CHEMBIO DIAGNOSTICS, INC.
Form 10-K
March 05, 2015
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, 2014

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

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 $29,000,000.

As of March 2, 2015, the registrant had 9,627,248 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.

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 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. Outside the U.S., Chembio markets the SURE CHECK® HIV 1/2 Assay primarily through distributors. The SURE CHECK® HIV 1/2 Assay is Food & Drug Administration (FDA) approved, CLIA-waived, European CE-marked, and has been pre-qualified by the World Health Organization (WHO). Results are obtained in 15 minutes via a 2.5uL blood sample (i.e., fingerstick, serum, plasma, or venipuncture whole blood). The assay is stable at room temperature and provides 99.7% sensitivity and 99.9% specificity.

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

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

Regulatory Status of the lateral flow HIV tests

The FDA approved our Pre-Market Applications (hereinafter "PMA"; see "Governmental Regulations" and Glossary) in April 2006 for our SURE CHECK® HIV 1/2 (and also now Alere Clearview® Complete HIV 1/2) and for our HIV 1/2 STAT-PAK® products. Waivers under the Clinical Laboratory Improvement Act (hereinafter "CLIA"; see Governmental Regulations) were granted by the FDA for these two FDA-approved products in 2006 and 2007, respectively. A CLIA waiver is required in order for health care providers to administer these tests in the settings where they are most suited and needed, such as public health testing clinics, hospital emergency rooms and physicians' offices. The SURE CHECK® and HIV 1/2 STAT-PAK® products received CE Marks in July 2013 and March 2014, respectively, and the CE Marking for the DPP® HIV 1/2 Assay described below is expected in 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 2015. We are also pursuing CE Marking, anticipated during 2015, as stated above.

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 continue to pursue an FDA submission for this product, and are in the progress of studies to evaluate a version that has been developed for the US market, to meet the performance requirements for a combination test to detect both HIV and Syphilis, including a "reverse" algorithm that is currently in clinical use in the United States for syphilis testing.

DPP® TECHNOLOGY & DEVELOPMENT:

This year marked a critical year for Chembio in executing our strategy to leverage our 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:

- In October 2014, Chembio entered into an exclusive agreement with Integrated BioTherapeutics, Inc. (IBT), a biotechnology company focused on the discovery of novel vaccines and therapeutics for emerging infectious diseases. Under the terms of the agreement, Chembio will combine its patented DPP® technology with IBT's proprietary Ebola reagents to develop POC diagnostic tests for Ebola and febrile illness. Since announcing the partnership with IBT, the Company has made the following progress to develop DPP® Ebola and DPP® Febrile Illness Assays:
  - Developed DPP® Ebola Assays in Chembio's Research & Development facilities.
  - Successfully tested DPP® Ebola Assays in high containment (BSL4) laboratory, using wild type (real) Ebola virus, via IBT's partner in Canada.
  - Signed a Research Collaboration Agreement with the Centers for Disease Control and Prevention (CDC) to develop and validate DPP® Ebola and DPP® Febrile Illness Assays.
    - Continued to evaluate its DPP® Ebola test at CDC laboratory in Atlanta, GA, with an estimate of having product for field evaluation in 2Q of 2015.
  - Submitted DPP® Ebola pre-qualification application to World Health Organization (WHO) as well as Emergenct Use Authorization (EUA) for FDA
  - Contacted numerous organizations for Ebola funding, to accelerate the potential development, and potential manufacturing and supply, of DPP® Ebola and DPP® Febrile Illness Assays, to include both Ebola and Malaria.
- 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 partnership with an international diagnostics company to develop a POC diagnostic test for the early detection and monitoring of a specific type of cancer. The cancer project represents the first application of the DPP® technology outside the infectious disease field, also announced in October 2014.
- 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 has 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.

Additionally, Chembio's product pipeline includes a multiplex test that detects P24 HIV antigen as well as HIV 1/2 antibodies, and a rapid test for the detection of Hepatitis-C antibodies. These products are currently in development to meet the performance claims required for the U.S. market.

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 (and SDS) makes this election with respect to either (or both) of these products, Chembio could sell that respective (or both) product(s) in the United States market under Chembio/SDS brands 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.

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 [of] 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 Vigliancia 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, 2014 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 of this product in 2011, and $4,990,840 in 2012, all of which applied to the qualifying amount to obtain the right to the technology transfer (the "Qualifying Amount") for this product. In 2013, Bio-Manguinhos made $291,235 of purchases that applied to the Qualifying Amount for this product, and $3,320,010 of purchases in excess of the Qualifying Amount. In 2014, Bio-Manguinhos made $4,799,250 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 of this product in 2011 and $99,183 of this product in 2012 that applied to the Qualifying Amount. In addition, Bio-Manguinhos made purchases in excess of the Qualifying Amount equal to $1,314,117 in 2012, $1,736,700 in 2013 and $2,394,000 in 2014.

