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, 2016

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
Common Stock, $0.01 par value	The NASDAQ Stock Market LLC
Preferred Share Purchase Rights	The NASDAQ Stock Market LLC

Securities registered pursuant to section 12(g) of the Act:
None
(Title of Class)

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

Accelerated filer [X]
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 76,422,282.

As of March 3, 2017, the registrant had 12,299,122 common shares outstanding.

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

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PART I

ITEM 1. BUSINESS

FORWARD-LOOKING STATEMENTS

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

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

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

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

Our Business

General

The Company (Chembio Diagnostics, Inc. and its wholly-owned subsidiary Chembio Diagnostic Systems, Inc. are collectively referred to herein as the "Company") develops, manufactures, markets and licenses rapid point-of-care diagnostic tests (POCTs) that detect infectious diseases. Our main products currently commercially available are rapid tests for the detection of HIV 1/2 antibodies, and a multiplex rapid test for the detection of HIV and syphilis antibodies. The HIV 1/2 rapid tests employ in-licensed and proprietary lateral flow technologies (see "Our Rapid Test Technologies"), can be used with all blood matrices as samples, and are manufactured in a standard cassette format, a dipstick format, and a proprietary barrel format. The tests employing the cassette and proprietary barrel formats were approved by the FDA in 2006. The barrel format is exclusively distributed by a distributor in the United States and by Chembio and its designated distributors outside the United States. The exclusive U.S. distribution agreement for the barrel product terminated in accordance with its terms on May 31, 2016. Since June 1, 2016, Chembio and its subsequently designated distributors have distributed the product in the U.S. 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 our patented DPP® and the lateral flow platforms, we participate in the estimated $8 billion point-of-care (POC) 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 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, POC screening, diagnostic, or confirmatory results can improve health outcomes. More generally we believe there is and will continue to be a growing demand for diagnostic products that can provide accurate, actionable diagnostic information in a rapid, cost-effective manner at the point of care.

Our Products

Lateral Flow Rapid HIV Tests

All three of our lateral flow rapid HIV antibody detection tests are qualitative "yes/no" tests for the detection of antibodies to HIV 1 & 2 with visually interpreted results (one line "negative"; one line "positive") available within approximately 15 minutes. The tests are simple to use, have a shelf life of 24 months, and do not require refrigeration. The tests differ principally only in the method of test procedure, convenience and cost. One of our FDA-approved lateral flow HIV tests, SURE CHECK® HIV 1/2 Assay, incorporates a proprietary plastic "barrel" device that houses the lateral flow strip. This barrel format enables collection of samples directly (usually from a finger-stick whole blood sample) into the barrel's capillary tip. A sealed unitized buffer vial, assembled onto the top of the barrel, is removed and seated into a stand; the seal is then pierced by the barrel's capillary tip, thereby initiating the upward flow of the resulting sample-buffer solution through a filter, up into the vertical device's chamber and 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, we 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, we owned full rights related to the SURE CHECK® HIV 1/2 Assay, including sales, marketing, distribution and trademark rights, subject to the few still-effective transitional terms of the marketing and distribution agreement with Alere, Inc., which terminated (subject to a few post-termination transitional provisions) on May 31, 2016. Prior to this newly-executed agreement between SDS and Chembio, SDS had 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 then-existing marketing and distribution agreement with Alere. The January 2015 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.

Prior to June 1, 2016, our SURE CHECK® HIV 1/2 Assay was marketed exclusively in the U.S. as Clearview® Complete pursuant to the agreement with Alere described above. Since June 1, 2016, it has been marketed in the U.S. as Sure Check® HIV 1/2 Assay. Outside the U.S., we continue to market 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 second FDA-approved lateral flow HIV test, the HIV 1/2 STAT-PAK®, uses a more conventional rectangular plastic cassette format that houses the lateral flow strip. In this case, a sample is transferred by use of a separately provided transfer device ("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 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 was received in June 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 Application for our DPP® HIV Assay. In October 2014, the FDA granted CLIA-waiver status for this assay.

Our 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. In May 2015 we obtained approval for a CE Mark for the DPP® HIV 1/2 Assay for Oral Fluid, Serum, Plasma, Fingerstick Whole Blood and Venous Whole Blood. In 2016, we obtained WHO qualification in order to enable procurement of this product by the Global Fund and United Nations agencies, including programs underwritten by them.

