UNITED STATES
Securities and Exchange Commission
Washington, D.C. 20549

FORM 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2015

or

[ ] TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from_____ to _____.

Commission File No. 0-30379

CHEMBIO DIAGNOSTICS, INC.

(Exact name of registrant as specified in its charter)

Nevada	88-0425691
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
3661 Horseblock Road, Medford, NY	11763
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code (631) 924-1135

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
None	None

Securities registered pursuant to section 12(g) of the Act:
Common Stock, $0.01 par value
(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes __ No X

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes __ No X

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes X No__

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes X No __

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

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 [ ]
Non-accelerated filer [ ]
(Do not check if a smaller reporting company)

Accelerated filer [ ]
Smaller reporting company [X]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes __ No _X_

As of the last business day of the Company's most recently completed second fiscal quarter, the aggregate market value of voting and non-voting common equity held by non-affiliates* was $47,000,000.

As of March 2, 2015, the registrant had 9,628,248 common shares outstanding.

* Without asserting that any of the issuer's directors or executive officers, or the entities that own more than five percent of the outstanding shares of the Registrant's common stock, are affiliates, the shares of which they are beneficial owners have not been included in shares held by non-affiliates solely for this calculation.

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PART I

ITEM 1. BUSINESS

FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, and Section 27A of the Securities Act of 1933. Any statements contained in this report that are not statements of historical fact may be forward-looking statements. When we 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, we are identifying forward-looking statements. Forward-looking statements involve risks and uncertainties, which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. These factors include our research and development activities, distributor channels, market demand for our products, compliance with regulatory impositions; and our capital needs. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

Except as may be required by applicable law, we do not undertake or intend to update or revise our forward-looking statements, and we assume no obligation to update any forward-looking statements contained in this report as a result of new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. You should carefully review and consider the various disclosures we make in this report and our other reports filed with the Securities and Exchange Commission that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

We provide free of charge on our website at www.chembio.com our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable. Members of the public may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, and Washington, DC 20549. Members of the public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800–SEC–0330. The Internet address of the Commission is www.sec.gov. That website contains reports, proxy and information statements and other information regarding issuers, like Chembio, that file electronically with the Commission. Visitors to the Commission's website may access such information by searching the EDGAR database.

For further information about these and other risks, uncertainties and factors, please review the disclosure included in this report under "Part I, Item 1A, Risk Factors."

Our Business

General

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

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

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

PRODUCTS

Lateral Flow Rapid HIV Tests

All three of our lateral flow rapid HIV antibody detection tests are qualitative "yes/no" tests for the detection of antibodies to HIV 1 & 2 with visually interpreted results (one line "negative"; one line "positive") available within approximately 15 minutes. The tests are simple to use, have a shelf life of 24

months, and do not require refrigeration. The tests differ principally only in the method of test procedure, convenience and cost. One of our FDA-approved lateral flow HIV tests incorporates a proprietary plastic "barrel" device that houses the lateral flow strip. This barrel format enables collection of samples directly (usually from a finger-stick whole blood sample) into the barrel's capillary tip. A sealed unitized buffer vial, assembled onto the top of the barrel, is removed and seated into a stand; the seal is then pierced by the barrel's capillary tip, thereby initiating the upward flow of the resulting sample-buffer solution through a filter, up into the vertical device's chamber and onto the lateral flow strip. This results in a unique unitized and closed device system that can reduce the chance of exposure to potentially infectious samples.

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

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

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

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

Regulatory Status of the lateral flow HIV tests

The FDA approved our Pre-Market Applications (hereinafter "PMA"; see "Governmental Regulations" and Glossary) in April 2006 for our SURE CHECK® HIV 1/2 (and also now Alere Clearview® Complete HIV 1/2) and for our HIV 1/2 STAT-PAK® products. Waivers under the Clinical Laboratory Improvement Act (hereinafter "CLIA"; see Governmental Regulations) were granted by the FDA for these two FDA-approved products in 2006 and 2007, respectively. A CLIA waiver is required in order for health care providers to administer these tests in the settings where they are most suited and needed, such as public health testing clinics, hospital emergency rooms and physicians' offices. The SURE CHECK® and HIV 1/2 STAT-PAK® products received CE Marks in July 2013 and March 2014, respectively, and the CE Marking for the DPP® HIV 1/2 Assay received in May 2015. We have also updated our filing for CE Marking to reflect the new tradename of STAT-VIEW® HIV 1 / 2 Assay for sale in the EU market. Our HIV 1/2 STAT-PAK® Dipstick, although not FDA-approved, qualifies under FDA export regulations [See Government Regulation] to sell to customers outside the United States, subject to any required approval by the importing country. CE Mark has not been pursued for this product.

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

DPP® HIV 1/2 Assay

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

Regulatory Status of the DPP® HIV 1/2 Assay

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

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

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

DPP® HIV-Syphilis Multiplex Test

This product, launched in 2013, allows for the detection of antibodies to both HIV and Syphilis on a single test device within approximately 15 minutes. In certain global/public health settings (see Target Markets), this product may provide a more convenient and cost-effective means of rapid detecting both markers in a single test procedure at the point of care as compared with performing separate rapid tests for each indication. This product takes advantage of the multiplexing feature of DPP® which provides for a more robust reaction between the sample and biomarkers being tested for (HIV and Syphilis antibodies in this case), resulting in a greater ability by the user to visually interpret test results. We launched this product in Mexico in the fourth quarter of 2013 as a unitized product, meaning that each test kit was separately packaged to include each of the other components necessary to run this test, as compared with other configurations where a test kit of 20 or 30 devices is accompanied by one bottle of running buffer. The initial results of this launch have been very positive, and we experienced good results in Mexico during 2014 from the program. Building on this initial success, we continue to pursue commercialization efforts for this product in a number of additional international markets, where there is a great need to detect Mother-to-Child-Transmission of HIV and Syphilis globally. According to the CDC website, "approximately 370,000 babies are born with HIV, mostly in sub-Saharan Africa. Without treatment, more than half of these children will die before the age of 2. Through key interventions, such as routinely testing pregnant women for HIV, providing antiretroviral medications to HIV-infected pregnant women and their exposed infants, and promoting safe infant feeding practices, mother-to-child transmission of HIV can be decreased from about 35% to less than 5%. Another prominent cause of infant mortality is untreated maternal syphilis, which still

accounts for more than 500,000 stillbirths and infant deaths annually despite the fact that these deaths could be prevented through routine detection and treatment of syphilis during antenatal care".

Regulatory Status of the DPP® HIV-Syphilis Test

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

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

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

DPP® TECHNOLOGY & DEVELOPMENT

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

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

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

- The Company entered into a follow-on, milestone-based development agreement with a private contracting organization acting on behalf of the United States Centers for Disease Control and Prevention (CDC), for a multiplex POC influenza immunity test utilizing Chembio's patented Dual Path Platform (DPP®) technology.

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

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

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

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

PARTNERS INVOLVED IN MARKETING OUR PRODUCTS

Alere

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

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

be marketed exclusively by Alere in the U.S only, although on May 31, 2016, the Barrel Agreement will expire pursuant to its terms, and Chembio will also market the barrel product in the U.S. under the brand of SureCheck® HIV 1/2 Assay.

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

OEM DPP® Products

Oswaldo Cruz Foundation OEM DPP® Agreements

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

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

During 2010 and 2011, all of the initial products contemplated under the five agreements were approved for marketing by the applicable regulatory agencies in Brazil. The agreements between the Company and FIOCRUZ are unique examples of technology transfer collaborations between a private sector rapid test manufacturer and a public health organization. The five products categories for which FIOCRUZ can earn a separate right to request a technology transfer for that product only are: DPP® products for HIV screening, HIV Confirmatory, Leishmaniasis, Leptospirosis and Syphilis. Each technology transfer, and the provision by Chembio of the information and training that is required for this to occur, will occur only if FIOCRUZ purchases from Chembio the amount of that product that is specified in the respective agreement for that product. The actual amount of purchases for each product is totally at the discretion and option of FIOCRUZ and may be more or less than the amount needed to qualify for a technology transfer.

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

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

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

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

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

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

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

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

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

    2. With respect to Chembio's Canine Leishmania test, Bio-Manguinhos had qualified to request the technology transfer and did so request. Submission of the technology transfer information is in process at this time. Bio-Manguinhos purchased $2,000,817 and $99,183 of this product in 2011 and 2012 respectively, of this product in that applied to the Qualifying Amount. In addition, Bio-Manguinhos made purchases in excess of the Qualifying Amount equal to $1,314,117, $1,736,700, $2,394,000 and $3,772,482 in 2012, 2013, 2014 and 2015, respectively.

3.

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

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

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

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

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

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

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

Other OEM And License Agreements Related to DPP® Technology

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

In 2013 we entered into collaboration with Labtest, a private company in Brazil, for the distribution of a number of products in Brazil that would be co-branded with Labtest and Chembio trademarks. Under this agreement, upon request from Labtest, for which there is no requirement, Chembio will sell the appropriate DPP® components to Labtest for further manufacture and assembly in Brazil.

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

Our Rapid Test Technologies

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

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

Multiplexing is significantly improved as a result of the design of DPP® and this provides a significant advantage. For example, the HIV confirmatory test we developed for Bio-Rad that is described above employs six different markers related to various epitopes of the HIV antigen. We have a number of other products in development, including those being developed in sponsored development programs that involve the use of multiple (e.g. eight) test bands. Although all of these products could be visually read, we can also use handheld and desktop readers with our DPP®

products to objectively measure, quantify, record and report DPP® test results. Certain of the products we have and/or are developing incorporate some of these readers, and we are developing other products that may be used with or will require use of a reader. Also, platforms can incorporate labeling reagents that cannot be visually read except by employing a reader, such as fluorescence, though no products are currently utilizing such reagents.

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

Target Markets

Rapid HIV Tests

A large percentage of individuals that are HIV positive worldwide are unaware of their status. Part of the reason for this is that even those that do get tested in public health settings will often not return or call back for their test results when samples have to be sent out to a laboratory which can take up to several days to process. The increased availability, greater efficacy and reduced costs for anti-retroviral treatments (ARVs) for HIV has increased the demand for testing, as the stigma associated with the disease is lessened, and the ability to resume normal activities is substantially improved, providing a positive message to those potentially infected. The impact that rapid HIV testing has had on prevention efforts has in turn increased the demand for testing, particularly by public health programs worldwide, which have also become more effective in reducing the number of annual new infections in many, but by no means all, high prevalence regions.

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

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

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

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

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

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

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

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

Rapid HIV-Syphilis Test

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

Marketing Strategy

Our marketing strategy is to:

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

- We will support, review and assess the marketing and distribution efforts of our rapid HIV barrel test in the U.S.

- Outside the U.S., we will market our products primarily through commercial collaborators and distribution partners.

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

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

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

Competition

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

- Scientific and technological capability;

- Proprietary know-how;

- The ability to develop and market products and processes;

- The ability to obtain FDA or other required regulatory approvals;

- The ability to manufacture products that meet applicable FDA requirements, (i.e. FDA's Quality System Regulations) (see Governmental Regulation section);

- The ability to manufacture products cost-effectively;

- Access to adequate capital;

- The ability to attract and retain qualified personnel; and

- The availability of patent protection.

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

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

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

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

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

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

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

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

Research and Development

During 2015 and 2014, we spent $6.4 million and $4.8 million, respectively, on research and development (including regulatory activities). These expenses were in part underwritten by funding from R&D and milestones revenues of $2.3 million in 2015 and $1.7 million in 2014. All of our new product development activities involve employment of our DPP® technology. These activities include completing development of certain products and making significant progress toward the development of additional products.

Employees

At December 31, 2015, we employed approximately155 people. We have entered into employment contracts with our Chief Executive Officer and President, John J. Sperzel, our Chief Operating Officer, Sharon Klugewicz, and our Chief Science and Technology Officer, Javan Esfandiari. Due to the specific knowledge and experience of these executives regarding the industry, technology and market, the loss of the services of any one of them would likely have a material adverse effect on the Company. The contract with Ms. Klugewicz, has a term of two years ending May 2017. The contract with Mr. Esfandiari has a term of three years ending March 2016. The Company and Mr. Esfandiari currently are discussing terms for renewal of his employment agreement. We have obtained a key man insurance policy for Mr. Esfandiari. The contract with Mr. Sperzel provides that Mr. Sperzel will serve as the Chief Executive Officer and President of the Company through March 2017.

Governmental Regulation

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

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

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

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

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

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

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

Environmental Laws

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

Intellectual Property

Intellectual Property Strategy

Our intellectual property strategy is to: (1) build our own intellectual property portfolio around our DPP® technology; (2) pursue licenses, trade secrets and know-how within the area of rapid point-of-care testing, and (3) develop and acquire proprietary positions to reagents and new hardware platforms for the development and manufacture of rapid diagnostic tests.

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

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

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

Trademarks

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

Trade Secrets and Know-How

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

Lateral Flow Technology and Reagent Licenses

As part of the agreements executed in 2006 with Alere for the marketing of our HIV tests, we were granted non-exclusive licenses to certain lateral flow patents for certain products manufactured and marketed by Chembio including but not limited to our lateral flow HIV tests. This license allows us to produce, market and sell assays using lateral flow technologies specifically including our STAT-PAK®, SURE CHECK®, DIPSTICK®, and veterinary product lines. Under this license agreement, prior to February 3, 2015, we paid royalties to Alere ranging from 5% to 8½%, depending upon the country in which the products are sold. Even though the relevant patent has expired in most other jurisdictions, or were never issued in markets where we have sold these products, our manufacture of the products in the United States has required that we pay royalties under this license, which has been a substantial expense. In 2015 our lateral flow royalty expense to Alere was $30,000, and since 2007 we have incurred a total of $2.87 million in lateral flow royalty expenses. As of February 3, 2015 this royalty expense was no longer payable as the applicable patent expired at that time.

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

its lateral flow intellectual property, although some of the main patents have expired and we are not aware of any patent enforcement litigation that is ongoing with respect to the Alere lateral flow intellectual property.

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

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

Corporate History

On May 5, 2004, we completed a merger with Trading Solutions, Inc. through which Chembio Diagnostic Systems Inc. became our wholly-owned subsidiary, and through which the management and business of Chembio Diagnostic Systems Inc. became our management and business. As part of this transaction, we changed our name to Chembio Diagnostics, Inc. In 2003, we had sold our prior business, and as a result, we had no specific business immediately prior to the merger.

Since the formation of Chembio Diagnostic Systems Inc. in 1985, it has been involved in developing, manufacturing, selling and distributing in-vitro diagnostic tests, including rapid tests beginning in 1995, for a number of conditions in humans and animals.

On March 12, 2004, we implemented a 1-for-17 reverse split of our common stock. All references herein to shares of our common stock have been adjusted to reflect this reverse split.

On May 30, 2012, the Company effected a 1-for-8 reverse split of its common stock. This was done to allow the Company to move to the NASDAQ trading market from the OTCQB market, which occurred on June 7, 2012. 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 this reverse stock split also has been retroactively reflected for all periods in these financial statements.

Stockholder Rights Agreement

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

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

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

Glossary

AIDS	Acquired Immunodeficiency Syndrome. AIDS is caused by the Human Immunodeficiency Virus, HIV.
ALGORITHM (parallel or serial)	For rapid HIV testing this refers both to method or protocol (in developing countries to date) for using rapid tests from different manufacturers in combination to screen and confirm patients at the point-of-care, and may also refer to the specific tests that have been selected by an agency or ministry of health to be used in this way. A parallel algorithm uses two screening tests from different manufacturers and a tie-breaker test only if there is a discrepancy between the screening tests results. A serial algorithm only uses a second confirmatory test if there is a positive result from the screening test, meaning that the number of confirmatory tests used is equal to the positivity rate in the testing venue. A tie-breaker test resolves discrepancies between the screen and the confirmatory test.
ANTIBODY	A protein which is a natural part of the human immune system produced by specialized cells to neutralize antigens, including viruses and bacteria that invade the body. Each antibody producing cell manufactures a unique antibody that is directed against, binds to and eliminates one, and only one, specific type of antigen.
ANTIGEN	Any substance which, upon entering the body, stimulates the immune system leading to the formation of antibodies. Among the more common antigens are bacteria, pollens, toxins, and viruses.
ANVISA	The National Health Surveillance Agency of Brazil
ARVs	Anti-retroviral medications developed to fight AIDS
CDC	United States Centers for Disease Control and Prevention
CLIA waiver	Clinical Laboratory Improvement Act designation that allows simple tests to be performed in point-of-care settings such as doctor's offices, walk-in clinics and emergency rooms.
DIAGNOSTIC	Pertaining to the determination of the nature or cause of a disease or condition. Also refers to reagents or procedures used in diagnosis to measure proteins in a clinical sample.
FIOCRUZ	The Oswaldo Cruz Foundation of Brazil
FDA	United States Food and Drug Administration
IgG	IgG or Immunoglobulin are proteins found in human blood. This protein is called an "antibody" and is an important part of the body's defense against disease. When the body is attacked by harmful bacteria or viruses, antibodies help fight these invaders.
NGO	Non-Governmental Organization
OTC	Over-the-Counter
PEPFAR	The President's Emergency Plan for AIDS Relief
PMA	Pre-Marketing Approval –FDA approval classification for a medical device that is not substantially equivalent to a legally marketed device or is otherwise required by statute to have an approved application. Rapid HIV tests must have an approved PMA application before marketing of such a product can begin.
PROTOCOL	A procedure pursuant to which an immunodiagnostic test is performed on a particular specimen in order to obtain the desired reaction.
REAGENT	A chemical added to a sample under investigation in order to cause a chemical or biological reaction which will enable measurement or identification of a target substance.