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 of this product in 2011 and $165,750 of this product in 2012 that applied to the Qualifying Amount. In addition, Bio-Manguinhos made purchases in excess of the Qualifying Amount equal to $2,817,750 in 2012, $646,340 in 2013 and $4,617,891 in 2014.

b. With respect to the two variations of Chembio's Screen & Confirm Test, Bio-Manguinhos had not made any purchases in 2011, 2012, 2013 or 2014, and therefore had not qualified to request the technology transfer for either of them. In order to qualify, Bio-Manguinhos would need to purchase an additional $2.2 million of one of these tests, and an additional $2.08 million of the other test.

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 of this product in 2011, $819,000 in 2012, $390,000 in 2013 and $390,000 in 2014, all of which applied to the Qualifying Amount. In order to qualify for the technology transfer, Bio-Manguinhos would need to purchase an additional $195,000 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. In order to qualify for the technology transfer, Bio-Manguinhos would need to purchase an additional $225,000 of this product.

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- 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 agreement with FIOCRUZ, we have entered into certain other 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. 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 incorporating its patented DPP® technology, such as Dengue, as indicated in the DPP® Technology & Development section.

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 6 of these U.S. individuals, or almost 16%, unaware that they are infected. It is transmissions from these 250,000 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 lateral flow rapid HIV tests, the cassette and barrel, together represent approximately a 25% share of this market. Orasure Technologies, Inc., which was the first FDA-approved rapid HIV test, has lost nearly half its market share, now estimated to be approximately 55%. Trinity Biotech has an estimated 15% market share and Biolytical Laboratories, Medmira and Bio-Rad share the remaining 5%.

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, except for the 8.5% lateral flow royalties which was applicable to the sales of the products only until February 2015 when the applicable lateral flow patent of Alere's expired. 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 having Alere sell our products. 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 by Alere 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.

During 2014 we 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 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 is was developed for 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. We believe the price that Alere is charging for this product may be substantially higher than our and our competitors' antibody tests, as the antigen claim avails some customers of an additional reimbursement code. Moreover there is support by a number of key opinion leaders for the public health value of such 4th generation tests, and if Alere is able to successfully launch this product, it represents a significant competitive threat to Chembio as well as to each of the other rapid HIV test manufacturers (Orasure and Trinity primarily).

During 2011 Biolytical, Inc. of Vancouver, Canada received FDA approval and in 2012 received CLIA waiver of a flow-through rapid HIV test called "INSTI". The 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 2014 and 2013, we spent $4.8 million and $5.8 million, respectively, on research and development (including regulatory activities). These expenses were in part underwritten by funding from R&D and milestones revenues of $1.7 million in 2014 and $2.0 million in 2013. 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, 2014, we employed approximately 166 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 2015. The contract with Mr. Esfandiari has a term of three years ending March 2016. 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 by Alere Medical as Clearview® Complete HIV 1-2 and Clearview® HIV 1-2 STAT PAK®.

FDA approval of our DPP® HIV screening assay for use with oral fluid or blood samples was achieved by means of a PMA application. The Clinical Laboratory Improvement Act of 1988 ("CLIA") prohibits laboratories from performing in-vitro tests for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of, the health of human beings unless there is in effect for such laboratories a certificate issued by the United States Department of Health and Human Services (via the FDA) applicable to the category of examination or procedure performed. Although a certificate is not required for the Company, it considers the applicability of the requirements of CLIA in the design and development of its products. The statutory definition of "laboratory" is very broad, and many of our customers are considered labs. A CLIA waiver will remove certain quality control and other requirements that must be met for certain customers to use the Company's products and this is critical to the marketability of a product into the point-of-care diagnostics market. The Company has received a CLIA waiver for each of the two 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 contain 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 also licenses a group of lateral flow technology patents from Alere. Our lateral flow products, which are primarily our STAT-PAK®, SURE CHECK®, and DIPSTICK® product lines, may incorporate methods that are claimed under one of the patents licensed from Alere that we use in our tests. That U.S. Patent #6,485,982 is also referred to as the Charlton patent, which patent expired on February 3, 2015. This patent describes a test device and method for a colored particle immunoassay that determines the presence of an analyte 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, we pay 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 2014 our lateral flow royalty expense to Alere was $182,000, and since 2007 we have incurred a total of $2.83 million in lateral flow royalty expenses. As of February 3, 2015 this royalty expense was no longer payable as the applicable patent expires 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 will expire within the next couple of years and we are not aware of any patent enforcement litigation that is ongoing with respect to the Alere lateral flow intellectual property.

