

CHEMBIO DIAGNOSTICS, INC.
Form 424B5
July 29, 2016

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

**Prospectus Supplement
(to Prospectus dated April 5, 2016)**

2,000,000 Shares of Common Stock

Chembio Diagnostics, Inc.

\$6.00 per share

Pursuant to this prospectus supplement and the accompanying prospectus, we are offering 2,000,000 shares of our common stock, par value \$0.01 per share. Our common stock is traded on the NASDAQ Capital Market under the symbol CEMI. On July 28, 2016, the last reported sale price of our common stock on the NASDAQ Capital Market was \$6.95 per share.

Investing in our securities involves a high degree of risk. Please read Risk Factors beginning on page S-7 of this prospectus supplement, page 19 of the accompanying prospectus and the risk factors described in the documents incorporated by reference into this prospectus supplement.

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

	Per Share	Total
Public offering price	\$ 6.00	\$12,000,000
Underwriting discount ⁽¹⁾	\$ 0.42	\$840,000
Proceeds, before expenses, to us	\$ 5.58	\$11,160,000

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

The underwriters may also purchase up to an additional 300,000 shares of common stock from us at the public offering price, less the underwriting discount, within 30 days of the date of this prospectus supplement to cover over-allotments. If the underwriters exercise this option in full, the total discount will be \$966,000, and the total net proceeds to us, before expenses, will be \$12,834,000.

Delivery of the shares will take place on or about August 3, 2016, subject to the satisfaction of certain conditions and shall be in book-entry form only through the facilities of The Depository Trust Company against payment on or about August 3, 2016.

Craig-Hallum Capital Group

Sole Book-Running Manager

The Benchmark Company

Co-Manager

The date of this prospectus supplement is July 29, 2016

TABLE OF CONTENTS

TABLE OF CONTENTS

	Page
Prospectus Supplement	
<u>ABOUT THIS PROSPECTUS SUPPLEMENT</u>	<u>S-ii</u>
<u>PROSPECTUS SUPPLEMENT SUMMARY</u>	<u>S-1</u>
<u>THE OFFERING</u>	<u>S-6</u>
<u>RISK FACTORS</u>	<u>S-7</u>
<u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	<u>S-15</u>
<u>USE OF PROCEEDS</u>	<u>S-17</u>
<u>DILUTION</u>	<u>S-18</u>
<u>PRICE RANGE OF OUR COMMON STOCK</u>	<u>S-19</u>
<u>DIVIDEND POLICY</u>	<u>S-19</u>
<u>UNDERWRITING</u>	<u>S-20</u>
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	<u>S-23</u>
<u>INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE</u>	<u>S-24</u>
<u>LEGAL MATTERS</u>	<u>S-25</u>
<u>EXPERTS</u>	<u>S-25</u>
Prospectus	
<u>ABOUT THIS PROSPECTUS</u>	<u>ii</u>
<u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	<u>1</u>
<u>ABOUT CHEMBIO</u>	<u>2</u>
<u>RISK FACTORS</u>	<u>19</u>
<u>USE OF PROCEEDS</u>	<u>27</u>
<u>DESCRIPTION OF SECURITIES WE MAY OFFER</u>	<u>27</u>
<u>DESCRIPTION OF COMMON STOCK</u>	<u>28</u>
<u>DESCRIPTION OF PREFERRED STOCK</u>	<u>30</u>
<u>DESCRIPTION OF WARRANTS</u>	<u>32</u>
<u>DESCRIPTION OF UNITS</u>	<u>34</u>
<u>PLAN OF DISTRIBUTION</u>	<u>35</u>
<u>LEGAL MATTERS</u>	<u>36</u>
<u>EXPERTS</u>	<u>36</u>
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	<u>37</u>

S-i

TABLE OF CONTENTS

ABOUT THIS PROSPECTUS SUPPLEMENT

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

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

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

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

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

TABLE OF CONTENTS

PROSPECTUS SUPPLEMENT SUMMARY

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

Our Company

We develop, manufacture, market and license rapid point-of-care diagnostic tests (POCTs) that detect infectious diseases. Our main products currently 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 proprietary lateral flow technologies together with licensed reagents, 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. Our latest generation HIV 1/2 rapid antibody detection test incorporates our patented Dual Path Platform® (DPP®) POCT technology together with licensed reagents. The DPP® HIV 1/2 Assay detects antibodies to HIV 1 & 2 in oral fluid samples as well as in all blood matrices.