RETROVIRAL	A type of virus which contains the enzyme Reverse Transcriptase and is capable of transforming infected cells to produce diseases in the host such as AIDS.
SENSITIVITY	Refers to the ability of an assay to detect and measure small quantities of a substance of interest. The greater the sensitivity, the smaller the quantity of the substance of interest the assay can detect. Also refers to the likelihood of detecting the antigen when present.
SPECIFICITY	The ability of an assay to distinguish between similar materials. The greater the specificity, the better an assay is at identifying a substance in the presence of substances of similar makeup.
USDA	U.S Department of Agriculture
WHO	World Health Organization

ITEM 1A. RISK FACTORS

You should carefully consider each of the following risk factors and all of the other information provided in this Form 10-K before purchasing our Common Stock. The risks described below are those we currently believe may materially affect us. An investment in our Company involves a high degree of risk, and should be considered only by persons who can afford the loss of their entire investment.

Risks related to our industry, business and strategy

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

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

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

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

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

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

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

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

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

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

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

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

generation tests, and this product represents a significant competitive threat to Chembio as well as to each of the other rapid HIV test manufacturers (OraSure and Trinity primarily).

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

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

More generally, the point-of-care diagnostics industry is undergoing rapid technological changes, with frequent introductions of new technology-driven products and services. As new technologies become introduced into the point-of-care diagnostic testing market, we may be required to commit considerable additional efforts, time and resources to enhance our current product portfolio or develop new products. We may not have the available time and resources to accomplish this, and many of our competitors have substantially greater financial and other resources to invest in technological improvements. We may not be able to effectively implement new technology-driven products and services or be successful in marketing these products and services to our customers, which would materially harm our operating results.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks related to our Common Stock

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

The average daily trading volume of our Common Stock on the NASDAQ market was approximately 21,600 shares per day over the three months ended December 31, 2015 as compared with approximately 109,000 shares per day over the three months ended December 31, 2014. The liquidity of our stock depends on several factors, including but not limited to the financial results of the Company and overall market conditions, so it is not possible to predict whether this level of liquidity will continue, be sustained, or decrease.

Decreased trading volume in our stock would make it more difficult for investors to sell their shares in the public market at any given time at prevailing prices. Our management and larger stockholders exercise significant control over the Company.

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

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

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

ITEM 2. PROPERTIES

Our manufacturing, administrative offices and research facilities are located in Medford, New York. In addition we have warehousing space as well as some additional administrative offices located in Holbrook, New York. We lease approximately 39,660 square feet of industrial space in Medford for $27,988 per month. The space is utilized for research and development activities (approximately 5,440 square feet), offices (approximately 2,640 square feet) and production (approximately 31,580 square feet). The lease term expires on April 30, 2017. The lease provides for annual increases of two and one-half percent each year starting May 1, 2015. We lease approximately 21,450 square feet of industrial space in Holbrook for $15,097 per month. The space is utilized for offices (approximately 2,500 square feet) and warehousing (approximately 18,950 square feet). The lease term expires on April 30, 2018. The lease provides for annual increases of three percent each year starting March 1, 2015. The Company believes this space should be sufficient for its needs in the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. We know of no material, existing or pending legal proceedings against us, nor are we involved as a plaintiff in any material proceeding or pending litigation. There are no proceedings in which any of our directors, officers or affiliates, or any registered or beneficial shareholder, is an adverse party or has a material interest that is adverse to our interest.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our stock is quoted on the NASDAQ, under the symbol "CEMI." The table below sets forth the high and low bid prices per share of our common stock for each quarter of our two most recently completed fiscal years. These prices represent inter-dealer quotations without retail markup, markdown, or commission and may not necessarily represent actual transactions.

Fiscal Year 2015	**High Bid**		**Low Bid**
First Quarter	$	4.18	$3.41
Second Quarter	$	5.21	$3.90
Third Quarter	$	5.19	$2.85
Fourth Quarter	$	5.48	$3.48
Fiscal Year 2014	**High Bid**		**Low Bid**
First Quarter	$	3.88	$2.81
Second Quarter	$	3.56	$2.81
Third Quarter	$	3.85	$3.02
Fourth Quarter	$	5.19	$3.40

Holders

As of March 1, 2016, there were approximately 139 record owners of our common stock.

Dividends

The Company has never paid cash dividends on its common stock and has no plans to do so in the foreseeable future.

Recent Sales of Unregistered Securities

Not applicable.

ITEM 6. SELECTED FINANCIAL DATA

Presented in this table are selected financial data for the past five years ended December 31, 2015.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
SELECTED HISTORICAL FINANCIAL DATA
As of and For the Years Ended

Statement of Operations Data:	December 31, 2015		December 31, 2014		December 31, 2013		December 31, 2012		December 31, 2011	
TOTAL REVENUES	$ 24,255,485		$ 27,645,284		$ 29,549,609		$ 25,610,595		$ 19,388,036	
GROSS MARGIN[1]	10,486,827	43%	10,814,023	39%	12,300,159	42%	10,789,991	42%	9,390,303	48%
OPERATING COSTS:										
Research and development expenses[1]	6,377,839	26%	4,832,537	17%	5,834,249	20%	4,486,302	18%	4,878,119	25%
Selling, general and administrative expenses[1]	7,663,035	32%	7,531,739	27%	5,461,083	18%	4,851,587	19%	3,424,297	18%
	14,405,874		12,364,276		11,295,332		9,337,889		8,302,416	
INCOME (LOSS) FROM OPERATIONS	(3,554,047)		(1,550,253)		1,004,827		1,452,102		1,087,887	
OTHER INCOME (EXPENSES):	(3,238)		132		12,943		(1,584)		(12,325)	
INCOME (LOSS) BEFORE INCOME TAXES[1]	(3,557,285)	(15%)	(1,550,121)	(6%)	1,017,770	3%	1,450,518	6%	1,075,562	6%
Income tax provision (benefit)	(1,160,243)		(412,918)		486,952		509,237		(5,133,229)	
NET INCOME (LOSS)	$ (2,397,042)		$ (1,137,203)		$ 530,818		$ 941,281		$ 6,208,791	
Basic income (loss) per share	$ (0.25)		$ (0.12)		$ 0.06		$ 0.12		$ 0.79	
Diluted income (loss) per share	$ (0.25)		$ (0.12)		$ 0.06		$ 0.11		$ 0.73	
Weighted average number of shares outstanding, basic	9,626,028		9,530,320		8,994,080		7,986,030		7,874,807	
Weighted average number of shares outstanding, diluted	9,626,028		9,530,320		9,519,968		8,614,944		8,556,284	
Balance Sheet Data:										
Working capital	$ 9,479,968		$ 12,372,169		$ 4,221,011		$ 7,630,368		$ 6,133,956	
Total assets	20,816,344		25,010,192		24,486,592		17,335,150		15,485,744	
Total liabilities	3,154,838		5,286,030		4,309,490		3,460,630		2,991,110	
Shareholders' equity	17,661,506		19,724,162		20,177,102		13,874,520		12,494,634	

[1] percentage shown reflects the percentage of total revenues

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

This discussion and analysis should be read in conjunction with the accompanying Consolidated Financial Statements and related notes. Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of any contingent liabilities at the financial statement date and reported amounts of revenue and expenses during the reporting period. On an ongoing basis, we review our estimates and assumptions. Our estimates are based on our historical experience and other assumptions that we believe to be reasonable under the circumstances. Actual results are likely to differ from those estimates under different assumptions or conditions, but we do not believe such differences will materially affect our financial position or results of operations. Our critical accounting policies, the policies we believe are most important to the presentation of our financial statements and require the most difficult, subjective and complex judgments, are outlined below in "Critical Accounting Policies," and have not changed significantly.

In addition, certain statements made in this report may constitute "forward-looking statements". These forward-looking statements involve known or unknown risks, uncertainties and other factors that may cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These factors include, among others, 1) our ability to obtain necessary regulatory approvals for our products; and 2) our ability to increase revenues and operating income, which is dependent upon our ability to develop and sell our products, general economic conditions, demand for our products, and other factors. You can identify forward-looking statements by terminology such as "may," "could", "will," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continues" or the negative of these terms or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

Except as may be required by applicable law, we do not undertake or intend to update or revise our forward-looking statements, and we assume no obligation to update any forward-looking statements contained in this report as a result of new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. You should carefully review and consider the various disclosures we make in this report and our other reports filed with the Securities and Exchange Commission that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

All of the Company's future products that are currently being developed are based on its patented Dual Path Platform (DPP®), which is a unique diagnostic point-of-care platform that has certain advantages over lateral flow technology. The Company has completed development of several products that employ the DPP® technology which are currently marketed under Chembio's label (DPP® HIV 1/2 Screening Assay and DPP® HIV 1/2 –Syphilis Assay), or which may be marketed pursuant to private label license or distribution agreements such as those with the Oswaldo Cruz Foundation ("FIOCRUZ") and Bio-Rad.

Research and development ("R&D"), milestone, and grant and royalty revenues for the year ended December 31, 2015 increased to $2,369,000 from $1,696,000 in the prior-year, which was the result of additional grants awarded in 2015 over 2014. R&D expenses in the year of 2015 were $6.38 million, compared with $4.83 million in the prior-year.

Research & Development Activities

Sexually Transmitted Disease

- DPP® HIV-Syphilis Assay: The DPP® HIV-Syphilis Assay is a rapid, point-of-care (POC), multiplex test for the simultaneous detection of antibodies to HIV and to Treponema Pallidum (TP) bacteria (the causative agent of syphilis). This novel combination assay was developed to address the growing concern among public health officials regarding the rising co-infection rates of HIV and syphilis as well as mother-to-child transmission (MTCT) of HIV and syphilis. The product was successfully launched in Mexico during 2014, and received approval for commercial use by the Brazilian regulatory agency, Agência Nacional de Vigilância Sanitária (ANVISA). The DPP® HIV-Syphilis Assay is the only test cleared for commercialization in Brazil for rapid, POC detection of both HIV 1/2 and syphilis. We are developing a U.S. version of the DPP® HIV-Syphilis Assay, designed to meet the performance requirements for the "reverse" algorithm that is currently in clinical use for syphilis testing in the United States. We have completed our pre-clinical studies for this product with encouraging results, and are in the final stages of clinical site selection for our U.S. clinical studies. We plan to begin this clinical trial in the U.S. during first quarter of 2016, and expect that the trial will be completed in six to nine months from initiation.

Fever Disease

- DPP® Malaria Assay: The DPP® Malaria Assay is a rapid, POC, multiplex test for the simultaneous detection of plasmodium falciparum and other plasmodium infections. In January 2015, we received a grant from The Bill & Melinda Gates Foundation to expedite the development and feasibility testing of a POC DPP® Malaria Assay. The Company recently completed this project, which compared the new DPP® Malaria Assay to the world's leading currently-available POC malaria assay. Based on initial testing, the new DPP® Malaria Assay met the major objective of the feasibility project: a ten-fold improvement in sensitivity. Given these results, we plan to develop and commercialize a family of DPP® Malaria Assays.
- DPP® Fever Panel Assay: The DPP® Fever Panel Assay is a rapid, POC, multiplex test for the simultaneous detection of Malaria, Dengue, Chikungunya, Zika, Ebola, Lassa, and Marburg. In October 2015, we received a $2.1 million grant from the Paul G. Allen Ebola Program, to develop the DPP® Fever Panel Assay and a follow-on grant to add a test for the detection of Zika virus. We plan to be ready for field testing in the fourth quarter of 2016.
- DPP® Ebola Assay and DPP® Malaria-Ebola Assay: The DPP® Ebola Assay is a rapid POC test for the detection of Ebola and the DPP® Malaria-Ebola Assay is a rapid, POC, multiplex test for the simultaneous detection of Malaria and Ebola. In October 2014, we announced plans to develop, validate, and commercialize POC DPP® Assays for Ebola and Febrile Illness. We completed the development of the DPP® Ebola Assay and submitted it for Emergency Use Authorization (EUA) with the Food & Drug Administration (FDA) and World Health Organization (WHO). During the third and fourth quarters of 2015, we sold DPP® Ebola and DPP® Malaria-Ebola Assays to the Centers for Disease Control & Prevention (CDC) for field studies in West Africa, which is ongoing.

- DPP® Dengue Fever Assay: The DPP® Dengue Fever Assay is a rapid, POC, multiplex test for the simultaneous detection of IgG/IgM and NS1 antigens. We are currently conducting verification and validation studies, and we anticipate the production of pilot lots, to support preclinical studies. We anticipate starting pre-clinical studies in the second quarter of 2016. This program is fully funded by a partner. However, under the terms of our agreement, Chembio's partner is not being disclosed.
- DPP® Zika Assays: The DPP® Zika Assay is a rapid POC stand-alone test for the simultaneous detection of IgG/IgM antibodies and the DPP® Dengue/Chikungunya/Zika Assay is a rapid, POC, multiplex test for the simultaneous detection of IgG/IgM antibodies.
- In February 2016, we received a $550,000 grant from the Paul G. Allen Family Foundation to develop the DPP® Zika Assays, which we plan to be ready for field testing in 2016.

Technology Collaboration

- DPP® Cancer Assay: The DPP® Cancer Assay is a rapid, POC, multiplex test for the early detection and monitoring of a specific type of cancer. In October 2014, we entered into collaboration with an international diagnostics company to develop a POC diagnostic test for a specific type of cancer. This program is fully funded by a partner. However, under the terms of the agreement, neither Chembio's partner nor the specific type of cancer is being disclosed. The cancer project represents an application of the DPP® technology outside of the infectious disease field, and the scope of the agreement involves product development of a quantitative, reader-based cancer assay for two cancer markers, utilizing Chembio's DPP® technology and DPP® Micro Reader. During the third quarter of 2015, we completed successful feasibility, and our partner agreed to fund continued development of the DPP® Cancer Assay.
- DPP® Traumatic Brain Injury Assay: The DPP® Traumatic Brain Injury Assay is a rapid POC test for the detection of traumatic brain injury (TBI) and sports-related concussion. In January 2015, we entered into an agreement with the Concussion Science Group (CSG) Division of Perseus Science Group LLC, to combine CSG's patented biomarker with our proprietary DPP® platform and DPP® Micro Reader, to develop a semi-quantitative or quantitative POC test, to diagnose TBI. In May 2015, an Informational Meeting was conducted at the FDA to present the technology and intended use, as well to initiate dialogue regarding the regulatory pathway for this product. The DPP® Traumatic Brain Injury Assay is in the feasibility stage. We are currently working with several hospitals to finalize institutional review board (IRB) agreements and develop the plan for conducting initial studies of the DPP® Traumatic Brain Injury Assay using patient samples.
- DPP® FLU Immunostatus Assay: The DPP® FLU Immunostatus Assay is a rapid, POC, multiplex influenza immunity test. In November 2014, we entered into a follow-on, milestone-based development agreement with a contracting organization acting on behalf of the U.S. government, for a multiplex POC influenza immunity test utilizing our patented DPP® technology. We successfully completed the product development of a 7-band multiplex DPP® Flu Immunostatus Assay with a digital reader during the first quarter of 2015 and subsequently applied for additional funding in response to a new request for proposal (RFP) from the U.S. Government, for which we expect a response in the second quarter of 2016.

Regulatory Activities

DPP® HIV 1/2 Assay: 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. The Chembio DPP® HIV 1/2 Assay for rapid, POC detection of HIV is now cleared for commercialization and sale within the 28 member states of the European Union.

DPP® HIV-Syphilis: The DPP® HIV-Syphilis Assay is a rapid, POC, multiplex test for the simultaneous detection of antibodies to HIV and to Treponema Pallidum (TP) bacteria (the causative agent of syphilis). This novel combination assay was developed to address the growing concern among public health officials regarding the rising co-infection rates of HIV and syphilis as well as mother-to-child transmission (MTCT) of HIV and syphilis. The product was successfully launched in Mexico during 2014, and received approval for commercial use by the Brazilian regulatory agency, Agência Nacional de Vigilância Sanitária (ANVISA). The DPP® HIV-Syphilis Assay is the only test cleared for commercialization in Brazil for rapid, POC detection of both HIV 1/2 and syphilis. In December 2015, the application by way of technical file was submitted to the Notified Body for CE Mark consideration to commercialize within the European Union.