Regardless, the DPP® technology provides us with our own intellectual property. We believe it provides us with a freedom to operate, and that it also enables tests to be developed with improved sensitivity as compared with comparable tests on lateral flow platforms. The Company has signed and anticipates signing new development projects based upon the DPP® technology that will provide new manufacturing and marketing opportunities. We have filed other 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 in this Form 10-K 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.

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

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ITEM 1A. RISK FACTORS

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

Risks related to our industry, business and strategy

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

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

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

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

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

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

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

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

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

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

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

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

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

public health markets.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks related to our Common Stock

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

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

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

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

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

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

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 $27,305 per month. The space is utilized for research and development activities (approximately 4,160 square feet), offices (approximately 3,100 square feet) and production (approximately 32,400 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 $14,657 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 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

Fiscal Year 2013	High Bid	Low Bid
First Quarter	$5.75	$4.61
Second Quarter	$5.10	$4.10
Third Quarter	$5.32	$3.00

Fourth Quarter	$3.95	$3.19

Holders

As of March 1, 2015, there were approximately 142 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, 2014.

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

Statement of Operations Data:	December 31, 2014		December 31, 2013		December 31, 2012		December 31, 2011		December 31, 2010	
TOTAL REVENUES	$27,645,284		$29,549,609		$25,610,595		$19,388,036		$16,704,703	
GROSS MARGIN [1]	10,814,023	39%	12,300,159	42%	10,789,991	42%	9,390,303	48%	8,100,699	48%
OPERATING COSTS:										
Research and development expenses [1]	4,832,537	17%	5,834,249	20%	4,486,302	18%	4,878,119	25%	2,586,308	15%
Selling, general and administrative expenses [1]	7,531,739	27%	5,461,083	18%	4,851,587	19%	3,424,297	18%	2,940,721	18%
	12,364,276		11,295,332		9,337,889		8,302,416		5,527,029	
INCOME (LOSS) FROM OPERATIONS	(1,550,253)		1,004,827		1,452,102		1,087,887		2,573,670	
OTHER INCOME (EXPENSES):	132		12,943		(1,584)		(12,325)		(14,503)	
INCOME (LOSS) BEFORE INCOME TAXES [1]	(1,550,121)	-6 %	1,017,770	3 %	1,450,518	6 %	1,075,562	6 %	2,559,167	15%
Income tax (benefit) provision	(412,918)		486,952		509,237		(5,133,229)		-	
NET INCOME (LOSS)	$(1,137,203)		$530,818		$941,281		$6,208,791		$2,559,167	
Basic income (loss) per share	$(0.12)		$0.06		$0.12		$0.79		$0.33	

Diluted income (loss) per share	$(0.12)	$0.06	$0.11	$0.73	$0.29
Weighted average number of shares outstanding, basic	9,530,320	8,994,080	7,986,030	7,874,807	7,762,858
Weighted average number of shares outstanding, diluted	9,530,320	9,519,968	8,614,944	8,556,284	8,865,114
Balance Sheet Data:					
Working capital	$12,372,169	$4,221,011	$7,630,368	$6,133,956	$4,560,277
Total assets	25,010,192	24,486,592	17,335,150	15,485,744	9,086,174
Total liabilities	5,286,030	4,309,490	3,460,630	2,991,110	3,277,230
Shareholders' equity	19,724,162	20,177,102	13,874,520	12,494,634	5,808,944

(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"), Labtest, RVR and Bio-Rad.

Research and development ("R&D"), milestone, and grant and royalty revenues for the year ended December 31, 2014 decreased to $1,696,000 from $2,034,000 in the prior-year, which was the result of a winding down of grants in 2014 over 2013. R&D expenses in the year of 2014 were $4.83 million, compared with $5.83 million in the prior-year.

Research & Development Activities

Ebola Point-of-Care (POC) Test: In October 2014, we signed an agreement with Integrated BioTherapeutics, Inc. (IBT), to develop, validate, and commercialize a POC Ebola assay for the diagnostic market. This work involves

applying IBT's Ebola reagents with Chembio's proprietary DPP® technology to generate a multiplexed unitary assay to diagnose Ebola, including the potential of a febrile illness multiplex test for expanded applications. The outcome of preliminary feasibility testing is encouraging. We are working closely with the CDC laboratory in Atlanta, GA, and estimate we will have product available for field evaluation in 2Q of 2015. Additionally, we have applied for pre-qualification application to World Health Organization (WHO) as well as Emergency Use Authorization (EUA) with the FDA. We continue to seek funding for this project to accelerate development and potential supply.

Cancer POC Test: We have entered into a partnership with an international diagnostics company to develop a POC diagnostic test for the early detection and monitoring of a specific type of cancer. The cancer project represents the first application of the DPP® technology outside of the infectious disease field, as announced in October 2014. This scope of the agreement involves product development of an existing assay, utilizing Chembio's DPP® technology. The goal is to optimize the existing lateral flow assay design, conduct verification and validation studies, and to produce pilot lots to support preclinical studies. Under the terms of the agreement, neither Chembio's partner nor the specific type of cancer is being disclosed.