Previously, 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 that 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. We believe that 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. We believe that 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. As of December 31, 2016, there have been no sales of the DPP® HIV-Syphilis Assay in Brazil. This product also has been approved by the CDC, acting on behalf of the United States Agency of International Development, (USAID) for its global procurement scheme.

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

DPP® Technology & Development

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

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

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

We entered into a milestone-based development agreement with a private contracting organization acting on behalf of the CDC, for a multiplex POC influenza immunity test utilizing our patented Dual Path Platform (DPP®) technology.

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

In January 2015, we were 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. Our DPP® technology was selected for this grant due to its exceptional sensitivity and potential to aid the foundation in its goal of eradicating malaria. To achieve this goal, diagnostics must be capable of detecting the malaria parasite in infected, but asymptomatic, people. Current POC rapid diagnostics tests lack sufficient sensitivity to identify all individuals with transmissible infections.

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

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

PARTNERS INVOLVED IN MARKETING OUR PRODUCTS

Alere

On September 29, 2006, we executed marketing and license agreements with Alere. The marketing agreements (the Barrel Agreement and the Cassette Agreement) provide Alere with a 10-year exclusive right (until May 31, 2016) to market our rapid HIV tests in the United States under Alere's brands. The agreements also provide us with 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 the dates described below and elsewhere in this report, it is through the agreements with Alere that we were 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 intended 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, we 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, we may, at any time, terminate such agreement, which termination would become effective 60 days after the date notice was made. Under the Barrel Agreement, we and SDS may jointly issue a non-exclusivity notice, which notice shall be effective immediately. In the event that we make this election with respect to the cassette product, or that both we and SDS make this election with respect to the cassette product, then the electing party or parties could sell that respective product in the United States market under its own brand, and in such case, the lateral flow license that we have 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, we gave notice to Alere of our intent to terminate the Cassette Agreement and 60 days later, we began marketing the cassette product in the United States under the Chembio brand of HIV 1/2 STAT-PAK® assay. On May 31, 2016, the Barrel Agreement expired pursuant to its terms, and, given our January 2015 agreement with SDS, we now market the barrel product in the U.S. under the brand of SureCheck® HIV 1/2 Assay.

We have developed our own sales and marketing departments for the sales of our products in the U.S. and internationally. We also have appointed distributors in the U.S. and 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 us 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 us of the information and training that is required for this to occur, will occur only if FIOCRUZ purchases from us the amount of that product that is specified in the respective agreement for that product. The actual amount of purchases for each product is totally at the discretion and option of FIOCRUZ and may be more or less than the amount needed to qualify for a technology transfer.

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

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

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

Each agreement provides that the prototypes will be utilized both for a performance study that follows a protocol prepared and approved by Bio-Manguinhos and the Brazilian Ministry of Health, and also will be used for studies in Brazil for the registration procedures at ANVISA. Bio-Manguinhos will then apply to ANVISA to register the product. Within 120 days of the registration of the product with ANVISA, Bio-Manguinhos will make an advance technology transfer payment to us (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. We do not have recourse against Bio-Manguinhos if Bio-Manguinhos does not purchase the qualifying purchase amount of any product. In that case, we can only suspend further phases of the technology transfer, attempt to renegotiate the agreement, and/or retain any amounts previously paid by Bio-Manguinhos. We 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, 2016, Bio-Manguinhos had earned the status described below with respect to each of the five products:

1. With respect to our DPP® HIV1/2 Screen test, Bio-Manguinhos had qualified to request the technology transfer. It has requested, and has received, the technology transfer information. Bio-Manguinhos purchased $880,175, $4,990,840 and $291,235 of this product in 2011, 2012 and 2013, respectively, all of which applied to the qualifying amount to obtain the right to the technology transfer (the "Qualifying Amount") for this product. In 2013, 2014, 2015 and 2016 Bio-Manguinhos made $3,320,010, $4,799,250, $5,410,350 and $5,900, respectively, of purchases in excess of the Qualifying Amount.