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

There can be no assurance that any of the aforementioned Research & Development and/or Regulatory products or activities will result in any product approvals or commercialization, nor that any of the existing research and development activities, or any new potential development programs or collaborations will materialize or that they will meet regulatory or any other technical requirements and specifications, and/or that if continued, will result in completed products, or that such products, if they are successfully completed, can or will be successfully commercialized.

Recent Events

On February 19, 2016, the Company announced it had been awarded a $550,000 grant from philanthropist and entrepreneur Paul G. Allen to immediately initiate development of simple, cost-effective POC diagnostic tests to identify Zika virus and related febrile illnesses. The grant is managed by Mr. Allen's company, Vulcan Inc., and the funds come from the Paul G. Allen Family Foundation.

On March 7, 2016, the Company announced plans to collaborate with Bio-Manguinhos/Fiocruz to undertake to develop, register and commercialize POC DPP® Zika Assays for Brazil. The Company has developed a prototype DPP® Zika Assay and prototype DPP® Zika/Dengue/Chikungunya Assay, and we hope to receive additional funding, along with the grant mentioned above, to accelerate the development and testing of our DPP® Zika Assays. The Company anticipates receiving significant orders for DPP® Zika Assays in 2016.

RESULTS OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2015 AS COMPARED WITH THE YEAR ENDED DECEMBER 31, 2014

Income:

For the year ended December 31, 2015, Loss before income taxes was $(3,557,000) compared to Loss before income taxes of $(1,550,000) for the year ended December 31, 2014. Net Loss for the 2015 period was $(2,397,000) as compared to a Net Loss of $(1,137,000) for 2014. The change in Net Loss is primarily attributable to decreased revenue and gross margin, and increased operating expenses. Gross margin decreased in the year ended December 31, 2015 as compared with the year ended December 31, 2014, by $327,000, or 3.0%. The increased operating expenses, the most significant of which were an increase in wages and related expenses of $779,000, an increase in materials and supplies for R&D of $758,000, and increased clinical trial expenses of $161,000 , partially offset by decreased commission expenses of $141,000, accounted for most of the change in Net Loss.

Revenues:

Selected Product Categories:	For the years ended December 31, 2015	December 31, 2014	$ Change	% Change
Lateral Flow HIV Tests and Components	$ 9,957,882	$ 9,518,242	$ 439,640	4.62%
DPP® Tests and Components	11,265,876	15,655,680	(4,389,804)	-28.04%
Other	662,930	775,847	(112,917)	-14.55%
Net Product Sales	21,886,688	25,949,769	(4,063,081)	-15.66%
License and royalty revenue	52,753	23,257	29,496	126.83%
R&D, milestone and grant revenue	2,316,044	1,672,258	643,786	38.50%
Total Revenues	$ 24,255,485	$ 27,645,284	$ (3,389,799)	-12.26%

Revenues for our lateral flow HIV tests and related components during the year ended December 31, 2015 increased by approximately $440,000 from the same period in 2014. This was primarily attributable to increased sales to Africa, of approximately $1,576,000 and increased sales to Europe of $973,000, partially offset by decreased sales to the U.S. of $1,604,000, and decreased sales to Mexico of $458,000. Revenues for our DPP® products during the year ended December 31, 2015 decreased by approximately $4,390,000 over the same period in 2014, primarily for decreases in sales in Mexico of $3,455,000 and decreases in sales in Brazil to FIOCRUZ of $2,112,000, partially offset by increased sales in the U.S. of $1,011,000. The increase in R&D, and in milestone and grant revenue, was primarily due to revenues from certain development projects that were awarded during the period. R&D revenues include funds, recognized on an "as expenses are incurred" basis or on a milestone basis, from various grants, see footnote 14 of our financial statements.

Gross Margin:

Gross Margin related to Net Product Sales:	For the years ended December 31, 2015	December 31, 2014	$ Change	% Change
Gross Margin per Statement of Operations	$ 10,486,827	$ 10,814,023	$ (327,196)	-3.03%
Less: R&D, milestone, grant, license and royalties	2,368,797	1,695,515	673,282	39.71%
Gross Margin from Net Product Sales	$ 8,118,030	$ 9,118,508	$ (1,000,478)	-10.97%
Product Gross Margin %	37.09%	35.14%		

The overall gross margin dollar decrease of $327,000 included a $1,000,000 decrease in gross margin from net product sales and a $673,000 increase in non-product revenues. The decrease in net product sales gross margin of $1,000,000 is primarily attributable to the change in product sales compared to 2014. The net product sales gross margin decrease is comprised of two components, one is the decrease in product sales of $4,063,000, which at the 35.1% margin contributed $1,428,000 to the decrease, and the other is the increased change in margin percentage of 2.0% which contributed the balance of $427,000. The 2.0% increase in the percentage, from 35.1% in 2014 to 37.1% in 2015, was primarily due to increased efficiencies from our operations excellence program.

Research and Development:

This category includes costs incurred for clinical and regulatory affairs and for product research and development.

Selected expense lines:	For the years ended			
	December 31, 2015	December 31, 2014	$ Change	% Change
Clinical and Regulatory Affairs:				
Wages and related costs	$ 490,802	$ 448,852	$ 41,950	9.35%
Consulting	44,135	29,741	14,394	48.40%
Stock-based compensation	-	3,231	(3,231)	-100.00%
Clinical trials	366,469	205,589	160,880	78.25%
Other	80,960	93,780	(12,820)	-13.67%
Total Regulatory	982,366	781,193	201,173	25.75%
R&D Other than Regulatory:				
Wages and related costs	2,896,226	2,456,514	439,712	17.90%
Consulting	128,117	123,965	4,152	3.35%
Stock-based compensation	62,713	41,306	21,407	51.83%
Materials and supplies	1,779,046	1,021,516	757,530	74.16%
Other	529,371	408,043	121,328	29.73%
Total other than Regulatory	5,395,473	4,051,344	1,344,129	33.18%
Total Research and Development	**$ 6,377,839**	$ 4,832,537	$ 1,545,302	31.98%

Expenses for Clinical and Regulatory Affairs for the year ended December 31, 2015 increased by $201,000 as compared to the same period in 2014. This was primarily due to an increase of $161,000 in clinical trial expenses and increased wages and related costs of $42,000.

R&D expenses other than Clinical & Regulatory Affairs increased by $1,344,000 in the year ended December 31, 2015, as compared with the same period in 2014. The increases were primarily related to an increase in wages and related costs, and in material and supplies, to support our sponsored research and internal development programs.

Selling, General and Administrative Expense:

Selected expense lines:	For the years ended			
	December 31, 2015	December 31, 2014	$ Change	% Change
Wages and related costs	$ 3,060,407	$ 2,763,370	$ 297,037	10.75%
Consulting	311,488	456,658	(145,170)	-31.79%
Commissions	1,291,453	1,432,567	(141,114)	-9.85%
Stock-based compensation	271,674	399,334	(127,660)	-31.97%
Marketing materials	223,445	345,426	(121,981)	-35.31%
Investor relations/investment bankers	204,198	168,410	35,788	21.25%
Legal, accounting and compliance	879,887	662,522	217,365	32.81%
Travel, entertainment and trade shows	448,599	320,280	128,319	40.06%
Bad debt allowance (recovery)	-	28,000	(28,000)	-100.00%
Other	971,884	955,172	16,712	1.75%
Total S, G &A	**$ 7,663,035**	**$ 7,531,739**	**$ 131,296**	**1.74%**

Selling, general and administrative expenses for the year ended December 31, 2015, increased by $131,000 as compared with the same period in 2014, a 1.7% increase. This increase resulted primarily from increases in wages and related costs and travel expenses, which for 2015 included the continued development of a sales and marketing team over 2014, professional fees and in investor relations/investment bankers, which were partially offset by decreases in consulting, commissions (due to decreased sales to Brazil), stock-based compensation, and marketing materials.

Other Income and Expense:

	For the years ended			
	December 31, 2015	December 31, 2014	$ Change	% Change
Other (expense)	$ (4,814)	$ (5,707)	$ 893	15.65%
Interest income	2,412	5,839	(3,427)	-58.69%
Interest expense	(836)	-	(836)	100.00%
	-	-	-	
Total Other Income and (Expense)	$ (3,238)	$ 132	$ (3,370)	-2,553.03%

Other (expense) for the year ended December 31, 2015 decreased approximately $3,400, primarily due to decreased interest income, compared to the same period in 2014.

Income tax provision (benefit):

For the year ended December 31, 2015 the Company recognized a $(1,160,000) income tax benefit and increased its deferred tax assets by $(1,160,000). For the year ended December 31, 2014, the Company recognized a $(413,000) income tax benefit and increased its deferred tax assets by $(403,000). The effective tax rate used to recognize the benefit in 2015 was 32.0% compared to a 26.6% rate used in 2014 to record the amount charged. In both years non-deductible expenses for tax purposes accounted for most of the difference from the standard 34% U.S. tax rate. The Company maintains a full valuation allowance on research and development tax credits

MATERIAL CHANGES IN FINANCIAL CONDITION

Selected Changes in Financial Condition	As of			
	December 31, 2015	December 31, 2014	$ Change	% Change
Cash and cash equivalents	$ 5,376,931	$ 4,614,538	$ 762,393	16.52%
Accounts receivable, net of allowance for doubtful accounts of $52,000 and $52,000 at December 31, 2015 and 2014, respectively	2,422,971	8,338,889	(5,915,918)	-70.94%
Prepaid expenses and other current assets	1,256,879	1,066,473	190,406	17.85%
Fixed assets, net of accumulated depreciation	2,374,308	2,797,929	(423,621)	-15.14%
License agreements, net of current portion	100,000	256,875	(156,875)	-61.07%
Deferred tax asset, net of valuation allowance	5,467,143	4,031,302	1,435,841	35.62%
Accounts payable and accrued liabilities	2,801,432	4,946,030	(2,144,598)	-43.36%

Cash increased by $762,000 from December 31,2014, primarily due to net cash provided by operating activities for the year of 2015. In addition there were decreases in accounts receivable, net of allowance, of $5,916,000, fixed assets of $424,000 after depreciation, license agreements of $157,000, accounts payable and accrued liabilities of $2,145,000, and increases in non-current deferred tax asset of $1,436,000 and in prepaid expenses of $190,000.

The decrease in accounts receivable was primarily attributable to the lower amount of credit sales at the end of December 2015 versus December 2014. The decrease in fixed assets is primarily due to depreciation. The increase in prepaid and other current assets is due to the current portion of additional licenses. Deferred tax asset decrease is related to recording of a valuation allowance.

LIQUIDITY AND CAPITAL RESOURCES

	For the years ended			
	December 31, 2015	December 31, 2014	$ Change	% Change
Net cash provided by (used in) operating activities	$ 1,792,978	$ (3,820,299)	$ 5,613,277	146.93%
Net cash used in investing activities	(1,030,585)	(1,452,601)	422,016	29.05%
Net cash provided by financing activities	-	237,163	(237,163)	-100.00%
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	$ 762,393	$ (5,035,737)	$ 5,798,130	115.14%

The Company's cash increased as of December 31, 2015 by $762,000 from December 31, 2014, primarily due to net cash provided by operating activities and partially offset by cash used in investing activities for year of 2015.

The cash provided by operations in 2015 was $1,793,000, primarily due to a decrease in accounts receivable of $5,916,000, a decrease in inventories of $60,000 and an increase in deferred revenue of $13,000, partially offset by an increase in prepaid and other current assets of $191,000, a decrease in accounts payable and other accrued liabilities of $2,145,000 and a net loss net of non-cash items of $1,861,000. Net loss net of non-cash items includes net loss of $2,397,000, $1,171,000 in income tax benefit, partially offset by $1,373,000 in depreciation and amortization, and $334,000 in share-based compensation. The use of cash from investing activities is primarily the purchase of fixed assets and acquisition of licenses.

Fixed Asset Commitments

As of December 31, 2015, the Company had paid deposits on various pieces of equipment aggregating $30,918 which is reflected in Other Assets on the balance sheet. The Company is further committed to additional equipment-purchase obligation of $31,000 as various milestones are achieved by the various vendors.

RECENT DEVELOPMENTS AND CHEMBIO'S PLAN OF OPERATIONS FOR THE NEXT TWELVE MONTHS

During 2015, Chembio took important strategic steps to expand our patented DPP® technology to new markets. While the Company continues to strengthen its sexually transmitted disease business, we are also building robust product pipelines in two new areas: fever disease and technology collaborations. As sexually transmitted disease products continue to make important contributions to our business, we believe our new fever disease portfolio and technology collaborations will pave the way for future growth.

Sexually Transmitted Diseases

In the U.S. during 2015, Chembio recorded an increase in lateral flow sales of approximately $440,000 and an increase of DPP® sales of more than $1.0 million (primarily as a result of sales to the CDC for DPP® Malaria-Ebola and DPP® Ebola Assays), as compared to the respective U.S. sales in 2014. We are optimistic about the increasing demand for our products in the U.S. We will also have full control of SURE CHECK® HIV Assay, effective June 1, 2016, to add to our U.S. commercial efforts.

In Latin America, we experienced a decline in sales in 2015 due primarily to a $3.5 million decrease in sales of DPP® HIV-Syphilis Assay in Mexico, related to excess inventory from 2014, and a $2.1 million decrease in sales of DPP® HIV Assay in Brazil. We expect that our recently announced DPP® Zika Assay program will expand our sales in this region, and given our initial indications for 2016, we believe Latin America will continue to be a strong market for Chembio.

In Europe, Chembio's partners, AAZ and BioSure, launched sales of Chembio's SURE CHECK® HIV 1/2 self-testing kits in the U.K. and France, respectively. The launch of these private-label, self-testing kits in Europe was a great success, and we received kit orders that totaled approximately $1.0 million in 2015. HIV continues to pose a significant threat in Europe, and European health agencies aggressively promote the importance of testing for HIV. We believe our SURE CHECK® HIV 1/2 product is particularly well-suited for the emerging European self-testing segment, given its ability to provide simple, fast and reliable detection of antibodies to HIV 1 and HIV 2.

Another important advancement in our sexually transmitted disease business during 2015 is the progress made with our DPP® HIV-Syphilis Assay for the U.S. market. It is an important corporate priority to be the first-to-market in the U.S. with an HIV-Syphilis combination test. While the Company is already successfully marketing a DPP® HIV-Syphilis combo assay in Latin America, regulatory standards require additional enhancements for the U.S. market and completion of a clinical trial. We will initiate this clinical trial in the first quarter of 2016. We anticipate that the trial will be completed in six to nine months and cost between $1.0 and $1.5 million. We are also in the process of submitting the technical dossier for CE Mark which will allow us to commercialize the DPP® HIV-Syphilis Assay in Europe.

Fever Disease

In response to the Ebola outbreak in West Africa, our fever disease business was initiated in Q4 2014, and expanded rapidly through 2015. Today we are collaborating with several of the world's leading health organizations with the goal of containing the spread of fever diseases around the globe through accurate and early diagnosis. In the last year, our fever disease product portfolio has grown to include the following highly differentiated products:

- The DPP® Fever Panel Assay which is funded by the Paul G. Allen Ebola Program, is a point-of-care (POC) test for the simultaneous detection of Malaria, Dengue Fever, Chikungunya, Zika, Ebola, Lassa and Marburg;
- The DPP® Malaria-Ebola and DPP® Ebola Assays which were developed through a research collaboration agreement with the Centers for Disease Control and Prevention (CDC), are currently being field tested in West Africa;
- The DPP® Dengue Fever Assays which have been funded by an undisclosed entity, are currently being field tested in Asia;
- The DPP® Malaria Assay which has been funded by The Bill and Melinda Gates Foundation, is 10-times more sensitive than the current world-leading POC malaria test; and,
- The recently-announced DPP® Zika Assay, which has received initial funding from the Paul G. Allen Family Foundation.
- The recently-announced plans to collaborate with Bio-Manguinhos/Fiocruz to undertake development of POC Zika tests for the Ministry of Health in Brazil.

As we are excited by each of these programs, the DPP® Fever Panel Assay and the DPP® Zika Assay in particular highlight the power, versatility and broad applicability of our DPP® technology, and we believe both of these products to be truly groundbreaking. Our DPP® Fever Panel Assay will be the first POC diagnostic test capable of testing for multiple fever diseases simultaneously. We believe this product will significantly improve the diagnosis and care for people in regions where there is regular exposure to fever diseases and their causes. The sensitivity, specificity and multiplexing capability of the DPP® technology uniquely suits it for the fever disease market. Many of these diseases are present in the same regions with nearly identical symptoms. These factors make it difficult to make an accurate diagnosis and often delay appropriate treatment. Today, many available POC diagnostics are limited by their lack of the sensitivity and specificity required to identify asymptomatic patients. Further, there are currently no POC diagnostics capable of testing for multiple diseases simultaneously. For these reasons, Chembio is prioritizing development of our DPP® Fever Panel Assay.