DPP® HIV-Syphilis: We have developed and launched a version of this product for international sale. Studies have been initiated to evaluate a version of this test that has been developed for the US market, to meet the performance requirements for a combination test to detect both HIV and Syphilis, including a "reverse" algorithm that is currently in clinical use in the United States for syphilis testing.

DPP® Dengue Development: Based on our 2013 experience developing a DPP® Febrile Illness Assay in partnership with a U.S. government agency, we signed an agreement to develop a stand-alone DPP® Dengue Fever Assay which would be able to detect IgG/IGM and NS1 antigens. The goal is to conduct verification and validation studies, as well as produce pilot lots, to support preclinical studies. Under the terms of the agreement, Chembio's partner is not being disclosed.

DPP® FLU Immunostatus Assay –The Company entered into a follow-on, milestone-based development agreement in November 2014 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.

DPP® Brain Injury Test: 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 has agreed to pay Chembio milestone development payments during 2015.

DPP® Malaria POC Rapid Test: Chembio was awarded a grant from the Bill & Melinda Gates Foundation in January 2015 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.

Additionally, Chembio's product pipeline includes a multiplex test that detects P24 HIV antigen as well as HIV 1/2 antibodies, and a rapid test for the detection of Hepatitis-C antibodies. These products are currently in development to meet the performance claims required for the U.S. market.

Regulatory Activities

DPP® HIV 1/2 Screening Assay for Use with oral fluid or blood samples – We received Food and Drug Administration (FDA) approval of our Pre-Marketing Application (PMA) for this product in December 2012. In October 2014 , the FDA granted the waiver for DPP® HIV 1/2 Assay for Oral Fluid, Fingerstick Whole Blood and Venous Whole Blood under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations.

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 continue to pursue an FDA submission for this product, and are in the progress of studies to evaluate a version that has been developed for the US market, to meet the performance requirements for a combination test to detect both HIV and Syphilis, including a "reverse" algorithm that is currently in clinical use in the United States for syphilis testing.

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 January 19, 2015, the Company entered into a 2015 Omnibus Agreement (the "Omnibus Agreement") with StatSure Diagnostic Systems, Inc. ("SDS") to acquire certain rights from, and to settle certain matters with, SDS. Prior to execution of the Omnibus Agreement, SDS owned 50 percent of the rights to the SURE CHECK® HIV 1/2 Assay (the "Barrel Product") pursuant to the "2-Way Agreement", as defined below, and subject to the "3-Way Agreement", as defined below. The "2-Way Agreement" is defined as the Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, as amended, between Chembio and SDS, that establishes the respective rights of Chembio and SDS concerning the Barrel Product. The "3-Way Agreement" is defined as the HIV Barrel License, Marketing And Distribution Agreement, dated as of September 29, 2006, as amended, among Chembio, SDS and Alere Inc. ("Alere"), which grants to Alere exclusive U.S. marketing and distribution rights, through May 31, 2016, to the Barrel Product.

Pursuant to the Omnibus Agreement, beginning June 1, 2016, Chembio will own full rights to the SURE CHECK® HIV 1/2 Assay, including a perpetual, non-exclusive, transferable, sub-assignable license, and including sales, marketing, distribution and trademark rights, subject to the terms of the 3-Way Agreement. Chembio paid $400,000 to SDS in exchange for these rights. In addition certain amounts owed by SDS to Chembio were exchanged for manufacturing equipment owned by SDS. The license will be amortized over its useful life and the equipment will be depreciated over its excepted life.

For all sales of the Barrel Product made by Chembio outside the United States from July 1, 2014 until the close of business on May 31, 2016, SDS will receive an amount equal to 30% of Chembio's net sales. For all sales of the Barrel Product made by SDS outside the U.S. prior to the close of business on May 31, 2016, Chembio will receive an amount equal to 30% of SDS' net sales. Calculation of "net sales" will be based on the amount of revenues received, reduced by costs, royalties and sales commissions incurred. Until the close of business on May 31, 2016, each of Chembio and SDS will continue to receive payments from Alere under the terms of the 3-Way Agreement for sales of

the Barrel Product by Alere.

The 3-Way Agreement will continue to remain in effect pursuant to its terms. The 2-Way Agreement was terminated pursuant to the provisions of the Omnibus Agreement.

Also under the terms of the Omnibus Agreement, SDS and Chembio agreed to resolve all other matters between them, including matters set forth in the complaint recently filed by SDS against Chembio in the United States District Court for the Eastern District of New York.