2. With respect to our Canine Leishmania test, Bio-Manguinhos had qualified to request the technology transfer and did so request. Submission of the technology transfer information is in process at this time. Bio-Manguinhos purchased $2,000,817 and $99,183 of this product in 2011 and 2012 respectively, of this product in that applied to the Qualifying Amount. In addition, Bio-Manguinhos made purchases in excess of the Qualifying Amount equal to $1,314,117, $1,736,700, $2,394,000, $3,772,482 and $4,221,000 in 2012, 2013, 2014, 2015 and 2016, respectively.

3.

a. With respect to the three variations of our DPP® Syphilis test, all of which are covered by a single agreement, Bio-Manguinhos had qualified to request the technology transfer with respect to Trep only, and intends to do so in the near future. Bio-Manguinhos purchased $1,194,250, $165,750 of this product in 2011 and 2012, respectively that applied to the Qualifying Amount. In addition, Bio-Manguinhos made purchases in excess of the Qualifying Amount equal to $2,817,750, $646,340, $4,617,891 and $833,631 in 2012, 2013, 2014 and 2015, respectively no purchases of this product were made in 2016.

b. With respect to the two variations of our Screen & Confirm Test, Bio-Manguinhos had not made any purchases in 2011, 2012, 2013, 2014, 2015 or 2016, and therefore had not qualified to request the technology transfer for either of them. This agreement was terminated in December 2015.

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

4. With respect to our DPP® Confirmatory test, Bio-Manguinhos has qualified to request the technology transfer. Bio-Manguinhos made purchases of $560,000, $819,000, $390,000, $390,000, $156,000 and $39,000 of this product in 2011, 2012, 2013, 2014, 2015 and 2016 respectively, all of which applied to the Qualifying Amount. In addition, Bio-Manguinhos made purchases in excess of the Qualifying Amount equal to $485,940 in 2016.

5. With respect to our 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, 2015 and 2016. In order to qualify for the technology transfer, Bio-Manguinhos would need to purchase an additional $225,000 of this product.

As stated above, Bio-Manguinhos is not obligated to make any purchases. After the specified level of sales for a particular product has been achieved, FIOCRUZ may request that the technology for that product be transferred to FIOCRUZ together with an exclusive license to produce and sell that product in a defined territory. The license is to provide that we will receive a royalty on all sales. We do 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 because of our default, or if terminated by natural expiry, FIOCRUZ can continue to produce and commercialize the product without paying royalties.

Other OEM And License Agreements Related to DPP® Technology

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

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

In February 2014, we entered into a technology transfer and license agreement with RVR Diagnostics SDN BHD ("RVR"), a privately-held company in Malaysia. The agreement supports our strategy of establishing a market presence in Asia, in collaboration with RVR as a licensee, distributor, and contract manufacturer, depending on the circumstances. The agreements grant exclusive distribution rights to RVR in certain countries in the region and enable RVR to manufacture our DPP® HIV 1/2 Assay and DPP® HIV-Syphilis Assay, and potentially other products that are developed by us, such as Dengue, incorporating its patented DPP® technology as indicated in the DPP® Technology & Development section above. As indicated elsewhere, we acquired RVR in January 2017.

Our Rapid Test Technologies

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

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

Multiplexing is significantly improved as a result of the design of DPP® and this provides a significant advantage. For example, the HIV confirmatory test we developed for Bio-Rad that is described above employs six different markers related to various epitopes of the HIV antigen. We have a number of other products in development, including those being developed in sponsored development programs that involve the use of multiple (e.g. eight) test bands. Although all of these products could be visually read, we can also use handheld and desktop readers with our DPP® products to objectively measure, quantify, record and report DPP® test results. Certain of the products we have and/or are developing incorporate some of these readers, and we are developing other products that may be used with or will require use of a reader. Also, platforms can incorporate labeling reagents that cannot be visually read except by employing a reader, such as fluorescence, though no products are currently utilizing such reagents.

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

Target Markets

Rapid HIV Tests

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

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

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. Assuming that new legislation does not modify this requirement, of which there is no assurance, we expect this requirement 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 our 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.