Our new DPP® Zika Assay development also showcases the exceptional versatility and broad applicability of our DPP® technology. In February, the World Health Organization (WHO) declared the Zika virus a 'public health emergency of international concern,' and today the virus has spread to more than twenty countries. In response to the outbreak, we began exploring the feasibility of a POC DPP® Zika Assay. We are fortunate that the Paul G. Allen Family Foundation, recognizing the urgency of the matter, moved swiftly to provide Chembio with a grant to support the initiation of the project. We are pleased to report that in a few short weeks, we have developed a prototype assay and are in discussions with a number of agencies, all of which are interested in supporting the rapid development of this critical product. While this program is in the early stages, we hope that success with the DPP® Zika Assay, like our DPP® Ebola Assay, will further demonstrate Chembio's ability to rapidly and effectively deploy our DPP® technology to address the world's most serious health threats with POC treatment in a practical and efficient manner. The Company anticipates receiving significant orders for DPP® Zika Assays in 2016.

Technology Collaborations

Chembio's technology collaborations represent another important business area for the Company. In the fourth quarter of 2014, we signed collaborative agreements for both the development of the DPP® Cancer Assay for a specific form of cancer, and also for the DPP® Flu Immunostatus Assay. In 2015, we added two more important new collaborations for the development of the DPP® Traumatic Brain Injury Assay and the DPP® Micro Reader.

We are pleased with the progress made with each of these programs in 2015. The DPP® Cancer Assay, which is funded by an undisclosed entity, targets a specific form of cancer. During 2015, we successfully completed the feasibility phase of the program and moved into the product development stage, which is also funded by an undisclosed entity. The results to-date with this program have been highly encouraging. With success, we are hopeful that we'll be able to find additional applications for our DPP® technology in the broader oncology market.

We also made important advances with our DPP® Traumatic Brain Injury Assay program during the year. This project, which is funded by Perseus Science Group, LLC, is in the feasibility phase. We are currently working with several hospitals to finalize institutional review board (IRB) agreements and develop the plan for conducting initial studies of the DPP® Traumatic Brain Injury Assay using patient samples.

We are awaiting response on the most recent multi-year grant proposal for completion of the DPP® Flu Immunostatus Assay, a multiplex assay to monitor 9 different seasonal and pandemic flu viruses.

An addtional new technology collaboration was signed in the fourth quarter of 2015 with opTricon, a leading developer of mobile analysis devices for rapid diagnostic tests. Through our exclusive agreement, Chembio will launch the DPP® Micro Reader to complement a number of our proprietary assays for sexually transmitted diseases, certain fever diseases, and a specific form of cancer. We are particularly excited about offering this technology in combination with our assays. 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. Because the DPP® Micro Reader is simple, fast, palm-sized, battery-operated and cost-effective compared to traditional POC assay readers, it is unique in its attractiveness and utility, and we believe it will be well-received by the market. We are working to develop a suite of DPP® Assay-Reader kits, and we look forward to commercialization of these innovative and versatile diagnostic systems.

2015 was an exciting and transformative time for Chembio. During the year, we significantly expanded the horizon for the utility of our DPP® technology. This has led us to new and exciting applications beyond HIV to fever disease, brain injury, cancer and more. And in a short amount of time, we gained the attention of, and funding from, world-leading health organizations such as The Bill and Melinda Gates Foundation, the Paul G. Allen Family Foundation, the Centers for Disease Control and Prevention and Perseus Science who have aligned with Chembio and selected the DPP® technology to address some of the world's most serious diagnostic obstacles. The events and opportunities of 2015 have considerably changed Chembio by significantly expanding the potential application and markets for our DPP® technology. For many diseases, infections or conditions that requires exceptional sensitivity, specificity and/or the ability to multiplex, we believe our DPP® technology may become the development platform of choice. Looking ahead to 2016, we will continue to advance each of our development programs, and look for new opportunities and applications.

Critical Accounting Policies and Estimates

The preparation of the financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ materially from those estimates.

We believe that there are several accounting policies that are critical to understanding our historical and future performance, as these policies affect the reported amounts of revenue and the more significant areas involving management's judgments and estimates. These significant accounting policies relate to revenue recognition, research and development costs, valuation of inventory, valuation of long-lived assets and income taxes. These policies, and the related procedures, are described in detail below.

Revenue Recognition –

We recognize revenue for product sales in accordance with ASC 605, Revenue is recognized when there is persuasive evidence of an arrangement, delivery has occurred or services have been rendered, the sales price is determinable, and collectability is reasonably assured. Revenue typically is recognized at time of shipment. Sales are recorded net of discounts, rebates and returns.

For certain contracts, we recognize revenue from R&D, milestone and grant revenues when earned. Grants are invoiced after expenses are incurred. Revenues from projects or grants funded in advance are deferred until earned.

For certain collaborative research projects, we recognize revenue by defining milestones at the inception of the agreement and applying the milestone method of revenue recognition for relevant contracts.

Stock-Based Compensation –

We recognize the fair value of equity-based awards as compensation expense in our statement of operations. The fair value of our stock option awards was estimated using a Black-Scholes option valuation model. This valuation model's computations incorporate highly subjective assumptions, such as the expected stock price volatility and the estimated life of each award. The fair value of the options, after considering the effect of expected forfeitures, is then amortized, generally on a straight-line basis, over the related vesting period of the option. The fair value of our restricted shares is based on the market value of the shares at the date of grant and is recognized on a straight-line basis over the related vesting period of the award.

Research & Development Costs –

Research and development activities consist primarily of new product development, continuing engineering for existing products, regulatory and clinical trial costs. Costs related to research and development efforts on existing or potential products are expensed as incurred.

Valuation of Inventories –

Inventories are stated at the lower of cost or market, using the first-in, first-out method (FIFO) to determine cost. Our policy is to periodically evaluate the market value of the inventory and the stage of product life cycle, and record a reserve for any inventory considered slow moving or obsolete. For example, each additional 1% of obsolete inventory would reduce such inventory by approximately $36,000.

Allowance for doubtful accounts –

Our policy is to review our accounts receivable on a periodic basis, no less than monthly. On a quarterly basis an analysis is made of the adequacy of our allowance for doubtful accounts and adjustments are made accordingly. The current allowance is approximately 2% of accounts receivable. For example each additional 1% of accounts receivable that becomes uncollectible would reduce such balance of accounts receivable by approximately $24,000.

Income Taxes –

Income taxes are accounted for under ASC 740 authoritative guidance ("Guidance") which requires the asset and liability method of accounting for deferred income taxes. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities. Deferred tax assets or liabilities at the end of each period are determined using the tax rate expected to be in effect when taxes are actually paid or recovered.

The Guidance also requires that a valuation allowance be established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence needs to be considered, including a company's current and past performance, the market environment in which the company operates, length of carryback and carryforward periods and existing contracts that will result in future profits. The Company believes that it will be able to utilize its net operating loss carryforwards and has recorded a deferred tax asset. The Company still maintains a full valuation allowance on research and development tax credits.

The Guidance also prescribes a comprehensive model for recognizing, measuring, presenting and disclosing in the consolidated financial statements tax positions taken or expected to be taken on a tax return, including a decision whether to file or not to file in a particular jurisdiction.

The above listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by accounting principles, generally accepted in the United States of America, with no need for management's judgment in their application. There are also areas in which management's judgment in selecting any viable alternative would not produce a materially different result. See our audited financial statements and notes thereto which contain accounting policies and other disclosures required by accounting principles generally accepted in the United States of America.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The Consolidated Financial Statements and schedules that constitute Item 8 are attached at the end of this Annual Report on Form 10-K. An index to these Financial Statements and schedules is also included on page F-1 of this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

Not Applicable.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures. Under the supervision and with the participation of our senior management, consisting of our chief executive officer and our chief financial officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of the end of the period covered by this report (the "Evaluation Date"). Based on that evaluation, the Company's management, including our chief executive officer and chief financial officer, concluded that as of the Evaluation Date our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in our Exchange Act reports is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control Over Financial Reporting. The Company's management is responsible for establishing and maintaining an adequate system of internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f)). Our internal control over financial reporting is a process, under the supervision of our chief executive officer and chief financial officer, designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States. These internal controls over financial reporting processes include policies and procedures that:

a. Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;

b. Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and

c. Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance of achieving their control objectives.

In evaluating the effectiveness of our internal control over financial reporting, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework 2013. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our internal control over financial reporting was effective as of December 31, 2015.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting.

Management's report was not subject to attestation by our registered public accounting firm pursuant to the rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this annual report.

(b) Changes in Internal Control over Financial Reporting. There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or Rule 15d-15 under the Exchange Act that occurred during the Company's last fiscal quarter of the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors and Executive Officers

John J. Sperzel (52), President, Chief Executive Officer and Director. Mr. Sperzel was appointed Chief Executive Officer and President of Chembio Diagnostics, Inc. and a member of our Board in March 2014. Prior to joining the Company, Mr. Sperzel, was the President and CEO of International Technidyne Corporation (ITC) from September 2011 to December 2013. Mr. Sperzel served as President at Axis-Shield from September 2004 to September 2011. He also has held senior leadership positions at Bayer Diagnostics (Siemens Dx), Instrumentation Laboratory, and Boehringer Mannheim Diagnostics (Roche Dx). Mr. Sperzel graduated from Plymouth State College in New Hampshire, with a B.S. in Business Administration/Management. He currently serves on the board of directors of Diadexus, Inc., a company which the common stock is registered under the Securities Exchange Act of 1934, and as an advisor to the board of the Diagnostic Marketing Association, and was the president of the board of that Association in 2007. Mr. Sperzel's knowledge of, and experience in, the Company's specific business and its industry sector, together with the continuing current knowledge that he is accumulating about the Company in his position as CEO of the Company, made him an excellent candidate for serving on the Board.

Richard J. Larkin (59), Chief Financial Officer. Mr. Larkin was appointed as Chief Financial Officer of Chembio Diagnostics, Inc. upon consummation of the merger in 2004. Mr. Larkin oversees our financial activities and information systems. Mr. Larkin has been the Chief Financial Officer of Chembio Diagnostic Systems Inc. since September 2003. Prior to joining Chembio Diagnostic Systems Inc., Mr. Larkin served as CFO at Visual Technology Group ("VTG") from May 2000 to September 2003, and also led VTG's consultancy program that provided hands-on expertise in all aspects of financial service, including the initial assessment of client financial reporting requirements within an Enterprise Resource Planning (Manufacturing) environment through training and implementation. Prior to joining VTG, he served as CFO at Protex International Corporation from May 1987 to January 2000. Mr. Larkin holds a BBA in Accounting from Dowling College and is a member of the American Institute of Certified Public Accountants.

Javan Esfandiari (49), Chief Science and Technology Officer. Mr. Esfandiari joined Chembio Diagnostic Systems, Inc, in 2000. Mr. Esfandiari co-founded, and became a co-owner of Sinovus Biotech AB where he served as Director of Research and Development concerning lateral flow technology until Chembio Diagnostic Systems Inc. acquired Sinovus Biotech AB in 2000. From 1993 to 1997, Mr. Esfandiari was Director of Research and Development with On-Site Biotech/National Veterinary Institute, Uppsala, Sweden, which was working in collaboration with Sinovus Biotech AB on development of veterinary lateral flow technology. Mr. Esfandiari received his B.Sc. in Clinical Chemistry and his M. Sc. in Molecular Biology from Lund University, Sweden. He has published articles in various veterinary journals and has co-authored articles on tuberculosis serology with Dr. Lyashchenko.

Sharon Klugewicz (48), Chief Operating Officer. Prior to joining the Company in September 2012, Ms. Klugewicz, served as Senior Vice President, Scientific & Laboratory Services at Pall Corporation (NYSE:PLL), a world leader in filtration, separation and purification technologies. Prior to that, Ms. Klugewicz held a number of positions at Pall Corporation over her 20-year tenure there, including in the Pall Life Sciences Division, in Marketing Product Management, and Field Technical Services, which included a position as Senior Vice President, Global Quality Operations. Ms. Klugewicz holds an M.S. in Biochemistry from Adelphi University and a B.S. in Neurobiology from Stony Brook University.

Dr. Gary Meller M.D. (65), Director. Dr. Meller was elected to our Board of Directors on March 15, 2005, and currently serves on the Board's Audit, and Nominating And Corporate Governance Committees, including as Chairman of the Audit Committee. Dr. Meller has been the president of CommSense Inc., a healthcare business development company, since 2001. CommSense Inc. works with clients in Europe, Asia, North America, and the Middle East on medical information technology, medical records, pharmaceutical product development and financing, health services operations and strategy, and new product and new market development. From 1999 until 2001 Dr. Meller was the executive vice president, North America, of NextEd Ltd., a leading internet educational services company in the Asia Pacific region. Dr. Meller also was a limited partner and a member of the Advisory Board of Crestview Capital Master LLC, which was our largest shareholder. Dr. Meller is a graduate of the University of New Mexico School of Medicine and has an MBA from the Harvard Business School. Dr. Meller's experience in the medical field both domestic and foreign (especially his experience with CommSense Inc.) as well as his financing experience make him an excellent candidate for serving on the board.

Kathy Davis (59), Director and Chair of the Board. Ms. Davis was elected to the Board in May 2007, and was elected in March 2014 to serve as Chair of the Board. She currently serves on the Board's Audit, Compensation, and Nominating And Corporate Governance Committees, including as Chair of the Nominating And Corporate Governance Committee. In 2014, Ms. Davis also served on the Board's CEO Search Committee, and in 2013 she served on the Board's Special Committee for handling certain strategic opportunities. Since January 2007, Ms. Davis has been the owner of Davis Design Group LLC, a company that provides analytical and visual tools for public policy design. As of January 1 2016 Ms. Davis serves as Systems Advisor to the Mayor of Indianapolis. Previously, from February 2005 to December 2006, she served as the Chief Executive Officer of Global Access Point, a start-up company with products for data transport, data processing, and data storage network and hub facilities. From October 2003 to January 2005, Ms. Davis was Lieutenant Governor of the State of Indiana, and from January 2000 to October 2003 was Controller of the City of Indianapolis. From 1989 to 2003, Ms. Davis held leadership positions with agencies and programs in the State of Indiana including State Budget Director, Secretary of Family & Social Services Administration, and Deputy Commissioner of Transportation. From 1982 to 1989 Ms. Davis held increasingly senior positions with Cummins Engine, where she managed purchasing, manufacturing, engineering, and assembly of certain engine product lines. Ms. Davis also led the startup of and initial investments by a $50 million Indiana state technology fund, serves on the not-for-profit boards of Noble of Indiana, Lumina Foundation for Education, Indianapolis Foundation, Central Indiana Community Foundation, Western Governor's University Indiana, and Indiana University School of Public and Environmental Affairs. She holds a Bachelor of Science in Mechanical Engineering from the Massachusetts Institute of Technology and an MBA from Harvard Business School. Ms. Davis has varied experience in business, political and financial areas that made her an excellent candidate for serving on the Board.

Dr. Barbara DeBuono M.D., M.P.H., (60), Director**.** Dr. DeBuono, who was elected to the Company's Board of Directors in June 2011, currently serves on the Board's Compensation and Nominating And Corporate Governance Committees, including as Chair of the Compensation Committee. Ms. DeBuono is a renowned expert in public health innovation, health policy, education and research. She currently serves as a consultant to both public and private entities involved in healthcare, healthcare policy and healthcare products. From May 2011 to January 31,2012., Dr. DeBuono served as President and CEO of ORBIS International, which is dedicated to saving sight and eliminating avoidable blindness worldwide with headquarters in New York City. Previously, from 2009-2011, Dr. DeBuono was Chief Medical Officer, Partner and Global Director of Health and Social Marketing at Porter Novelli, and from 2000-2008 she was Executive Director, Public Health and Government at Pfizer Inc. Dr. DeBuono has served as Commissioner of Health for the state of New York and as Director of Health in Rhode Island and she was honored by the CDC Foundation in 2005 as one of five Public Health Heroes nationwide. She serves as adjunct professor at The George Washington University School of Public Health, and is a co-founder of The MAIA Foundation, a charity dedicated to women's health in sub-Saharan Africa. A Fellow of the American College of Physicians, Dr. DeBuono received her B.A. from the University of Rochester, her M.D. from the University of Rochester School of Medicine, and a Masters in Public Health (M.P.H.) from Harvard University School of Public Health.

Dr. DeBuono's experience in and knowledge of, both domestic and international, public health services, public health innovations, and the medical field make her an excellent candidate for serving on the board.