RESULTS OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2014 AS COMPARED WITH THE YEAR ENDED DECEMBER 31, 2013

Income:

For the year ended December 31, 2014, Loss before income taxes was $(1,550,000) compared to Income before taxes of $1,018,000 for the year ended December 31, 2013. Net Loss for the 2014 period was $(1,137,000) as compared to a Net Income of $531,000 for 2013. The change from Net Income to Net Loss is primarily attributable to decreased revenues, decreased gross margin, and increased operating expenses. Gross margin decreased in the year ended December 31, 2014 as compared with the year ended December 31, 2013, by $1,486,000, or 12.1%. This decreased gross margin and increased operating expenses, the most significant of which were an increase in wages and related expenses of $940,000, an increase in commissions of $530,000, consulting expenses of $171,000, marketing materials of $279,000, stock-based compensation of $169,000, travel and entertainment of $130,000 and change in bad debt allowance of $61,000, partially offset by decreased clinical trial expenses of $1,310,000, accounted for most of the change in Net Loss.

Revenues:

Selected Product Categories:	For the years ended December 31, 2014	December 31, 2013	$ Change	% Change
Lateral Flow HIV Tests and Components	$9,518,242	$20,248,364	$(10,730,122)	-52.99 %
DPP® Tests and Components	15,655,680	6,592,660	9,063,020	137.47 %
Other	775,847	674,762	101,085	14.98 %
Net Product Sales	25,949,769	27,515,786	(1,566,017)	-5.69 %
License and royalty revenue	23,257	4,906	18,351	374.05 %
R&D, milestone and grant revenue	1,672,258	2,028,917	(356,659)	-17.58 %
Total Revenues	$27,645,284	$29,549,609	$(1,904,325)	-6.44 %

Revenues for our lateral flow HIV tests and related components during the year ended December 31, 2014 decreased by approximately $10,730,000 from the same period in 2013. This was primarily attributable to decreased sales to South America, of approximately $6,500,000, decreased sales to the U.S. of $1,890,000, and decreased sales to Africa of $2,255,000. Revenues for our DPP® products during the year ended December 31, 2014 increased by approximately $9,063,000 over the same period in 2013, primarily for sales in Brazil to FIOCRUZ. The decrease in R&D, and in milestone and grant revenue, was primarily due to a reduction in revenue from certain development projects that were nearing completion during the period, partially offset by $1,125,000 in revenue from the license contract we signed in February 2014 with RVR Diagnostics. R&D revenues include funds, recognized on an "as expenses are incurred" basis, from a Phase II NIH grant for Leptospirosis, which was effective as of June 1, 2009, and from a Phase II grant for Tuberculosis, which was effective March 1, 2011, as well as a development contract with Battelle entered into in the fourth quarter of 2014.

Gross Margin:

Gross Margin related to Net Product Sales:	For the years ended December 31, 2014	December 31, 2013	$ Change	% Change
Gross Margin per Statement of Operations	$10,814,023	$12,300,159	$(1,486,136)	-12.08 %
Less: R&D, milestone, grant, license and royalties	1,695,515	2,033,823	(338,308)	-16.63 %

Gross Margin from Net Product Sales	$9,118,508	$10,266,336	$(1,147,828)	-11.18 %
Product Gross Margin %	35.14 %	37.31 %		

The overall gross margin dollar decrease of $1,486,000 included a $1,148,000 decrease in gross margin from net product sales and a $338,000 decrease in non-product revenues. The decrease in net product sales gross margin of $1,148,000 is primarily attributable to the change in product mix compared to 2013, particularly the reduction of sales to our U.S. distributor in the third and fourth quarters which were at much higher margins. The net product sales gross margin decrease is comprised of two components, one is the decreased change in margin percentage of 2.2% which contributed $564,000 to the decrease, and the other is the decrease in product sales of $1,566,000, which at the 37.3% margin contributed the balance of $584,000. The 2.2% decrease in the percentage, from 37.3% in 2013 to 35.1% in 2014, was primarily due to a larger amount of unapplied overhead along with the reduced sales to our U.S. distributor.

Research and Development:

This category includes costs incurred for product research and development, regulatory approvals, technical support, evaluations and registrations.

Selected expense lines:	For the years ended December 31, 2014	December 31, 2013	$ Change	% Change
Clinical and Regulatory Affairs:				
Wages and related costs	$448,852	$436,088	$12,764	2.93 %
Consulting	29,741	53,493	(23,752)	-44.40 %
Stock-based compensation	3,231	19,478	(16,247)	-83.41 %
Clinical trials	205,589	1,515,212	(1,309,623)	-86.43 %
Other	93,780	82,852	10,928	13.19 %
Total Regulatory	781,193	2,107,123	(1,325,930)	-62.93 %
R&D Other than Regulatory:				
Wages and related costs	2,456,514	2,224,882	231,632	10.41 %
Consulting	123,965	106,155	17,810	16.78 %
Stock-based compensation	41,306	86,023	(44,717)	-51.98 %
Materials and supplies	1,021,516	975,503	46,013	4.72 %
Other	408,043	334,563	73,480	21.96 %
Total other than Regulatory	4,051,344	3,727,126	324,218	8.70 %
Total Research and Development	$4,832,537	$5,834,249	$(1,001,712)	-17.17 %

Expenses for Clinical & Regulatory Affairs for the year ended December 31, 2014 decreased by $1,326,000 as compared to the same period in 2013. This was primarily due to a decrease of $1,309,000 in clinical trial expenses.