Our product pipeline, which currently includes a test for Hepatitis-C and a multiplex test that detects HIV and syphilis specific antibodies (which we are already selling outside the United States), is based on our 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 our patented DPP® and the lateral flow platforms, we participate in the estimated \$8 billion point-of-care market segment of the estimated nearly \$50 billion global in-vitro diagnostic market that has an overall growth rate exceeding 3% per annum. POCTs, by providing prompt and early diagnosis, can reduce patient stays, lower overall costs, improve therapeutic interventions and improve patient outcomes. POCTs can also prevent needless hospital admissions, simplify testing procedures, avoid delays from central lab batching, and eliminate the need for return visits.

In the areas of infectious and sexually transmitted diseases (such as HIV and syphilis), the utility of POCTs, 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 United States 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.

Our Products

Lateral Flow Rapid HIV Tests. All three of our lateral flow rapid HIV antibody detection tests are qualitative (yes/no tests for the detection of antibodies to HIV 1 & 2 with visually interpreted results (one line = negative ; one line = positive)

available within approximately 15 minutes. The tests are simple to use, have a shelf life of 24 months, and do not require refrigeration. The tests differ principally only in the method of test procedure, convenience and cost.

One of our U.S. Food and Drug Administration (FDA)-approved lateral flow HIV tests, also known as SURE CHECK® HIV 1/2 Assay, incorporates a proprietary plastic barrel device that houses the lateral flow strip. This barrel format enables collection of samples directly (usually from a finger-stick whole blood sample) into the barrel's capillary tip. A sealed unitized buffer vial, assembled onto the top of the barrel, is removed and seated into a stand; the seal is then pierced by the barrel's capillary tip, thereby initiating the upward flow of the resulting sample-buffer solution through a filter, up into the vertical device's chamber and

S-1

TABLE OF CONTENTS

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. Results are obtained in 15 minutes via a 2.5uL blood sample (i.e., fingerstick, serum, plasma, or venipuncture whole blood). The assay is stable at room temperature and provides 99.7% sensitivity and 99.9% specificity. SURE CHECK® HIV 1/2 Assay is marketed by Chembio and its designated distributors worldwide.

Our second lateral flow HIV test, the HIV 1/2 STAT-PAK®, 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 into a sample well or port of the cassette that houses the lateral flow strip, which is positioned horizontally or flat.

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

The FDA approved our Pre-Market Applications (PMA) in April 2006 for our SURE CHECK® HIV 1/2 Assay and for our HIV 1/2 STAT-PAK® products. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) sets forth standards for clinical laboratory testing performed on humans in the United States, and a CLIA waiver must be obtained in order for a non-certified laboratory to perform certain tests. Waivers under CLIA were granted by the FDA for these two FDA-approved products in 2006 and 2007, respectively. A CLIA Waiver is required in order for health care providers to administer these tests in the settings where they are most suited and needed, such as public health testing clinics, hospital emergency rooms and physicians' offices. The SURE CHECK® 1/2 and HIV 1/2 STAT-PAK® products received CE Marks in July 2013 and March 2014, respectively. Our HIV 1/2 STAT-PAK® Dipstick, although 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. CE Mark has not been pursued for this product.

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

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

In December 2012, we received FDA approval of our Pre-Marketing Approval. In October of 2014 the FDA granted CLIA Waiver status. The DPP® HIV 1/2 Assay product is qualified for procurement under PEPFAR for use with all sample matrices, and in June, 2016, we obtained WHO qualification in order to enable procurement of this product by the Global Fund and United Nations agencies, including programs underwritten by them. In May 2015 we received approval for a CE Mark for the DPP® HIV 1/2 Assay for Oral Fluid, Serum, Plasma, Fingerstick Whole Blood and Venous Whole Blood.

S-2

TABLE OF CONTENTS

In June 2010, Agência Nacional de Vigilância Sanitária (ANVISA), the Brazilian regulatory agency responsible for the supervision of medical devices, approved the DPP® HIV 1/2 Assay for marketing in Brazil through our collaboration with the Oswaldo Cruz Foundation (FIOCRUZ), Brazil's leading public health institute. Since this time, we have sold and marketed over eight million DPP® HIV 1/2 Assay tests in Brazil through this partnership.