Dr. Peter Kissinger, Ph.D. (71), Director. Dr. Kissinger, who was elected to the Company's Board of Directors in June 2011**,** currently serves on the Company's Audit, and Compensation Committees. Dr. Kissinger is a scientist, entrepreneur and academic, with a multi-faceted career in biotechnology and biomedical technologies. He is the founder of Bioanalytical Systems, Inc. (NASDAQ: BASI), which he led from 1974-2007, and is Professor of Chemistry at Purdue University, West Lafayette, Indiana. Dr. Kissinger's academic research has involved the study of modern liquid chromatography techniques, and in vivo methodology for drug metabolism and the neurosciences. Dr. Kissinger has published more than 240 scientific papers and is a Fellow of the American Association of Pharmaceutical Scientists and the American Association for the Advancement of Science. In 2005, he became the Chairman of Prosolia, which markets mass spectrometry innovations for life science, industrial and homeland security applications. In 2007, he and Candice Kissinger founded Phlebotics, Inc., a medical device company focused on diagnostic information for intensive care medicine. He is a columnist for the trade publication Drug Discovery News. Dr. Kissinger received a B.S. in Chemistry from Union College, Schenectady, N.Y. and a Ph.D. in Analytical Chemistry from the University of North Carolina in Chapel Hill. Dr. Kissinger has knowledge of and experience in biotechnology and biomedical technologies as well as publicly-traded companies, all of which make him an excellent candidate for serving on the board.

Section 16(a) Beneficial Ownership Reporting Compliances

Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), requires the Company's directors, executive officers and beneficial owners of more than 10% of the Company's common stock to file with the Securities and Exchange Commission initial reports of ownership and reports of changes in ownership of common stock and other equity securities of the Company. The Company believes that during the year ended December 31, 2015, each person who was an officer, director and beneficial owner of more than 10% of the Company's common stock complied with all Section 16(a) filing requirements.

Code of Ethics

The Company has adopted a code of ethics that applies to its principal executive officer, principal financial officer, controller, and persons performing similar functions. A copy of the Company's code of ethics is available on the Company's website at www.chembio.com.

Identification of Audit Committee; Audit Committee Financial Expert

The Company's board of directors has established an audit committee. Katherine L. Davis, Dr. Pete Kissinger and Dr. Gary Meller each serves on the audit committee, with Dr. Meller serving as chairman. The Company's board of directors has determined that, based on his past experience, Dr. Meller is an audit committee financial expert and is independent.

ITEM 11. EXECUTIVE COMPENSATION

The following table summarizes all compensation recorded by the Company in each of the last two completed fiscal years for our principal executive officer and our two most highly compensated executive officers other than our principal executive officer whose annual compensation exceeded $100,000.

Name / Principal Position	Year	Salary[1] ($)	Bonus[2] ($)	Stock Awards ($)	Option Awards[3] ($)	All Other Compensation[5] ($)	Total ($)
John J. Sperzel[4]	2015	$ 375,000	$ 70,000	$ -	$ -	$ -	$ 445,000
CEO	2014	$ 298,558	$ -	$ -	$ 669,625	$ -	$ 968,183
Javan Esfandiari	2015	$ 304,130	$ 60,000	$ -	$ -	$ 10,520	$ 374,650
CSTO	2014	$ 315,000	$ 90,000	$ -	$ -	$ 9,825	$ 414,825
Sharon Klugewicz	2015	$ 259,000	$ 40,000	$ -	$ -	$ 5,180	$ 304,180
COO	2014	$ 259,616	$ 75,000	$ -	$ -	$ 4,182	$ 338,798

1 Salary is total base salary. John Sperzel's 2014 salary reflects his base pay from commencement of his employment on March 13, 2014 until the end of 2014.
2 Bonuses earned in 2015 and 2014 were partially based on reaching certain objectives, which included revenue dollar levels and operating profit levels. Additional amounts earned were discretionary.

3 The estimated fair value of any option or common stock granted was determined in accordance with ASC 718, "Stock-Based Payment".
4 Mr. Sperzel also serves as a director on the Company's board of directors. Mr. Sperzel does not receive any compensation for this director role.

5 Other compensation includes an employer match to 401(K) contributions and car allowances where applicable.

Employment Agreements

Mr. Sperzel. Effective March 13, 2014 (the "Effective Date"), the Company entered into an Employment Agreement with John J. Sperzel III to serve as the Company's CEO for a term of three years. Mr. Sperzel's annual base salary is $375,000, with the possibility of a discretionary, performance-based annual cash bonus of up to 40% of his base salary. The Employment Agreement also provides for a grant of 250,000 options to purchase shares of the Company's common stock, 43,132 of which will be incentive stock options under the Company's 2008 Stock Incentive Plan (the "Plan"), and 206,868 of which will be non-qualified stock options. The options will become exercisable at the rate of 50,000 shares per year for each of the first through the fifth anniversary of the Effective Date. In the event Mr. Sperzel's employment is terminated by reason of disability or for "cause," as defined in the Employment Agreement, all compensation, including his base salary, his right to receive a performance bonus, and the vesting of any unvested options, will cease as of his termination date, and Mr. Sperzel will receive no severance benefits. If the Company terminates Mr. Sperzel's employment without cause or Mr. Sperzel terminates his employment for a reasonable basis, as defined in the Employment Agreement (which includes involuntary termination within a six-month period upon a "Change of Control"), then the Company will pay Mr. Sperzel his base salary for a period of six months as severance and all of his unvested stock options immediately shall become vested. The Employment Agreement also contains provisions prohibiting Mr. Sperzel from (i) soliciting the Company's employees for a period of 24 months following his termination, (ii) soliciting the Company's customers, agents, or other sources of distribution of the Company's business for a period of twelve months following his termination, and (iii) except where termination is involuntary upon a "Change in Control," engaging or participating in any business that directly competes with the business activities of the Company in any market in which the Company is in business or plans to do business during the period in which he is entitled to severance, or for a period of six months if he is not entitled to severance payments under the Employment Agreement. The foregoing description of the Employment Agreement is qualified in its entirety by reference to the full text of the Employment Agreement.

Mr. Esfandiari. The Company entered into an employment agreement effective March 5, 2013 (the "Employment Agreement"), with Mr. Esfandiari to continue as the Company's Chief Scientific and Technology Officer for an additional term of three years through March 5, 2016. The Company and Mr. Esfandiari currently are discussing terms for renewal of his employment agreement. Mr. Esfandiaris's salary under the Employment Agreement is $304,500 for the year ended March 5, 2016, and he is eligible for a performance-based bonus of up to 50% of his base salary for each year, which is in the same proportions as described below under "Executive Bonus Plan". The Company also granted Mr. Esfandiari, pursuant to the Company's 2008 Stock Incentive Plan, incentive stock options to purchase 30,000 shares of the Company's common stock. The price per share of these options is equal to the fair market value of the Company's common stock as of the close of the market on March 5, 2013, which is the trading date on which the Agreement was entered into. Of these stock options, options to purchase 10,000 shares vest on each of the first three anniversaries of the effective date of the Employment Agreement. Mr. Esfandiari is eligible to participate in any profit sharing, stock option, retirement plan, medical and/or hospitalization plan, and/or other benefit plans except for disability and life insurance that the Company may from time to time place in effect for the Company's executives during the term of Mr. Esfandiari's employment agreement. If Mr. Esfandiari's employment agreement is terminated by the Company without cause, or if Mr. Esfandiari terminates his employment agreement for a reasonable basis, as defined in the Employment Agreement, including within 12 months of a change in control, the Company is required to pay as severance Mr. Esfandiari's salary for twelve months.

Ms. Klugewicz. The Company entered into an employment agreement dated May 22, 2015 with Ms. Klugewicz (the "Employment Agreement"), effective May 22, 2015 (the "Effective Date"). The Agreement provides that she will serve as the Company's COO for a term of two years. Ms. Klugewicz will receive an annual salary of $265,000, with the option of a discretionary, performance-based annual cash bonus of up to 37.5% of her base salary. In the event Ms. Klugewicz's employment is terminated by reason of disability or for "cause", as defined in the Employment Agreement, all compensation including her base salary, her right to receive a performance bonus, and the vesting of any unvested options, will cease as of her termination date, and Ms. Klugewicz will receive no severance benefits. If the Company terminates Ms. Klugewicz's employment without cause or Ms. Klugewicz terminates her employment for a reasonable basis, as defined in the Employment Agreement (which definition includes involuntary termination within a six-month period upon a "Change of Control"), then the Company will pay Ms. Klugewicz her base salary for a period of six months as severance, and all her unvested stock options shall immediately become vested. The Employment Agreement also contains provisions prohibiting Ms. Klugewicz from (i) soliciting the Company's employees for a period of twenty-four months following her termination, (ii) soliciting the Company's customers, agents, or other sources of distribution of the Company's business for a period of twelve months following her termination, and (iii) for a period of twelve months following termination of this Agreement,

except where termination is involuntary upon a "Change in Control," engaging or participating in any business that directly competes with the business activities of the Company in any market in which the Company is in business or plans to do business. The foregoing description of the Employment Agreement is qualified in its entirety by reference to the full text of the Employment Agreement.

None of the other officers of the Company has an employment contract with the Company.

Executive Bonus Plan

The Company has established a bonus plan for its executives who do not have a contract. For the fiscal year ended December 31, 2015, there were four executives eligible for this bonus plan. Each executive can earn up to 25% of that executive's salary in the form of a cash bonus. The Compensation Committee determined that 80% of the executive's bonus will be quantitative factors, based on the budget, and the other 20%, which will be based on other factors, will be discretionary. For 2015, the quantitative 80% portion of the plan called for attaining certain revenue goals, and for attaining certain operating profit goals.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END 2015

	Option Awards					Stock Awards		
Name	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price ($)	Option Expiration Date	Option Vesting Date	Number of Shares of Stock That Have Not Vested (#)	Market Value of Shares of Stock That Have Not Vested ($)	Foot-note
John J. Sperzel	25,000		3.4163	3/21/2021	3/13/2015			5
	25,000		3.4163	3/21/2021	3/13/2015			2
		18,132	3.4163	3/21/2021	3/13/2016			5
		31,868	3.4163	3/21/2021	3/13/2016			2
		50,000	3.4163	3/21/2021	3/13/2017			2
		50,000	3.4163	3/21/2021	3/13/2018			2
		50,000	3.4163	3/21/2021	3/13/2019			2
Javan Esfandiari	10,000		5.44	3/5/2018	3/5/2014			1
	10,000		5.44	3/5/2018	3/5/2015			1
		10,000	5.44	3/5/2018	3/5/2016			1
	4,765		5.56	2/26/2018	2/26/2013			4
	7,969		4.00	2/16/2017	2/16/2012			3
	12,500		2.16	3/4/2015	3/5/2013			1
	12,500		2.16	3/4/2015	3/5/2012			1
	12,500		2.16	3/4/2015	3/5/2010			1
Sharon Klugewicz	2,500		4.50	5/22/2018	5/22/2014			1
	2,500		4.50	5/22/2018	5/22/2015			1
	630		5.56	2/26/2018	2/26/2013			4
	12,000		4.45	9/4/2017	9/4/2013			5
	12,000		4.45	9/4/2017	9/4/2014			5
	12,000		4.45	9/4/2017	9/4/2015			5

1 Options issued in connection with an employment contract and under the 2008 Stock Incentive Plan.
2 Options issued in connection with the start of employment with the Company and not under a Plan.
3 On February 16, 2012, the Company determined to grant on February 16, 2012, to certain employees of the Company, options to purchase an aggregate of 203,125 shares of the Company's common stock. The exercise price for these options was the last traded market price for the Company's common stock on February 16, 2012, which was $4.00 per share. The options become exercisable on the effective date of the grant. Each option granted will expire and terminate, if not exercised sooner, upon the earlier to occur of (a) 30 days after termination of the employee's employment with the Company or (b) the fifth anniversary of the effective date of grant.
4 On February 26, 2013, the Company determined to grant on February 26, 2013 to certain employees of the Company, options to purchase an aggregate of 16,360 shares of the Company's common stock. The exercise price for these options was the last traded market price for the Company's common stock on February 26, 2013, which was $5.56 per share. The options become exercisable on the effective date of the grant. Each option granted will expire and terminate, if not exercised sooner, upon the earlier to occur of (a) 30 days after termination of the employee's employment with the Company or (b) the fifth anniversary of the effective date of grant.
5 Options issued in connection with the start of employment with the Company and under the 2008 Stock Incentive Plan.

Director Compensation

Effective January 1, 2015, all non-employee directors are paid $25,000 annual fee in semi-annual payments. In addition, once every five years, on the date of the annual meeting of shareholders at which a director is elected or re-elected (every 5 years), that director receives stock options to acquire, subject to vesting as described below, 46,875 shares of the Company's common stock, with an exercise price equal to the market price on the date of the grant. Stock options to acquire 9,375 shares become exercisable on the date of grant, and options to acquire an additional 9,375 shares become exercisable on the date of each of the four succeeding annual meetings of shareholders if and to the extent that the non-employee director is reelected as a director at each such annual meeting. [These options grants also are described in note 1 below.] Beginning in April 2014, the non-employee board chair was paid a monthly fee of $6,500, and as of January 1, 2015, this monthly fee was adjusted to $4,167. The audit committee chair is paid an annual fee of $2,500, paid semi-annually. In addition, the non-employee directors are paid $1,000 for each board of directors' meeting attended, and paid $500 for each telephonic board of directors meeting. The non-employee directors who are members of a committee of the board of directors are paid $500 for each committee meeting attended, or $750 for each committee meeting attended if that non-employee director is the committee chair. Directors also may be paid for serving on ad hoc committees of the Board.

DIRECTOR COMPENSATION

Name	Fees Earned or Paid in Cash ($) [1]	Option Awards ($) [2]	Total ($)
Katherine L. Davis	$ 82,500	$ -	$ 82,500
Barbara DeBuono	30,250	-	30,250
Pete Kissinger	48,500	-	48,500
Gary Meller	58,500	-	58,500

1 Fees earned or paid in cash represents a yearly fee and fees for meeting expenses: (a) Ms. Davis received a $25,000 annual fee as a member of the board of directors, a $4,167 monthly fee as chair aggregating $50,000 and $7,500 in meeting fees earned during 2015; (b) Dr. DeBuono received a $25,000 annual fee as a member of the board of directors and 5,250 in meeting fees; (c) Dr. Kissinger received a $25,000 annual fee as a member of the board of directors, $18,000 in fees as a member of a Special Committee and $5,500 in meeting fees; (d) Dr. Meller received a $25,000 annual fee as a member of the board of directors, $2,500 in fees as chairperson of the Audit Committee, $24,000 in fees as a member of a Special Committee and $7,000 in meeting fees.

2 Each non-employee member of the board of directors is granted, once every five years, options to purchase 46,875 shares of the company's common stock with an exercise price equal to the market price on the date of the grant as part of annual non-employee board compensation. One-fifth of these options are exercisable on the date of grant, one-fifth become exercisable on the first anniversary of the date of grant, and additional one-fifths become exercisable on the second through fourth anniversaries of the date of grant. The fair value of options at the date of grant was estimated using the Black-Scholes option pricing model.

Compensation Committee Interlocks and Insider Participation

No executive officer of the Company served as a member of the Board of any other public company during the year ended December 31, 2015, except for Mr. Sperzel who serves on the Board of Directors of Diadexus, Inc. No member of the Compensation Committee served as an executive officer of any other public company during the year ended December 31, 2015. No interlocking relationship exists between the members of our Compensation Committee and the Board or compensation committee of any other company. As of March 1, 2015, the members of the Compensation Committee were Dr. Barbara DeBuono (Chairman), Katherine Davis, and Dr. Peter Kissinger, each of whom is deemed by the Board of Directors to be independent.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth certain information regarding the beneficial ownership of our common stock by each person or entity known by us to be the beneficial owner of more than 5% of the outstanding shares of common stock, each of our directors, each of our "named executive officers", and all of our directors and executive officers as a group as of March 1, 2016.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percent of Class
John J. Sperzel (1) 3661 Horseblock Road Medford, NY 11763	100,000	1.03%
Esfandiari, Javan (2) 3661 Horseblock Road Medford, NY 11763	134,844	1.39%
Larkin, Richard (3) 3661 Horseblock Road Medford, NY 11763	66,514	.69%
Ippolito, Tom (4) 3661 Horseblock Road Medford, NY 11763	38,916	.40%
Steele, Michael (5) 3661 Horseblock Road Medford, NY 11763	36,785	.38%
Lambotte, Paul (6) 3661 Horseblock Road Medford, NY 11763	51,630	.53%
Klugewicz, Sharon (7) 3661 Horseblock Road Medford, NY 11763	12,000	.12%
Meller, Gary (8) 3661 Horseblock Road Medford, NY 11763	123,750	1.28%
Davis, Katherine L. (9) 3661 Horseblock Road Medford, NY 11763	77,046	.80%
DeBuono, Barbara (10) 3661 Horseblock Road Medford, NY 11763	46,188	.48%
Kissinger, Peter (11) 3661 Horseblock Road Medford, NY 11763	50,629	.52%
GROUP (12)	**738,302**	**7.36%**
Wellington Management Company, LLP 280 Congress Street Boston, MA 02210	1,092,780	11.35%
Norman H. Pessin 366 Madison Ave, 14th Floor New York, NY 10017	884,087	9.18%

Beneficial ownership is determined in accordance with the Rule 13d-3(a) of the Securities Exchange Act of 1934, as amended, and generally includes voting or investment power with respect to securities. Except as subject to community property laws, where applicable, the person named above has sole voting and investment power with respect to all shares of our common stock shown as beneficially owned by that person.