R&D expenses other than Clinical & Regulatory Affairs increased by $324,000 in the year ended December 31, 2014, as compared with the same period in 2013. 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, 2014	December 31, 2013	$ Change	% Change
Wages and related costs	$2,763,370	$2,068,173	$695,197	33.61 %
Consulting	456,658	279,688	176,970	63.27 %
Commissions	1,432,567	902,393	530,174	58.75 %
Stock-based compensation	399,334	169,502	229,832	135.59 %
Marketing materials	345,426	112,326	233,100	207.52 %
Investor relations/investment bankers	168,410	214,786	(46,376)	-21.59 %
Legal, accounting and compliance	662,522	621,429	41,093	6.61 %
Travel, entertainment and trade shows	320,280	190,698	129,582	67.95 %
Bad debt allowance (recovery)	28,000	(33,450)	61,450	-183.71%
Other	955,172	935,538	19,634	2.10 %

Total S, G &A	$7,531,739	$5,461,083	$2,070,656	37.92 %

Selling, general and administrative expenses for the year ended December 31, 2014, increased by $2,071,000 as compared with the same period in 2013, a 37.9% increase. This increase resulted primarily from increases in wages and related costs, which for 2014 included the development of a sales and marketing team and the COO (not included in the first six months of 2013), consulting expenses, the cost of the CEO search, and commissions due to increased sales to Brazil, which were partially offset by a decrease in investor relations/investment bankers.

Other Income and Expense:

	For the years ended December 31, 2014	December 31, 2013	$ Change	% Change
Other income (expense)	$(5,707)	$ 7,500	$(13,207)	-176.09%
Interest income	$5,839	$ 5,778	$61	1.06 %
Interest expense	-	(335)	335	-100.00%
Total Other Income and (Expense)	$132	$ 12,943	$(12,811)	-98.98 %

Other income (expense) for the year ended December 31, 2014 decreased approximately $13,000, primarily due to a loss on the sales of a fixed asset of $5,700 from a gain on the sale of a fixed asset $7,500 in the same period in 2013.

Income tax (benefit) provision:

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). For the year ended December 31, 2013, the Company charged $487,000 to income tax expense and reduced the deferred tax asset by $458,000. The effective tax rate used to recognize the benefit in 2014 was 26.6% compared to a 47.8% rate used in 2013 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, 2014	December 31, 2013	$ Change	% Change
Cash and cash equivalents	$4,614,538	$9,650,275	$(5,035,737)	-52.18 %
Accounts receivable, net of allowance for doubtful accounts of $52,000 and $24,000 at December 31, 2014 and 2013, respectively	8,338,889	4,592,121	3,746,768	81.59 %
Inventories	3,638,299	3,188,726	449,573	14.10 %
Fixed assets, net of accumulated depreciation	2,797,929	1,978,232	819,697	41.44 %
Deposits and other assets	245,870	44,367	201,503	454.17 %
Deferred tax asset, net of valuation allowance	4,031,302	3,590,207	441,095	12.29 %
Accounts payable and accrued liabilities	4,946,030	4,309,490	636,540	14.77 %
Deferred revenue	340,000	-	340,000	100.00 %

Cash decreased by $5,036,000 from December 31, 2013, primarily due to net cash used in operating activities for the year of 2014. In addition there were increases in accounts receivable, net of allowance, of $3,747,000, inventories of $450,000, fixed assets of $1,488,000 before depreciation, deposits and other assets of $202,000 and deferred taxes of $441,000. We experienced an increase in accounts payable and accrued liabilities of $637,000 and deferred revenue of $340,000.

The increase in accounts receivable was primarily attributable to the higher amount of credit sales at the end of December 2014 versus December of 2013 as well as some extended terms granted to certain customers. The increase in inventories is due to an increase in a component used in our products while a vendor refurbishes their facility. The increase in fixed assets is primarily due to the new warehouse facility. The increase in deposits and other assets is due to additional rental deposits and related capitalized expenses. Deferred tax asset increase is related to the provision for

income tax benefit.