With our four U.S.-manufactured rapid HIV tests, all of which are FDA-approved, we are 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, our SURE CHECK® HIV 1/2 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.). Following the June 2014 termination of the STAT-PAK® agreement with Alere, and the May 31, 2016 termination of the SURE CHECK® agreement with Alere, we no longer have to share any portion of the net sales proceeds for these products with Alere. These changes resulted in our incurring expenditures related to hiring sales representatives, establishing agreements and associated discounts with distributors, incurring advertising and marketing expenditures, warehousing, customer service and technical support. If Alere's new competitive product is indeed successful, our ability to retain a significant share of the market that has been established for our products may be enhanced by our having control of the marketing of our products, rather than relying on Alere to sell both our products while it is also selling its own competing product. We are leveraging the same sales force for U.S. Sales of our DPP® HIV 1/2 Assay.

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 we can be the exclusive development and manufacturing partner supporting leading marketing organizations.

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

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

Competition

There are several established rapid HIV tests which are already in the marketplace that compete with our lateral flow HIV tests and DPP® HIV 1/2 Assay. These include OraSure (sold by OraSure Technologies), Alere Determine® rapid test product (sold by Alere, Inc.), and INSTI (sold by Biolytical, Inc.). Our competitors may have significant advantages over us, including being substantially larger and having greater financial, research, manufacturing and marketing resources. Industry competition in general is based on the following:

Scientific and technological capability;

Proprietary know-how;

The ability to develop and market products and processes;

The ability to obtain FDA or other required regulatory approvals;

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

The ability to manufacture products cost-effectively;

Access to adequate capital;

The ability to attract and retain qualified personnel; and

The availability of patent protection.

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

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

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

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

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

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

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

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

Research and Development

During 2016, 2015 and 2014, we spent $8.4 million, $6.4 million and $4.8, respectively, on research and development (including regulatory activities). These expenses were in part underwritten by funding from R&D and milestones revenues of $3.7 million in 2016, $2.3 million in 2015 and $1.7 million in 2014. All of our new product development activities involve employment of our DPP® technology. These activities include completing development of certain products and making significant progress toward the development of additional products.

Employees

At December 31, 2016, we employed approximately 131 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 Mr. Sperzel has a term of three years ending March 13, 2017. The contract with Ms. Klugewicz, has a term of two years ending May 2017. The contract with Mr. Esfandiari has a term of three years ending March 2019. The Company and Mr. Sperzel currently are discussing terms for renewal of his employment agreement. We have obtained a key man insurance policy for Mr. Esfandiari.

Governmental Regulation

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

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

If the medical device does not qualify for the 510(k) procedure (either because it is not substantially equivalent to a legally marketed device or because it is required by statute and the FDA's implementing regulations have an approved application), the FDA must approve a Pre-Marketing Application ("PMA") before marketing can begin. PMA's must demonstrate, among other matters, that the medical device provides a reasonable assurance of safety and effectiveness. A PMA application is typically a complex submission, including the results of non-clinical and clinical studies. Preparing a PMA application is a much more expensive, detailed and time-consuming process as compared with a 510(K) pre-market notification. The Company has approved PMAs for the two rapid HIV tests now marketed in the U.S.: both our HIV 1/2 STAT-PAK® and our SURE CHECK® 1/2 HIV.

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

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

We are 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 us 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.

We have obtained patent coverage on our 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 our 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

We have 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. We selectively and strategically foreign files its patent applications based on a number of economic and strategic factors related to the invention.

Trademarks

We have filed and obtained trademarks for our products, including DPP®, SURE CHECK®, and STAT-PAK® and also for the SampleTainer® used in certain DPP® products. Our DPP® trademark is also registered under the European convention (ECT). We 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. We possess 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 us, including but not limited to our lateral flow HIV tests. This license allows us to produce, market and sell assays using lateral flow technologies specifically including our STAT-PAK®, SURE CHECK®, DIPSTICK®, and veterinary product lines. Under this license agreement, prior to February 3, 2015, we paid royalties to Alere ranging from 5% to 8½%, depending upon the country in which the products are sold. Between 2007 and 2015 we incurred a total of $2.87 million in lateral flow royalty expenses. As of February 3, 2015 this royalty expense was no longer payable.

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 our best interests. 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 our lateral flow or DPP® products will not be granted to third parties and that licenses to such patents, will be available on reasonable terms, if any. In the past Alere has aggressively enforced its lateral flow intellectual property, although some of the main patents have expired and we are not aware of any patent enforcement litigation that is ongoing with respect to the Alere lateral flow intellectual property.