The beneficial ownership percent in the table is calculated with respect to the number of shares (9,628,248) of the Company's common stock outstanding as of March 1, 2016. With respect to each stockholder, the denominator is the sum of the number of common shares outstanding and the number, if any, of outstanding options included in that stockholder's beneficial ownership. Each stockholder's beneficial ownership is calculated as the number of shares of common stock owned plus the number of shares of common stock into which any preferred stock, warrants, options or other convertible securities owned by that stockholder can be converted within 60 days.

The term "named executive officer" refers to our principal executive officer, our two most highly compensated executive officers other than the principal executive officer who were serving as executive officers at the end of 2015, and two additional individuals for whom disclosure would have been provided but for the fact that the individuals were not serving as executive officers of the Company at the end of 2015.

(1) Includes 100,000 shares issuable upon exercise of options exercisable within 60 days. Does not include 150,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(2) Includes 42,734 shares issuable upon exercise of options exercisable within 60 days.
(3) Includes 23,217 shares issuable upon exercise of options exercisable within 60 days.
(4) Includes 20,399 shares issuable upon exercise of options exercisable within 60 days.
(5) Includes 36,785 shares issuable upon exercise of options exercisable within 60 days.
(6) Includes 41,630 shares issuable upon exercise of options exercisable within 60 days.
(7) Includes 12,000 shares issuable upon exercise of options exercisable within 60 days. Does not include 24,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(8) Includes 18,750 shares issuable upon exercise of options exercisable within 60 days. Does not include 28,125 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(9) Includes 18,750 shares issuable upon exercise of options exercisable within 60 days. Does not include 28,125 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(10) Includes 48,829 shares issuable upon exercise of options exercisable within 60 days.
(11) Includes 45,188 shares issuable upon exercise of options exercisable within 60 days.
(12) Includes footnotes (1)-(10).

Equity Compensation Plan Information

	Combined Equity Compensation Plans - Information as of December 31, 2015		
Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column (a)
	(a)	(b)	(c)
Equity compensation plans approved by security holders[1]	649,478	$ 3.75	753,455
Equity compensation plans not approved by security holders	-	-	-
Total	649,478	$ 3.75	753,455

1 The "Number of Securities to be Issued Upon Exercise of Outstanding Warrants and Rights" represents 312,860 from the 2008 Stock Incentive Plan, 129,750 under the 2014 Stock Incentive Plan and 206,868 issued outside of the Plans. The 2008 Stock Incentive Plan was increased by 125,000 units at the Annual Stockholder meeting held September 23, 2011. The "Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans" represents 83,205 from the 2008 Stock Incentive Plan and 670,250 under the 2014 Stock Incentive Plan.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The executive officers of the Company are as follows: John J. Sperzel, president, chief executive officer and member of the board of directors of the Company, Sharon Klugewicz, chief operating officer, Richard J. Larkin, chief financial officer of the Company, and Javan Esfandiari, chief science and technology officer of the Company.

The Company entered into an employment agreement effective March 5, 2013, with Mr. Esfandiari to continue as the Company's Chief Scientific and Technology Officer for an additional term of three years through March 5, 2016. The Company also entered into an employment agreement effective May 22, 2015, with Ms. Klugewicz to serve as Chief Operating Officer for a term of two years. On March 13, 2014, Mr. Siebert, the former Chief Executive Officer, retired from the Company and entered into a six-month Consulting Agreement with the Company. On March 13, 2014, the Company entered into an employment agreement (the "Employment Agreement") with John J. Sperzel III to serve as its Chief Executive Officer beginning on March 13, 2014 for a term of three years. See Item 11 for additional information.

Director Independence

Our common stock trades on the NASDAQ. Accordingly, we are subject to the corporate the governance standards of NASDAQ, which require, among other things, that the majority of the board of directors be independent. We define an "independent" director in accordance with the NASDAQ Global Market's requirements for independent directors. Under this definition, we have determined that each of Katherine Davis, Barbara DeBuono, Peter Kissinger, and Gary Meller currently qualify as independent directors. We do not list this "independent" definition on our internet website.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Audit Fees

For the years ended December 31, 2015 and 2014 the Company engaged BDO USA, LLP as its independent accounting firm to perform an audit of the Company's annual financial statements included on Form 10-K, including reviews of the quarterly financial statements and assistance with and review of documents filed with the SEC, for $161,000 and $128,000 respectively in fees.

Audit-Related Fees

For the years ended December 31, 2015 and 2014, the Company's independent accounting firm, BDO USA, LLP, did not provide the Company with any assurance and related services reasonably related to the performance of the audit or review of the Company's financial statements that are not reported above under "Audit Fees."

Tax Fees

For the years ended December 31, 2015 and 2014, the Company's independent accounting firm, BDO USA, LLP, billed the Company $23,600 and $18,350, respectively for professional services for tax compliance, tax advice and tax planning.

All Other Fees

For the year ended December 31, 2015, the Company's independent accounting firm, BDO USA, LLP, billed the Company $69,600 for services in connection with other matters. For the year ended December 31, 2014, the Company's independent accounting firm, BDO USA, LLP, did not provide the Company with any services for other matters.

Audit Committee Pre-Approval Policies

The Audit Committee approves in advance all audit and non-audit services performed by the independent accounting firm. There are no other specific policies or procedures relating to the pre-approval of services performed by the independent accounting firm.

ITEM 15.

EXHIBITS INDEX

Number	Description
3.1	Articles of Incorporation, as amended. (1)
3.2	Amended and Restated Bylaws. (2)
4.1	2008 Stock Incentive Plan, as amended. (3)
4.2	Form of Option, for 2008 Stock Incentive Plan (4)
4.3	2014 Stock Incentive Plan (5)
4.4	Form of Option, for 2014 Stock Incentive Plan (6)
4.5	Rights Agreement, dated March 8, 2010 (7)
4.6	Form of Warrant (to be filed by amendment)
4.7	Rights Agreement, dated March 8, 2016 (14)
4.8	Form of Warrant (to be filed by amendment)
10.1*	Employment Agreement dated March 13, 2014 with John J. Sperzel III (4)
10.2*	Employment Agreement dated March 5, 2013 with Javan Esfandiari (8)
10.3*	Employment Agreement dated June 12, 2015 with Sharon Klugewicz (9)
10.3	HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Alere and StatSure. (10)
10.4	HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (10)
10.5	Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (10)
10.6	Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (10)
10.8	Secured Revolving Demand Note, dated as of April 30, 2013, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (11)
10.9	Loan and Security Agreement, dated as of April 30, 2013, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (11)
10.10	2015 Omnibus Agreement (12)
14.1	Ethics Policy (13)
21	List of Subsidiaries
23.1	Consent of BDO USA, LLP, Independent Registered Public Accountants.
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Definition Linkbase Document
101.LAB	XBRL Taxonomy Label Linkbase Document
101.PRE	XBRL Taxonomy Presentation Linkbase Document

1	Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on July 29, 2010.
2	Incorporated by reference to the Registrant's registration statement on Form SB-2 (File No. 333-85787) filed with the Commission on August 23, 1999 and the Registrant's Forms 8-K filed on May 14, 2004, December 20, 2007 and April 18, 2008.
3	Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on August 3, 2012.
4	Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on May 8, 2014.
5	Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on April 29, 2014.
6	Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on August 7, 2014.
7	Incorporated by reference to the Registrant's registration statement on Form 8-A filed with the Commission on March 11, 2010.
8	Incorporated by reference to the Registrant's Annual Report on Form 10-K filed with the Commission on March 7, 2013.
9	Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on June 17, 2015.
10	Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on October 5, 2006.
11	Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on August 8, 2013.
12	Incorporated by reference to the Registrant's Annual Report on Form 10-K filed with the Commission on March 5, 2015.
13	Incorporated by reference to the Registrant's Annual Report on Form 10-KSB filed with the Commission on March 30, 2006.

(*)	An asterisk (*) beside an exhibit number indicates the exhibit contains a management contract, compensatory plan or arrangement which is required to be identified in this report.

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CHEMBIO DIAGNOSTICS, INC.

Date: March 8, 2016

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

In accordance with the requirements of the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signatures	Title	Date
/s/ John J. Sperzel John J. Sperzel	Chief Executive Officer, President and Member Of The Board (Principal Executive Officer)	March 8, 2016
/s/ Richard J. Larkin Richard J. Larkin	Chief Financial Officer (Principal Financial & Accounting Officer)	March 8, 2016
/s/ Gary Meller Gary Meller	Director	March 8, 2016
/s/ Katherine L. Davis Katherine L. Davis	Director & Chair of the Board	March 8, 2016
/s/ Peter T. Kissinger Peter T. Kissinger	Director	March 8, 2016
/s/ Barbara DeBuono Barbara DeBuono	Director	March 8, 2016

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders of
Chembio Diagnostics, Inc.
Medford, New York

We have audited the accompanying consolidated balance sheets of Chembio Diagnostics, Inc. and Subsidiary (the "Company") as of December 31, 2015 and 2014 and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Chembio Diagnostics, Inc. and Subsidiary as of December 31, 2015 and 2014, and the consolidated results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

BDO USA, LLP

/s/ BDO USA, LLP

Melville, New York
March 8, 2016

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS
AS OF

- ASSETS -

	December 31, 2015	December 31, 2014
CURRENT ASSETS:		
Cash and cash equivalents	**$ 5,376,931**	$ 4,614,538
Accounts receivable, net of allowance for doubtful accounts of $52,000 and $52,000 at December 31, 2015 and 2014, respectively	**2,422,971**	8,338,889
Inventories	**3,578,025**	3,638,299
Prepaid expenses and other current assets	**1,256,879**	1,066,473
TOTAL CURRENT ASSETS	**12,634,806**	17,658,199
FIXED ASSETS, net of accumulated depreciation	**2,374,308**	2,797,929
OTHER ASSETS:		
Deferred tax asset, net of valuation allowance	**5,467,143**	4,031,302
License agreements, net of current portion	**100,000**	256,875
Deposits on manufacturing equipment	**30,918**	20,017
Deposits and other assets	**209,169**	245,870
TOTAL ASSETS	**$ 20,816,344**	$ 25,010,192
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	**$ 2,801,432**	$ 4,946,030
Deferred revenue	**353,406**	340,000
TOTAL CURRENT LIABILITIES	**3,154,838**	5,286,030
TOTAL LIABILITIES	**3,154,838**	5,286,030
COMMITMENTS AND CONTINGENCIES (Note 13)		
STOCKHOLDERS' EQUITY:		
Preferred stock – 10,000,000 shares authorized, none outstanding	-	-
Common stock - $.01 par value; 100,000,000 shares authorized, 9,628,248 and 9,611,139 shares issued and outstanding for 2015 and 2014, respectively	**96,282**	96,112
Additional paid-in capital	**47,890,642**	47,556,426
Accumulated deficit	**(30,325,418)**	(27,928,376)
TOTAL STOCKHOLDERS' EQUITY	**17,661,506**	19,724,162
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 20,816,344**	$ $ 25,010,192

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the years ended	
	December 31, 2015	December 31, 2014
REVENUES:		
Net product sales	**$ 21,886,688**	$ 25,949,769
License and royalty revenue	**52,753**	23,257
R&D, milestone and grant revenue	**2,316,044**	1,672,258
TOTAL REVENUES	**24,255,485**	27,645,284
Cost of product sales	**13,768,658**	16,831,261
GROSS MARGIN	**10,486,827**	10,814,023
OPERATING EXPENSES:		
Research and development expenses	**6,377,839**	4,832,537
Selling, general and administrative expenses	**7,663,035**	7,531,739
	14,040,874	12,364,276
LOSS FROM OPERATIONS	**(3,554,047)**	(1,550,253)
OTHER INCOME (EXPENSE):		
Other expense	**(4,814)**	(5,707)
Interest income	**2,412**	5,839
Interest expense	**(836)**	-
	(3,238)	132
LOSS BEFORE INCOME TAXES (BENEFIT)	**(3,557,285)**	(1,550,121)
Income tax provision (benefit)	**(1,160,243)**	(412,918)
NET LOSS	**$ (2,397,042)**	$ (1,137,203)
Basic loss per share	**$ (0.25)**	$ (0.12)
Diluted loss per share	**$ (0.25)**	$ (0.12)
Weighted average number of shares outstanding, basic	**9,626,028**	9,530,320
Weighted average number of shares outstanding, diluted	**9,626,028**	9,530,320

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2015 AND 2014

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount	Amount	Amount	Amount
Balance at December 31, 2013	**9,324,783**	**$ 93,248**	**$ 46,875,027**	**$ (26,791,173)**	**$ 20,177,102**
Common Stock:					
New Stock from Offering	-	-	-	-	-
Options:					
Exercised	**286,356**	**2,864**	**234,299**	**-**	**237,163**
Stock option compensation	-	-	**447,100**	-	**447,100**
Net loss	**-**	**-**	**-**	**(1,137,203)**	**(1,137,203)**
Balance at December 31, 2014	**9,611,139**	**$ 96,112**	**$ 47,556,426**	**$ (27,928,376)**	**$ 19,724,162**
Options:					
Exercised	**17,109**	**170**	**(170)**	**-**	**-**
Stock option compensation	-	-	**334,386**	-	**334,386**
Net loss	**-**	**-**	**-**	**(2,397,042)**	**(2,397,042)**
Balance at December 31, 2015	**9,628,248**	**$ 96,282**	**$ 47,890,642**	**$ (30,325,418)**	**$ 17,661,506**

See accompanying notes to consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED

	December 31, 2015	December 31, 2014
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	**$ 30,174,083**	$ 23,898,516
Cash paid to suppliers and employees	**(28,382,681)**	(27,724,654)
Interest received	**2,412**	5,839
Interest paid	**(836)**	-
Net cash provided by (used in) operating activities	**1,792,978**	(3,820,299)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of license	**(550,000)**	-
Acquisition of and deposits on fixed assets	**(480,585)**	(1,452,601)
Net cash used in investing activities	**(1,030,585)**	(1,452,601)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from option and warrant exercises	**-**	237,163
Proceeds from credit line	**700,000**	-
Repayment of credit line	**(700,000)**	-
Payment of capital lease obligation	**-**	-
Net cash provided by financing activities	**-**	237,163
(DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	**762,393**	(5,035,737)
Cash and cash equivalents - beginning of the period	**4,614,538**	9,650,275
Cash and cash equivalents - end of the period	**$ 5,376,931**	$ 4,614,538
RECONCILIATION OF NET LOSS TO NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES:		
Net Loss	**$ (2,397,042)**	$ (1,137,203)
Adjustments:		
Depreciation and amortization	**1,372,563**	739,297
Provision for (benefit from) deferred taxes	**(1,170,969)**	(403,375)
Provision for (recovery of) doubtful accounts	**-**	28,000
Share based compensation	**334,386**	447,100
Changes in assets and liabilities:		
Accounts receivable	**5,915,918**	(3,774,768)
Inventories	**60,274**	(449,573)
Prepaid expenses and other current assets	**(190,960)**	32,906
Deposits and other assets	**-**	(279,223)
Accounts payable and accrued liabilities	**(2,144,598)**	636,540
Customer deposits and deferred revenue	**13,406**	340,000
Net cash provided by (used in) operating activities	**$ 1,792,978**	$ (3,820,299)
Supplemental disclosures for non-cash investing and financing activities:		
Deposits on manufacturing equipment transferred to fixed assets	**$ 20,017**	$ 603,627

See accompanying notes to condensed consolidated financial statements

NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. and its subsidiary, Chembio Diagnostic Systems, Inc. (collectively, the "Company" or "Chembio"), develop, manufacture, and market rapid diagnostic tests that detect infectious diseases. The Company's main lateral flow products are three rapid tests for the detection of HIV antibodies in whole blood, serum and plasma samples, two of which were approved by the FDA in 2006; the third is sold for export only. Lateral Flow Rapid HIV tests represented nearly 46% of the Company's product revenues in 2015. The Company's products based on its patented DPP® platform represented approximately 51% of the Company's product revenues in 2015. The Company also has other rapid tests that together represented approximately 3% of sales in 2015. The Company's products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments both domestically and internationally. Chembio's products are sold under the Company's STAT-PAK®, SURE CHECK® or DPP® registered trademarks, or under the private labels of its marketing partners, for example the Clearview® label owned by Alere, Inc. ("Alere"), which is the Company's exclusive marketing partner for one of its rapid HIV lateral flow test products in the United States. All of the Company's products that are currently being developed are based on its patented Dual Path Platform (DPP®), which is a unique diagnostic point-of-care platform that has certain advantages over lateral flow technology. In December 2012, the Company received FDA approval for its DPP® HIV 1/2 Assay for the detection of HIV antibodies in saliva, whole blood, serum and plasma samples, which was CLIA-Waived in October 2014.