LIQUIDITY AND CAPITAL RESOURCES

	For the years ended December 31, 2014	December 31, 2013	$ Change	% Change
Net cash (used in) provided by operating activities	$(3,820,299)	$2,277,614	$(6,097,913)	-267.73%
Net cash used in investing activities	(1,452,601)	(885,609)	(566,992)	64.02 %
Net cash provided by financing activities	237,163	5,306,411	(5,069,248)	-95.53 %
(DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	$(5,035,737)	$6,698,416	$(11,734,153)	17-5.18%

The Company's cash decreased as of December 31, 2014 by $5,036,000 from December 31, 2013, primarily due to net cash used in operating activities and investing activities for year of 2014.
The cash used in operations in 2014 was $3,820,000, primarily due to an increase in accounts receivable of $3,775,000, an increase in inventories of $450,000, an increase in other assets of $279,000, a decrease in prepaid and other current assets of $33,000, and a net loss net of non-cash items of $326,000, partially offset by an increase in accounts payable and other accrued liabilities of $637,000 and an increase in deferred revenue of $340,000. Net loss net of non-cash items includes net loss of $1,137,000, $403,000 in benefit for income taxes, partially offset by $739,000 in depreciation and amortization, an increase in allowance for doubtful accounts of $28,000, and $447,000 in share-based compensation. The use of cash from investing activities is primarily the purchase of fixed assets. The increase in cash from financing activities was proceeds from option exercises.

Fixed Asset Commitments

As of December 31, 2014, the Company had paid deposits on various pieces of equipment aggregating $20,000 which is reflected in Other Assets on the balance sheet. The Company is further committed to additional equipment-purchase obligation of $9,000 as various milestones are achieved by the various vendors.

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

During 2014, Chembio began executing a strategy designed to position the Company for future growth. This strategy impacts the entire Chembio business, including commercial operations, manufacturing operations, product development, research collaborations, and regulatory affairs.

Our first step took place in April 2014, when we made an important decision to terminate our existing U.S. HIV 1/2 STAT-PAK® distribution agreement in June 2014. We then established the first ever Chembio U.S. sales and marketing team. In October 2014, we achieved a significant milestone when the FDA granted a CLIA waiver for our lead product, the point-of-care DPP® HIV 1/2 Assay, for use with oral fluid or blood samples. This waiver, for the first time, granted us the opportunity to market the DPP® HIV 1/2 Assay to the broad healthcare community. To support our direct sales and marketing initiative, and to ensure a successful launch of this product, we established agreements with a number of premier distribution partners (e.g., McKesson/PSS, Fisher Healthcare, Henry Schein, Medline) for the distribution of both DPP® HIV 1/2 and HIV 1/2 STAT-PAK® Assays in the U.S. Looking ahead to 2015, we expect to further expand our commercialization team and distribution partnerships in order to build on the sales initiative we created in 2014.

Another important achievement during 2014 was our strong performance in Latin America, where we saw significant uptake of our DPP® HIV 1/2, DPP® Syphilis and our combination DPP® HIV-Syphilis Assays. Thanks to the support of our long-term commercial partners in this region, we had very considerable sales growth in Brazil and Mexico during the year, with sales in Brazil increasing nearly 90% as compared to the prior year, which helped us achieve 137% growth in DPP® sales as compared to 2013. It is important to note that interest in our DPP® HIV-Syphilis Assay has been significant from healthcare agencies around the world, leading us to believe that this product will continue to represent a great growth opportunity in Latin America and throughout the world.

On the operational front, Chembio made important investments in 2014, which we expect to contribute to our success in 2015 and beyond. In May 2014, we established a Chembio warehouse and distribution center in Holbrook, NY and made improvements to our manufacturing facility in Medford, NY. Our partnership with RVR (Malaysia) continues to progress according to key milestones and we expect the facility in Kuala Lumpur to begin production of commercial product in 2015.

During the year, we made the decision to streamline our internal product development pipeline to focus on four key projects that we believe are most likely to result in high-value assays that will address critical needs. These programs include a multiplex test that detects HIV and Syphilis specific antibodies (which we are already selling internationally), a multiplex rapid test for earlier detection of HIV by detecting P-24 antigen as well as antibodies, a test for Hepatitis-C, and improvements to our oral fluid detection technology. These projects are all based on our 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. We believe these programs will create the next generation of Chembio-branded products and fuel our continued growth at home and abroad.

Another key element to our strategy in 2014 was partnering. During the last 6 months, we entered into a number of important research collaborations that leverage our patented DPP® platform technology to develop diagnostics for some of the most serious diseases and health crises worldwide. These partnerships involve the development of DPP® tests for certain febrile illnesses (e.g., malaria, dengue fever, Ebola), traumatic brain injury (including sports-related concussion), flu immunostatus, and a specific form of cancer. We are proud to be working along side some of the world's leading and most influential health organizations in these endeavors, including the Centers for Disease Control and Prevention (CDC) and the Bill & Melinda Gates Foundation. In each of these collaborations, our objective is to develop new and valuable products that will be commercialized via Chembio's sales teams and distributor partners globally.