DPP® HIV-Syphilis Multiplex Test. This product, launched in 2013, allows for the detection of antibodies to both HIV and syphilis on a single test device within approximately 15 minutes. We believe that in certain global/public health settings this product may provide a more convenient and cost-effective means of rapid detecting both markers in a single test procedure at the point of care as compared with performing separate rapid tests for each indication. This product takes advantage of the multiplexing feature of DPP® which provides for a more robust reaction between the sample and biomarkers being tested for (HIV and syphilis antibodies in this case), resulting in a greater ability by the user to visually interpret test results. We launched this product in Mexico in the fourth quarter of 2013 as a unitized product, meaning that each test kit was separately packaged to include each of the other components necessary to run this test, as compared with other configurations where a test kit of 20 or 30 devices is accompanied by one bottle of running buffer. We believe that the initial results of this launch have been very positive and that we experienced good results in Mexico during 2014 from the program. Building on this initial success, we continue to pursue commercialization efforts for this product in a number of additional international markets where there is a great need to detect Mother-to-Child-Transmission of HIV and syphilis globally.

In December 2014, DPP® HIV-Syphilis Multiplex was granted approval from ANVISA. As of June 30, 2016, there have been no sales of DPP® HIV-Syphilis Multiplex in Brazil.

This product has been approved by the U.S. Centers for Disease Control (CDC), acting on behalf of the United States Agency of International Development (USAID), for its global procurement scheme.

We are developing a United States version of the DPP® HIV-Syphilis Assay, designed to meet the performance requirements for the reverse algorithm that is currently in clinical use for syphilis testing in the United States. We have completed our pre-clinical studies for this product with encouraging results, and are in the final stages of clinical site selection for our United States clinical studies. We began this clinical trial in the United States during the first quarter of 2016, and expect that the trial will be completed in the first quarter of 2017.

DPP® Technology & Development

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

the Company entered into an agreement in October 2014 to develop a POC diagnostic test for dengue fever virus, the DPP® Dengue Fever Assay, which has been developed and is able to detect IgG/IGM and NS1 antigens.

the Company announced in October 2014 a collaboration with an international diagnostics company to develop a POC diagnostic test for the early detection and monitoring of a specific type of cancer. At that time, the cancer project represented the first application of the DPP® technology outside the infectious disease field.

the Company has entered into milestone-based development agreements with a private contracting organization acting on behalf of the CDC, for a multiplex POC influenza immunity test utilizing Chembio's patented DPP® technology.

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

biomarker will be combined with Chembio's proprietary DPP® platform to develop a semi-quantitative or quantitative point-of-care test to diagnose TBI. CSG agreed to pay Chembio milestone development payments during 2015.
S-3

TABLE OF CONTENTS

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

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

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

Competition

There are several established rapid HIV tests which are already in the marketplace that compete with our lateral flow HIV tests and DPP® HIV 1/2 Assay. These include OraSure (sold by OraSure Technologies), Alere Determine® rapid test product (sold by Alere, Inc.), and INSTI (sold by Biolytical, Inc.).

Our competitors may have significant advantages over us. Many of our competitors are substantially larger and have greater financial, research, manufacturing and marketing resources, which gives them an advantage over us in developing new products and reaching potential customers. If our competitors choose to focus on research and development of technology similar to our products, they could potentially because of their larger size devote significantly more resources to such research and development than we are able to devote to our products which could render our products obsolete. In general, we believe that these competitors have, and will continue to have, substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do. However, we believe that our suite of products differentiates us from these competitors, and we will be competitive on the basis of the breadth and quality of our product offerings.

TABLE OF CONTENTS**Intellectual Property**

We own or license a number of trademarks covering our company and our products. Our intellectual property strategy is to: (1) build our own intellectual property portfolio around our DPP® technology; (2) pursue licenses, trade secrets and know-how within the area of rapid point-of-care testing, and (3) develop and acquire proprietary positions to reagents and new hardware platforms for the development and manufacture of rapid diagnostic tests. We also rely upon trade secrets and continuing technological innovations to develop and maintain our competitive position.