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES:

(a) ***Principles of Consolidation:***

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany transactions and balances have been eliminated in consolidation.

(b) ***Use of Estimates:***

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make assumptions and estimates that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting periods covered thereby. Actual results could differ from these estimates. Judgments and estimates of uncertainties are required in applying the Company's accounting policies in certain areas. The following are some of the areas requiring significant judgments and estimates: determinations of the useful lives of assets, estimates of allowances for doubtful accounts, inventory reserves, stock-based compensation and deferred tax assets.

(c) ***Fair Value of Financial Instruments:***

The carrying value for cash and cash equivalents, accounts receivable and accounts payable, approximate fair value because of the immediate or short-term maturity of these financial instruments.

(d) ***Statements of Cash Flows:***

For purposes of the statements of cash flows, the Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents.

(e) ***Concentrations of Credit Risk:***

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of temporary cash investments and trade receivables. The Company places its temporary cash instruments with well-known financial institutions and, at times, may maintain balances in excess of the FDIC insurance limit. The Company monitors the credit ratings of the financial institutions to mitigate this risk. Concentration of credit risk with respect to trade receivables is principally mitigated by the Company's ability to obtain letters of credit from certain foreign customers, and its diverse customer base both in number of customers and geographic locations. As of December 31, 2014, we had a significant concentration of outstanding credit with one customer in Brazil. We currently do not require collateral for accounts receivable.

(f) ***Inventories:***

Inventories, consisting of material, labor and manufacturing overhead, are stated at the lower of cost or market. Cost is determined on the first-in, first-out method.

(g) ***Fixed Assets:***

Fixed assets are stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets, which range from three to seven years. Leasehold improvements are amortized over the useful life of the asset or the lease term, whichever is shorter. Deposits paid for fixed assets are capitalized and not depreciated until the related asset is placed in service.

(h) ***License Agreements:***

In February 2008, the Company entered into a sublicense agreement for which it had initially recorded an asset of $1,000,000. This asset is being expensed over an estimated economic life of ten years, based on the expected lifespan of our then current HIV products. The current portion of this asset is $100,000 as of December 31, 2015 and 2014 and is reported in prepaid expenses and other current assets. The long-term portion as of December 31, 2015 and 2014 is $100,000 and $200,000, respectively and is reflected in other assets on the consolidated balance sheet.

In January 2015, the Company entered into a sublicense agreement for which it had initially recorded an asset of $400,000. This asset is being expensed over the life of the patent of 22 months. The current portion of this asset is $181,818 as of December 31, 2015 and is reported in prepaid expenses.

In August 2015, the Company entered into a sublicense agreement for which it had initially recorded an asset of $100,000. This asset is being validated and will be expensed over the estimated economic life of the product(s) which will utilize this sublicense. This asset as of December 31, 2015, is reported in prepaid expenses.

(i) ***Impairment of Long-Lived Assets and Intangible Assets***

Long-lived assets to be held and used are analyzed for impairment whenever events or changes in circumstances indicate that the related carrying amounts may not be recoverable. The Company evaluates at each balance sheet date whether events and circumstances have occurred that indicate possible impairment. If there are indications of impairment, the Company uses future undiscounted cash flows of the related asset or asset grouping over the remaining life in measuring whether the assets are recoverable. In the event such cash flows are not expected to be sufficient to recover the recorded asset values, the assets are written down to their estimated fair value. We believe that the carrying values of our long-lived tangible and intangible assets were realizable at December 31, 2015 and 2014, respectively.

(j) ***Revenue Recognition:***

The Company recognizes revenue for product sales in accordance with ASC 605, revenue is recognized when there is persuasive evidence of an arrangement, delivery has occurred or services have been rendered, the sales price is fixed and determinable, and collectability is reasonably assured. Revenue typically is recognized at time of shipment. Sales are recorded net of discounts, rebates and returns.

For certain contracts, the Company recognizes revenue from non-milestone contracts and grant revenues when earned. Grants are invoiced after expenses are incurred. Revenues from projects or grants funded in advance are deferred until earned.

The Company follows Financial Accounting Standards Board ("FASB") issued authoritative guidance ("guidance") prospectively for the recognition of revenue under the milestone method. The Company applies the milestone method of revenue recognition for certain collaborative research projects defining milestones at the inception of the agreement.

(k) ***Research and Development:***

Research and development (R&D) costs are expensed as incurred.

(l) ***Stock-Based Compensation:***

Stock-based compensation expense is calculated using the Black-Scholes valuation model based on awards ultimately expected to vest, reduced for forfeitures, and expensed on a straight-line basis over the requisite service period of the grant.

(m) ***Income Taxes:***

The Company accounts for income taxes under an asset and liability approach which recognizes deferred tax assets and liabilities based on the difference between the financial statement carrying amounts and the tax bases of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse.

The Company follows a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken, or expected to be taken, in a tax return. The guidance relates to, among other things, classification, accounting for interest and penalties associated with tax positions, and disclosure requirements. Any interest and penalties accrued related to uncertain tax positions will be recorded in tax expense.

The Company assesses the realizability of its net deferred tax assets on an annual basis. If, after considering all relevant positive and negative evidence, it is more likely than not that some portion or all of the net deferred tax assets will not be realized, the Company would reduce the net deferred tax assets by a valuation allowance. The realization of the net deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of net operating loss carryforwards.

(n) ***Loss Per Share***

The following weighted average shares were used for the computation of basic and diluted earnings per share:

	For the years ended	
	December 31, 2015	December 31, 2014
Basic	**9,626,028**	9,530,320
	-	-
Diluted	**9,626,028**	9,530,320

Basic loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted loss per share for the year ended December 31, 2015 and 2014 reflects the potential dilution from the exercise or conversion of other securities into common stock, if dilutive.

The following securities, presented on a common share equivalent basis, have been used in the diluted per share computations:

	For the years ended	
	December 31, 2015	December 31, 2014
1999, 2008 and 2014 Plan Stock Options	-	-

There were 658,631 and 798,475 options and warrants outstanding as of December 31, 2015 and 2014, respectively, which were not included in the calculation of diluted income per share for the years ended because their effect would have been anti-dilutive.

(o) ***Recent Accounting Pronouncements Affecting the Company:***

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, "Revenue from Contracts with Customers" ("ASU 2014-09"), which supersedes nearly all existing revenue recognition guidance under accounting principles generally accepted in United States ("U.S. GAAP"). The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP.

The standard is effective for annual periods beginning after December 15, 2016, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients; or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our consolidated financial statements and have not yet determined the method by which we will adopt the standard in 2018.

In November 2015, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2015-17, *Income Taxes (Topic 740) Balance Sheet Classification of Deferred Assets.* This ASU is intended to simplify the presentation of deferred taxes on the balance sheet and will require an entity to present all deferred tax assets and deferred tax liabilities as non-current on the balance sheet. Under the current guidance, entities are required to separately present deferred taxes as current or non-current. Netting deferred tax assets and deferred tax liabilities by tax jurisdiction will still be required under the new guidance. This guidance will be effective for Chembio beginning in 2018, with early adoption permitted. The Company does not believe this new accounting standard update will have a material impact on its consolidated financial statements.

In February 2016, the FASB issued Accounting Standards Update ("ASU") 2016-02, which amends the ASC and creates Topic 842, Leases. Topic 842 will require lessees to recognize lease assets and lease liabilities for those leases classified as operating leases under previous US GAAP on the balance sheet. This guidance is effective for annual periods beginning after December 15, 2018 and early adoption is permitted. The Company is currently assessing the impact on its consolidated financial position and results of operations.

NOTE 3 — INVENTORIES:

Inventories consist of the following at:

	December 31, 2015	December 31, 2014
Raw materials	**$ 2,248,371**	$ 2,323,863
Work in process	**370,340**	346,494
Finished goods	**959,314**	967,942
	$ 3,578,025	$ 3,638,299

NOTE 4 — FIXED ASSETS:

Fixed assets consist of the following at:

	December 31, 2015	December 31, 2014
Machinery and equipment	**$ 3,862,698**	$ 3,508,944
Furniture and fixtures	**436,588**	388,040
Computer and telephone equipment	**326,170**	315,916
Leasehold improvements	**2,012,945**	1,955,817
	6,638,401	6,168,717
Less accumulated depreciation and amortization	**(4,264,093)**	(3,370,788)
	$ 2,374,308	$ 2,797,929

There were no capital leases at the end of December 31, 2015. Fixed assets at December 31, 2015 also include $100,000 in equipment, which has been delivered and set-up but is undergoing validation and as such is currently not being depreciated. Depreciation expense for the 2015 and 2014 years aggregated $893,305 and $616,943, respectively.

As of December 31, 2015 and 2014, the Company had paid deposits on various pieces of equipment aggregating $30,918 and $20,017, respectively. The Company is further committed to an additional obligation of $31,008 as various milestones are achieved by the various vendors.

NOTE 5 — ACCOUNTS PAYABLE AND ACCRUED LIABILITIES:

Accounts payable and accrued liabilities consist of the following at:

	December 31, 2015	December 31, 2014
Accounts payable – suppliers	**$ 1,260,520**	$ 1,980,120
Accrued commissions	**129,192**	947,451
Accrued royalties / license fees	**732,301**	1,034,062
Accrued payroll	**146,962**	106,487
Accrued vacation	**244,810**	219,924
Accrued bonuses	**177,700**	265,500
Accrued expenses – other	**109,947**	392,486
TOTAL	**$ 2,801,432**	$ 4,946,030

NOTE 6 — DEFERRED RESEARCH AND DEVELOPMENT REVENUE:

The Company recognizes income from R&D milestones when those milestones are reached and non-milestone contracts and grants when earned. Grants are invoiced after expenses are incurred. Any projects or grants funded in advance are deferred until earned. As of December 31, 2015 and 2014, there were $353,406 and $340,000 unearned advanced revenues, respectively.

NOTE 7 — TERM NOTE, REVOLVING DEMAND NOTE, VEHICLE FINANCING AND LICENSE FEE PAYABLE:

On April 30, 2013, the Company entered into a new demand loan agreement ("Demand Note") with HSBC Bank, USA ("HSBC"). The Demand Note allowed the Company to draw on the line from time to time an amount up to an aggregate of $2,000,000 outstanding at any one time. The accrued interest on the Demand Note was payable monthly at an interest rate equal to one-quarter percent above prime per annum. The Company could repay any or all of the principal balance outstanding at any time. This was a demand note for which the bank lender could demand repayment of the entire loan, with accrued interest, at any time. The loan was subject to annual reviews, as well as an annual 30-day clean-up, during which there could be no amounts outstanding. In January 2016 HSBC notified the Company that it could no longer extend the credit and the Demand Note was cancelled.

The Security Agreement, related to the Demand Note, contained covenants that placed restrictions on the Company's operations, including covenants relating to mergers, debt restrictions, capital expenditures, tangible net worth, net profit, leverage, fixed charge coverage, employee loan restrictions, distribution restrictions (common stock and preferred stock), dividend restrictions, restrictions on lease payments to affiliates, restrictions on changes in business, asset sale restrictions, restrictions on acquisitions and intercompany transactions, and restrictions on fundamental changes in the Company and in its business.

The Company currently maintains its operating, payroll, and primary cash accounts at HSBC. During the year ended December 31, 2015, the Company had drawn down an aggregate of $700,000 on the Demand Note and each withdrawal was paid back within 30 days and all covenants were met.

NOTE 8 — INCOME TAXES:

The (benefit from) provision for income taxes for the years ended December 31, 2015 and 2014, is comprised of the following:

	2015	2014
Current		
Federal	**$ -**	$ (16,119)
State	**10,726**	6,576
Total current (benefit) provision	**10,726**	(9,543)
Deferred		
Federal	**(1,171,865)**	(449,452)
State	**896**	46,077
Total deferred (benefit) provision	**(1,170,969)**	(403,375)
Total (benefit) provision	**$ (1,160,243)**	$ (412,918)

The Company had an ownership change as described in Internal Revenue Code Sec. 382 during 2004 ("2004 change"). As a result, the Company's net operating losses prior to the 2004 change of $5,832,516 were subject to an annual limitation of $150,608 and for the first five (5) years are entitled to a BIG (Built-In-Gains) of $488,207 per year. These net operating losses expire in 2018 through 2024.

The Company had a second ownership change during 2006 ("2006 change"). The net operating losses incurred between the 2004 change and the 2006 change of $8,586,861 were subject to an annual limitation of $1,111,831 and for the first five (5) years are entitled to a BIG of $1,756,842 per year. These net operating losses expire in 2018 through 2028.

After applying the above limitations, at December 31, 2015, the Company has post-change net operating loss carry-forwards of approximately $15,815,108 which expire between 2020 and 2035. In addition the Company has research and development tax credit carryforwards of approximately $1,518,414 for the year ended December 31, 2015, which expire between 2025 and 2035.

	2015	2014
Current assets		
Inventory reserves	**$ 242,532**	$ 311,931
Accrued expenses	**91,143**	286,616
Current deferred tax assets	**333,675**	598,547
Less valuation allowances	**-**	-
Net current deferred asset	**$ 333,675**	$ 598,547
Noncurrent assets		
Net operating loss carry-forwards	**$ 5,365,401**	$ 3,986,618
Research and development credit	**1,518,414**	1,175,725
Other credits	**97,339**	107,967
Other	**210,553**	149,923
Gross noncurrent deferred tax assets	**7,191,707**	5,420,233
Depreciation	**(206,150)**	(213,206)
Noncurrent deferred tax assets	**6,985,557**	5,207,027
Less valuation allowances	**(1,518,414)**	(1,175,725)
Net noncurrent deferred tax assets	**$ 5,467,143**	$ 4,031,302

A reconciliation of the Federal statutory rate to the effective rate applicable to income (loss) before income taxes is as follows:

	Year Ending December 31,	
	2015	2014
Federal income tax at statutory rates	**(34.00)%**	(34.00)%
State income taxes, net of federal benefit	**.23%**	0.28%
Nondeductible expenses	**1.38%**	4.54%
Change in valuation allowance	**9.46%**	9.47%
Tax credits	**(9.46)%**	(9.47)%
Change in tax rates	**.00%**	1.96%
Other	**.34%**	0.58%
Income tax (benefit)	**(32.05)%**	(26.64)%

Interest and penalties, if any, related to income tax liabilities are included in income tax expense. As of December 31, 2015, the Company does not have a liability for uncertain tax positions.

The Company files Federal and state income tax returns. Tax years for fiscal 2012 through 2014 are open and potentially subject to examination by the federal and state taxing authorities.

NOTE 9 — STOCKHOLDERS' EQUITY:

(a) ***Common Stock***

During 2015, options to purchase 41,141 shares of the Company's common stock were exercised on a cashless basis into 17,109 shares of common stock at exercise prices ranging from $2.16 to $3.60.

During 2014, options to purchase 318,750 shares of the Company's common stock were exercised, either for cash or cashless into 286,356 shares of common stock at an exercise price of $1.04.

(b) ***Preferred Stock***

The Company has 10,000,000 shares of preferred stock authorized and none outstanding. These shares can become issuable upon an approved resolution by the board of directors and the filing of a Certificate of Designation with the state of Nevada.

(c) ***Options***

During 2015, the Company did not issue options to purchase common stock.

During the fourth quarter of 2014, the Company issued 36,000 options to purchase common stock to a newly-hired vice-president of the Company. The options are exercisable in three equal annual installments starting on the first anniversary of the date of issue. The options issued have an exercise price of $4.35 per share, which was the last traded price of the common stock on the day issued. The options expire five years from date of issue.

During the second quarter of 2014 the Company issued options to two of its directors pursuant to the Company's compensation policy for directors. Each director was issued 46,875 options to purchase common stock. The options become exercisable in five equal annual installments starting on the date of issue. The options issued have an exercise price of $3.480 per share, which was the last traded price of the common stock on the day issued. The options expire five years from date of issue.

The Company entered into an employment agreement, effective March 13, 2014 ("Employment Agreement"), with Mr. Sperzel to serve as the Company's Chief Executive Officer, which included issuing incentive and non-incentive stock options to purchase 250,000 shares of the Company's common stock. The options become exercisable in five equal annual installments starting on the first anniversary of the effective date of the Employment Agreement. The exercise price for these options was to be equal to the volume-weighted average trading price for the Company's common stock on March 13, 2014, which was $3.416 per share. The options expire seven years from date of issue.

(d) ***Warrants***

As of December 31, 2015 and 2014, the Company had no warrants outstanding to purchase shares of common stock.

NOTE 10 — RIGHTS AGREEMENT:

In March 2010, the Company entered into a Rights Agreement (the "Rights Agreement") between the Company and Action Stock Transfer Corp., as Rights Agent. The Rights Agreement expired at the end of November 2015. Pursuant to the Rights Agreement, the Company declared a dividend distribution of one preferred share purchase right (a "Right") for each outstanding share of Common Stock, $0.01 par value (the "Common Stock"), of the Company. The Board of Directors set the payment date for the distribution of the Rights as March 8, 2010, and the Rights were distributed to the Company's shareholders of record on that date. The description and terms of the Rights are set forth in the Rights Agreement.