We are happy to report that in 2014 and early 2015 we received a number of key regulatory approvals that will further facilitate our plan for growth. In October, the FDA granted a CLIA Waiver for our lead product, the point-of-care DPP® HIV 1/2 Assay, for use with oral fluid or blood samples. The HIV 1/2 STAT-PAK® Assay received CE Mark in March 2014 and we have updated our filing for CE Marking to reflect the new trade name of STAT-VIEW® HIV 1/2 Assay (formerly SURE CHECK®) for sale in the EU market. The CE Marking for the DPP® HIV 1/2 Assay is expected in 2015. In February 2015, the DPP® HIV-Syphilis Assay was granted approval from the Brazilian ANVISA. Recently, we submitted the DPP® HIV-Syphilis Assay for evaluation by both 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.

We believe 2015 will mark a number of significant events for the Company, including further development of the newly-formed U.S. sales team, the ex-US commercial expansion of the DPP® HIV-Syphilis Assay, the pursuit of a DPP® HIV-Syphilis Assay for the U.S. market, and progress on key product development and research initiatives that will strengthen DPP® as a branded platform technology. We are optimistic that, the strategy we implemented in 2014 will strengthen our base business in POC infectious disease testing, create new opportunities to leverage our patented DPP® technology, advance our key development programs and commercial partnerships, and establish the foundation for a successful 2015 and beyond.

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 1% of accounts receivable. For example each additional 1% of accounts receivable that becomes uncollectible would reduce such balance of accounts receivable by approximately $83,000.

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. Prior to 2011 and through September 30, 2011, the Company had a full valuation allowance recorded against deferred tax assets since it was not more likely than not that the Company would realize the benefits of such deferred tax assets. During 2011, the Company determined based upon the guidance under ASC 740 that it was more likely than not that it would realize the benefit of such deferred tax assets. As result, the Company reversed the valuation allowance previously recorded against the deferred tax assets. 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. Based on this evaluation, our Chief Executive and Chief Financial Officers concluded that our internal control over financial reporting was effective as of December 31, 2014.

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 (51), 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 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 (58), 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 (48), 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 (47), 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. (64), 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 (58), 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. 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., (59), 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. (70), 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, 2014, 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, principal accounting 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 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[6] ($)	Total ($)
John J. Sperzel[4]	2014	$298,558	$-	$ -	$669,625	$ -	$968,183
CEO	2013	n/a	n/a	n/a	n/a	n/a	n/a
Lawrence A. Siebert[5, 7]	2014	$84,703	$87,000	$ -	$-	$ 147,462	$319,165
CEO	2013	$290,000	$50,750	$ -	$21,610	$ 10,240	$372,600
Javan Esfandiari	2014	$315,000	$90,000	$ -	$-	$ 9,825	$414,825
CSTO	2013	$292,462	$44,625	$ -	$141,078	$ 8,697	$486,862
Sharon Klugewicz	2014	$259,616	$75,000	$ -	$-	$ 4,182	$338,798
COO	2013	$233,642	$5,950	$ -	$18,551	$ 3,542	$261,685

1 Salary is total base salary. John Sperzel's salary reflects his base pay from commencement of his employment on March 13, 2014 until the end of 2014.
2 Bonuses earned in 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 Mr. Siebert also served as a director on the Company's board of directors until March 13, 2014. Mr. Siebert did not receive any compensation for this director role.
6 Other compensation includes an employer match to 401(K) contributions and car allowances where applicable.
7 Mr. Siebert served as Chief Ececutive Officer of the Company until March 13, 2014, for which he received a salary at the annual rate of $290,000. From March 13, 2014 to September 13, 2014, Mr. Siebert was a consultant to the Company pursuant to a six-month agreement for which he received total compensation of $145,000. These consulting fees are included in the table under "All Other Compensation".
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 Senior Vice President of Research and Development for an additional term of three years through March 5, 2016. Mr. Esfandiari's salary under the Employment Agreement is $300,000 for the first year, with possible increases for the second year and /or for the third year. Mr. Esfandiari is eligible for a performance-based bonus of up to 50% of his base salary for each respective 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 date on which the Agreement was effective. 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, 2013 with Ms. Klugewicz (the "Employment Agreement"), effective May 22, 2013 (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 $250,000, with the option of a discretionary, performance-based annual cash bonus of up to 37.5% of her base salary. The Employment Agreement also provides for a grant of 5,000 options to purchase shares of the Company's common stock, vesting at a rate of 2,500 shares on each of the first and second anniversaries of the Effective Date. 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.

Neither Mr. Larkin, Mr. Ippolito, Mr. Lambotte nor Mr. Steele 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, 2014, there were three 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 2014, 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 2014

	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