Patents

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

U.S. Patent No.	Issued	Expires	Nature	Type	Description
7,189,522	3/13/2007	6/30/2025	test device	utility	a test device for determining the presence of a ligand in a sample
7,682,801	3/23/2010	6/30/2025	test device and method	utility	a test device and a method for determining the presence of a ligand in a sample
7,879,597	2/1/2011	6/30/2025	test device	utility	a test device for determining multiple ligands in a sample
8,507,259	8/13/2013	6/30/2025	test device	utility	a test device for determining the presence of a ligand in a sample

Trademarks

The Company has filed and obtained U.S. trademarks for certain products, including DPP®, SURE CHECK®, STAT-PAK®, STAT-VIEW® and also for the SampleTainer® used in certain DPP® products, and has also filed for U.S. trademarks for DPP® MICRO READER and NEXT GENERATION DPP®. The DPP® trademark is also registered in Australia, Canada, the EU, Japan, Mexico, Turkey and Uganda, and registrations are pending in multiple other countries. STAT-PAK® is registered in the EU, Mexico, and in various African countries, and registrations are pending in other countries. SampleTainer® is registered in Australia, China, EU, Japan, Russia, Turkey, and various African countries, and registrations are pending in multiple other countries. STAT-VIEW® and NEXT GENERATION DPP® are registered in the EU. SURE CHECK® is registered in Mexico and registrations are pending in various other countries.

Recent Developments

On July 25, 2016, the Company filed a Form 8-K with the SEC that includes a preliminary unaudited estimate of the financial results for the three and six month periods ended June 30, 2016. That Form 8-K has been incorporated by reference into this prospectus supplement and the accompanying prospectus. The preliminary financial results estimate provided in the Form 8-K includes estimates only, and is subject to change upon completion of the review of our financial statements as of and for the three months ended June 30, 2016. Additional information and disclosures would be required for a more complete understanding of our financial position and results of operations as of June 30,

2016. The Form 8-K filed on July 25, 2016 also includes information concerning recent developments in the Company's business.

Corporate Information

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

S-5

TABLE OF CONTENTS

THE OFFERING

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

Common stock we are offering

2,000,000 shares

Common stock outstanding immediately after this offering

11,686,242 shares⁽¹⁾

Over-allotment option

We have granted the underwriters an option to purchase up to an aggregate of 300,000 additional shares of our common stock to cover any over-allotments. This option is exercisable, in whole or in part, for a period of 30 days from the date of this prospectus supplement

Net proceeds

The net proceeds to us from the sale of the common stock offered, after deducting underwriting discounts and commissions and estimated offering expenses, will be approximately \$10.8 million, or \$12.5 million if the underwriters exercise their over-allotment option in full.

Use of proceeds

We intend to use the net proceeds received from the sale of the securities for general corporate purposes. See Use of Proceeds of this prospectus supplement for additional information.

NASDAQ Capital Market symbol

CEMI

Risk Factors

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

⁽¹⁾ The number of shares to be outstanding after this offering is based on 9,686,242 shares of our common stock outstanding as of July 28, 2016 (prior to this offering), and excludes as of that date 623,424 shares of our common stock subject to outstanding stock options having a weighted average exercise price of \$4.26 per share; and

721,515 shares of our common stock reserved for future issuance pursuant to our existing stock option plan.

S-6

TABLE OF CONTENTS

RISK FACTORS

*You should carefully consider each of the following risk factors and all of the other information provided in this prospectus. 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. In addition, you should consider the risks discussed in the accompanying prospectus, including the sections of the accompanying prospectus entitled *Special Note Regarding Forward-Looking Statements and Risk Factors*, and those set forth under the heading *Item 1.A Risk Factors* in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 that we have incorporated by reference into this prospectus supplement. Although we believe that these risks are the most important for you to consider, you should read this section in conjunction with our financial statements, the notes to those financial statements and our management's discussion and analysis of financial condition and results of operations included in our periodic reports and incorporated into this prospectus supplement by reference.*

Risks related to 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, manufacturing, 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 U.S. Department of Agriculture (USDA) as well as by non-governmental organizations such as the International Organization for Standardization (ISO) and WHO. We have implemented a quality control system that is intended to comply with applicable regulations. Although FDA approval is not required for the export of our products, there are export regulations promulgated by the FDA that specifically relate to the export of our products that require compliance with FDA quality system regulation 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.

S-7

Because we may not be able to obtain or maintain the necessary regulatory approvals for some of our products, we

TABLE OF CONTENTS

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 satisfies the central 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.

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