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

Separation and Distribution of Rights. The Rights were to be evidenced by the certificates for shares of Common Stock registered in the names of the holders thereof, and not by separate rights certificates until the earlier to occur of (i) the close of business on the tenth business day following a public announcement that an Acquiring Person (as defined in the Rights Agreement) acquired a Combined Ownership (as defined in the Rights Agreement) of 15% or more of the outstanding shares of the Common Stock (the "Shares Acquisition Date") or (ii) the later of (A) the close of business on the tenth business day (or such later date as may be determined by action of the Board of Directors prior to such time as any person or group of affiliated or associated persons becomes an Acquiring Person) after the date that a tender or exchange offer or intention to commence a tender or exchange offer by any person is first published, announced, sent or given within the meaning of Rule 14d-4(A) under the Securities Exchange Act of 1934, as amended, the consummation of which would result in any person having Combined Ownership of 15% or more of the outstanding shares of the Common Stock, or (B) if such a tender or exchange offer has been published, announced, sent or given before the date of the Rights Agreement, then the close of business on the tenth business day after the date the Rights Agreement was entered into (or such later date as may be determined by action of the Board of Directors prior to such time as any person becomes an Acquiring Person); (the earlier of such dates referred to in (i) and (ii), which date may include any such date that is after the date of the Rights Agreement but prior to the issuance of the Rights, being called the "Distribution Date").

NOTE 11 — EMPLOYEE STOCK OPTION PLAN:

Effective June 3, 2008, the Company's stockholders voted to approve the 2008 Stock Incentive Plan ("SIP"), with 625,000 shares of Common Stock available to be issued. At the Annual Stockholder meeting on September 22, 2011 the Company's stockholders voted to approve an increase to the shares of Common Stock issuable under the SIP by 125,000 to 750,000. Under the terms of the SIP, the Compensation Committee of the Company's Board has the discretion to select the persons to whom awards are to be granted. Awards can be stock options, restricted stock and/or restricted stock units. The awards become vested at such times and under such conditions as determined by the Compensation Committee. As of December 31, 2015, there were 353,935 options exercised, 312,860 options outstanding and 83,205 options still available to be issued under the SIP.

Effective June 19, 2014, the Company's stockholders voted to approve the 2014 Stock Incentive Plan ("SIP14"), with 800,000 shares of Common Stock available to be issued. Under the terms of the SIP14, the Compensation Committee of the Company's Board has the discretion to select the persons to whom awards are to be granted. Awards can be stock options, restricted stock and/or restricted stock units. The awards become vested at such times and under such conditions as determined by the Compensation Committee. As of December 31, 2015, there were no options exercised, 129,750 options outstanding and 670,250 options still available to be issued under the SIP14.

The Company's results for the years ended December 31, 2015 and 2014 include stock-based compensation expense totaling $334,400 and $447,100, respectively. Such amounts have been included in the Consolidated Statements of Operations within cost of goods sold ($- and $700, respectively), research and development ($62,700 and $44,500, respectively) and selling, general and administrative expenses ($271,700 and $401,900, respectively). In accordance with ASC 718 the Company has not recorded a deferred tax asset related to the net operating losses resulting from the exercise of disqualifying stock options in the accompanying financial statements. The cumulative amount of unrecognized tax benefits at December 31, 2015 was immaterial, and if the Company is able to utilize this benefit in the future it would result in a credit to additional paid-in capital.

Stock option compensation expense in the years ended December 31, 2015 and 2014 represents the estimated fair value of options outstanding which is being amortized on a straight-line basis over the requisite vesting period of the entire award.

The Company did not grant any stock options during the year ended December 31, 2015. The weighted average estimated fair value of stock options granted in the year ended December 31, 2014 was $3.52 per share. The fair value of options at the date of grant was estimated using the Black-Scholes option pricing model. The expected volatility is based upon historical volatility of our stock and other contributing factors. The expected term is based on the Company's historical experience with similar type options.

The weighted-average assumptions made in calculating the fair values of options are as follows:

For the year ended	December 31, 2014
Expected term (in years)	4.50-6.30
Expected volatility	61.50-96.10%
Expected dividend yield	n/a
Risk-free interest rate	.83-1.52%

The Company granted no new options during the year ended December 31, 2015 to employees.

The following table provides stock options activity for the year ended December 31, 2015:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2014	**691,869**	**$ 3.66**	**3.97 years**	**$ 334,636**
Granted	-	$ -		
Exercised	41,141	$ 2.25		
Forfeited/expired/cancelled	1,250	$ 4.30		
Outstanding at December 31, 2015	**649,478**	**$ 3.75**	**3.21 years**	**$ 1,032,362**
Exercisable at December 31, 2015	**359,228**	**$ 3.89**	**2.03 years**	**$ 522,039**

The following table summarizes information about stock options outstanding at December 31, 2015:

	Stock Options Outstanding				Stock Options Exercisable		
Range of Exercise Prices	Shares	Average Remaining Contract Life (Year)	Weighted Average Exercise Price	Aggregate Intrinsic Value	Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value
0.0000 to 3.000	92,063	0.73	$ 2.80	$ 232,919	92,063	$ 2.80	$ 232,919
3.0001 to 3.500	343,750	4.73	3.43	651,863	87,500	3.44	165,060
3.5001 to 4.000	15,720	1.05	3.95	21,689	15,720	3.95	21,689
4.0001 to 4.500	122,320	1.87	4.37	117,971	98,320	4.37	94,451
4.5001 to 6.000	75,625	1.90	5.30	7,920.00	65,625	5.28	7,920
Total	649,478	3.21	$ 3.75	$ 1,032,362	359,228	$ 3.89	$ 522,039

As of December 31, 2015, there was $297,000 of net unrecognized compensation cost related to stock options that are not vested, which is expected to be recognized over a weighted average period of approximately 2.05 years. The total fair value of shares vested during the years ended December 31, 2015 and 2014, was $357,000 and $283,000, respectively.

NOTE 12 — GEOGRAPHIC INFORMATION AND ECONOMIC DEPENDENCY:

FASB Guidance establishes standards for the way that business enterprises report information about operating segments in financial statements and requires that those enterprises report selected information. It also establishes standards for related disclosures about product and services, geographic areas, and major customers.

Sales to Africa increased in 2015 primarily due to increased sales in Uganda by approximately $1,344,500, and Nigeria by approximately $287,500. Sales in Asia increased slightly by $76,200. European sales increased by $972,500. Sales decreased in 2015 to North America from decreased sales to Mexico of $3,913,400 and by decreased sales in the U.S from approximately $7,208,000 to $6,563,000. Sales decreases in 2015 to South America were primarily from decreased sales in Brazil from approximately $12,253,500 to $10,141,800

The Company produces only one group of similar products known collectively as "rapid medical tests". Management believes that it operates in a single business segment. Net sales by geographic area are as follows:

	For the years ended	
	December 31, 2015	December 31, 2014
Africa	**$ 3,673,199**	$ 2,097,353
Asia	**172,250**	96,061
Europe	**1,164,476**	191,947
North America	**6,525,951**	11,134,691
South America	**10,350,812**	12,429,717
	$ 21,886,688	$ 25,949,769

Sales to Africa increased in 2015 primarily due to increased sales in Uganda by approximately $1,344,500, and Nigeria by approximately $287,500. Sales in Asia increased slightly by $76,200. European sales increased by $972,500. Sales decreased in 2015 to North America from decreased sales to Mexico of $3,913,400 and by decreased sales in the U.S from approximately $7,208,000 to $6,563,000. Sales decreases in 2015 to South America were primarily from decreased sales in Brazil from approximately $12,253,500 to $10,141,800.

NOTE 13 — COMMITMENTS AND CONTINGENCIES:

Employment Contracts:

The Company has contracts with three key employees. The contracts call for salaries presently aggregating $944,500 per year. One contract expires in May 2017, one expires in March 2016 and one contract expires in March 2017. The following table is a schedule of future minimum salary commitments:

2016	$	690,800
2017		181,200

Pension Plan:

The Company has a 401(k) plan established for its employees. Effective January 1, 2011 the Company elected to match 40% of the first 5% (or 2% of salary) that an employee contributes to their 401(k) plan. Expenses related to this matching contribution aggregated $90,915 and $82,750 for the years ended December 31, 2015 and 2014, respectively.

Obligations Under Operating Leases:

The Company leases industrial space used for office, R&D and manufacturing facilities, currently with a monthly rent of $27,988. The current lease expires on April 30, 2017. The lease provides for annual increases of 2 1/2 percent each year starting May 1, 2016. In February of 2014, the Company entered into a lease, effective March 1, 2014, for another facility located a short distance from its current facility currently with a monthly rent of $15,097. The space is used primarily for warehousing and provides for additional office space. The lease expires on April 30, 2018. The lease provides for annual increases of three percent each year starting March 1, 2016.

The following is a schedule of future minimum rental commitments (assuming no increases):

Years ending December 31,

2016	$	527,151
2017		306,018
2018		64,067
	$	**897,236**

Rent expense was $511,900 and $476,000 for the years ended December 31, 2015 and 2014, respectively.

Economic Dependency:

The following table delineates sales the Company had to customers in excess of 10% of total sales for the periods indicated:

	For the years ended				Accounts Receivable As of	
	December 31, 2015		December 31, 2014		December 31, 2015	December 31, 2014
	Sales	% of Sales	Sales	% of Sales		
Customer 1	$ 10,132,512	46%	$ 12,253,526	47%	$ 775,209	$ 6,230,886
Customer 2	4,526,908	21%	6,618,251	26%	700,656	386,270

The following table delineates purchases the Company had with vendors in excess of 10% of total purchases for the periods indicated.

	For the years ended				Accounts Payable As of	
	December 31, 2015		December 31, 2014		December 31, 2015	December 31, 2014
	Purchases	% of Purc.	Purchases	% of Purc.		
Vendor 1	$ 794,536	11%	$ 1,331,647	14%	$ 90,075	$ 200,855
Vendor 2	*	*	$ 1,594,838	17%	*	-

In the table above the asterisk (*) indicates that purchases from the vendor did not exceed 10% for the period indicated.

The Company currently buys materials which are purchased under intellectual property rights agreements and are important components in its products. Management believes that other suppliers could provide similar materials on comparable terms. A change in suppliers, however, could cause a delay in manufacturing and a possible loss of sales, which would affect operating results adversely.

NOTE 14 — COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENTS:

In 2015 and 2014, the Company earned $2,316,044 million and $1,672,258 million, respectively, from research revenues and milestones. The Company is now involved in additional feasibility and development contracts related to its DPP® technology. The total expended on R&D, excluding regulatory, in 2015 and 2014, was approximately $5.4 million and $4.1 million, respectively.

a. National Institutes of Health (NIH) Grant:

In March 2011, the Company received a $2.9 million, three-year grant from the United States National Institutes of Health to complete development of a test for Tuberculosis. Grants are invoiced after expenses are incurred. The Company earned, for the years ended December 31, 2015 and 2014, $- and $388,000, respectively from this grant. The Company has earned $2,850,000 from this grant from inception through December 31, 2015, of which $1,019,000 was paid to sub-contractors.

b. Battelle/CDC DPP® Influenza Immunity Test:

In November 2014, the Company entered into a follow-on, milestone-based development agreement bringing the total up to $1,253,100 based on Chembio's previous successful initial development of a multiplex rapid point-of-care ("POC") influenza immunity test utilizing its patented Dual Path Platform (DPP®) technology. The follow-on agreement contemplates a period of approximately six months in which the follow-on development activity is to be completed. For the years ended December 31, 2015 and 2014, the Company earned $216,850 and $115,000, respectively from this grant. The Company has earned $1,253,100 from this grant from inception through December 31, 2015.

c. Cooperative research agreement with a U.S. government agency:

In May 2013, the Company was awarded a cooperative research agreement with a U.S. government agency for up to $883,000 for an eight-month development project to develop rapid POC diagnostic tests for five infectious diseases associated with febrile illness. For the years ended December 31, 2015 and 2014, the Company earned $- and $117,000, respectively from this grant. The Company has earned $883,000 from this grant from inception through December 31, 2015.

d. RVR DPP® technology transfer agreement:

In February 2014, the Company entered into a technology transfer agreement with RVR Diagnostics for $1,500,000. The agreement was modified in September 2014 and September 2015. Per the agreement, as modified, the Company earned $125,000 and $1,125,000 in milestone payments during 2015 and 2014. The Company has earned $1,250,000 from this grant from inception through December 31, 2015.

e. Dengue agreement:

In October 2014, the Company entered into a development agreement with an international diagnostics company for $300,000. Revenue for this agreement is being recognized under a proportional performance method. For the years ended December 31, 2015 and 2014, the Company earned $240,000 and $60,000, respectively from this grant. The Company has earned $300,000 from this grant from inception through December 31, 2015.

f. Brain Injury agreement:

In January 2015, the Company entered into a technology development agreement with Perseus Science Group LLC for $946,000. Revenue for this agreement is being recognized under a proportional performance method. The Company earned $469,600 for the year ended December 31, 2015 from this agreement.

g. Malaria agreement:

In January 2015, the Company was awarded a grant from The Bill & Melinda Gates Foundation for $307,000. The Company earned $307,000 for the year ended December 31, 2015 from this agreement.

h. Cancer agreement:

In October 2014, the Company entered into a technology development agreement with an international diagnostics company for $320,000. Revenue for this agreement is being recognized under a proportional performance method. The Company earned $205,000 for the year ended December 31, 2015 from this agreement.

i. Fever panel agreement:

In October 2015, the Company entered into an agreement with Paul G. Allen Ebola Program for $2,118,265. Revenue for this agreement is being recognized under a proportional performance method. The Company earned $408,500 for the year ended December 31, 2015 from this agreement.

Governmental Regulation:

All of the Company's existing and proposed diagnostic products are regulated by the United States Food and Drug Administration (FDA), United States Department of Agriculture, certain state and local agencies, and/or comparable regulatory bodies in other countries. Most aspects of development, production, and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing, and record keeping are subject to review. After marketing approval has been granted, Chembio must continue to comply with governmental regulations. Failure to comply with these regulations can result in significant penalties.

NOTE 15 — SUBSEQUENT EVENTS:

February 19, 2016, the Company announced it had been awarded a $550,000 grant from philanthropist and entrepreneur Paul G. Allen to immediately initiate development of simple, cost-effective POC diagnostic tests to identify Zika virus and related febrile illnesses. The grant is managed by Mr. Allen's company, Vulcan Inc., and the funds come from the Paul G. Allen Family Foundation.

On March 7, 2016, the Company announced plans to collaborate with Bio-Manguinhos/Fiocruz to undertake to develop, register and commercialize POC DPP® Zika Assays for Brazil. The Company has developed a prototype DPP® Zika Assay and prototype DPP® Zika/Dengue/Chikungunya Assay, and we hope to receive additional funding, along with the grant mentioned above, to accelerate the development and testing of our DPP® Zika Assays. The Company anticipates receiving significant orders for DPP® Zika Assays in 2016.

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

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

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

Exhibit 21

List of Subsidiaries

Chembio Diagnostic Systems, Inc. (Delaware)

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Chembio Diagnostics, Inc.
Medford, New York

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-69460, No. 333-141555, No. 333-151785, and No. 333-203633) of Chembio Diagnostics, Inc. and subsidiary of our report, dated March 8, 2016 relating to the consolidated financial statements which appears in this Form 10-K.

/s/ BDO USA, LLP
BDO USA, LLP
Melville, New York

March 8, 2016

EXHIBIT 31.1

CERTIFICATION

I, John J. Sperzel, certify that:

1. I have reviewed this Form 10-K of Chembio Diagnostics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 8, 2016 /s/ John J. Sperzel

John J. Sperzel, Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION

I, Richard J. Larkin, certify that:

1. I have reviewed this Form 10-K of Chembio Diagnostics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 8, 2016 /s/ Richard J. Larkin

Richard J. Larkin, Chief Financial Officer

EXHIBIT 32

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K (the "Report") of Chembio Diagnostics, Inc. (the "Company") for the year ended December 31, 2015, each of the undersigned John J. Sperzel, the Chief Executive Officer of the Company, and Richard J. Larkin, the Chief Financial Officer of the Company, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of the undersigneds' knowledge and belief:

(1) This Form 10-K for the year ended December 31, 2015 fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in this Form 10-K for the year ended December 31, 2015 fairly presents, in all material respects, the financial condition and results of operations of Chembio Diagnostics, Inc. for the periods presented therein.

Dated: March 8, 2016 /s/ John J. Sperzel
John J. Sperzel
Chief Executive Officer

Dated: March 8, 2016 /s/ Richard J. Larkin
Richard J. Larkin
Chief Financial Officer