and to file the same, with all exhibits and other related documents, with the Commission, with full power and authority to perform any necessary or appropriate act in connection with the amendment(s).

Pursuant to the requirements of the Securities Act, this Registration Statement has been signed below by the following persons in the capacities and on the dates indicated.

By: /s/ Katherine L. Davis

24, 2015

Katherine L. Davis

Director

April

By: /s/ Barbara

DeBuono

Dr. Barbara DeBuono

Director

April 24, 2015

By: /s/ Peter Kissinger

24, 2015

Dr. Peter Kissinger

Director

April

By: /s/ Gary Meller

2015

Dr. Gary Meller

Director

April 24,

By: /s/ John J. Sperzel III

24, 2015

John J. Sperzel III

Director

April

EXHIBIT INDEX

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