Regardless, the DPP® technology provides us with our own intellectual property. We believe it provides us with a freedom to operate, and that it also enables tests to be developed with improved sensitivity as compared with comparable tests on lateral flow platforms. We have signed and anticipate 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 Information

We are a Nevada corporation that was formed in December 1985. Since inception, we have been involved in developing, manufacturing, selling and distributing medical diagnostic tests, including rapid tests that detect a number of diseases and other conditions in humans and animals.

On May 30, 2012, we effected a 1-for-8 reverse split of its common stock. The effect of this reverse stock split also has been retroactively reflected for all periods in these financial statements.

Stockholder Rights Agreement

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

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

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

Glossary

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

ITEM 1A. RISK FACTORS

You should carefully consider each of the following risk factors and all of the other information provided in this Form 10-K before purchasing our Common Stock. The risks described below are those we currently believe may materially affect us. An investment in our Company involves a high degree of risk, and should be considered only by persons who can afford the loss of their entire investment. Although we believe that these risks are the most important for you to consider, you should read this section in conjunction with our financial statements, the notes to those financial statements and our management's discussion and analysis of financial condition and results of operations included in our periodic reports and incorporated into this prospectus supplement by reference.

Risks related to our industry, business and strategy

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

All of our proposed and existing products are subject to regulation in the U.S. by the U.S. Food and Drug Administration, the U.S. Department of Agriculture and/or other domestic and international governmental, public health agencies, regulatory bodies or non-governmental organizations. In particular, we are subject to strict governmental controls on the development, 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 control system that is intended to comply with applicable regulations. Although FDA approval is not required for the export of our products, there are export regulations promulgated by the FDA that specifically relate to the export of our products that require compliance with FDA quality system regulation ("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 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. The 4th generation product that is now FDA-approved was apparently modified as compared to the initial international version, and it may perform more satisfactorily. Alere received FDA approval of this modified product in August 2013 and CLIA waiver for it in December 2014. Alere is also aggressively pursuing development of the market for this product. Moreover there is support by a number of key opinion leaders for the public health value of such 4th generation tests, and this product represents a significant competitive threat to Chembio as well as to each of the other rapid HIV test manufacturers (OraSure and Trinity primarily).

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

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

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

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

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

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

A number of our components and critical raw materials are provided by third-party suppliers, some of which may be sole-source suppliers, which impacts our ability to manufacture or sell certain products 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, 2015 and 2016. We estimate that our resources are sufficient to fund our needs through the end of 2017 and beyond. 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, among others, (1) the level of revenues; (2) the extent to which, if any, that revenue level improves operating cash flows; (3) our investments in research and development, facilities, marketing, regulatory approvals, and other investments we may determine to make; and (4) our investment in capital equipment and the extent to which it improves cash flow through operating efficiencies. There are no assurances that we will generate positive cash flow for 2017 or, in the alternative, be successful in raising sufficient capital to fund our needs after 2017.

Our U.S. market sales are difficult to predict in 2017 given (i) our early June 2014 termination of the agreement with a third party for exclusive distribution of our cassette product in the U.S; and (ii) the May 31, 2016 termination of the agreement with a third party for exclusive distribution of our barrel product in the U.S. As a result of these terminations, we expect to continue to experience higher average revenue per unit, and a lower volume of U.S. sales, of the cassette and barrel products. Higher revenue per unit is anticipated because we previously sold these products to the exclusive U.S. distributor at a significantly lower price than the price at which the distributor resold these products to customers (including re-sellers and distributors) in the United States. However at this point with respect to the barrel product, this can occur only after any inventory that the exclusive U.S. distributor has accumulated is consumed, which may take several months. In addition, in marketing these products directly, we are incurring substantial costs associated with developing our sales and marketing organization and channel distribution partners.

We believe that underlying demand for HIV rapid testing in the United States remains strong, and that the restoration of some of the funding cutbacks from sequestration and the implementation of the Affordable Care Act and of the United States Preventive Services Task Force recommendations will have a positive impact on the development of the market. On the other hand, it is possible that changes to healthcare law in 2017 and thereafter could change this and/or have a negative impact on the market for our products. 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 international sales increases or cause international 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.

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

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

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

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

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

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

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

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

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

We have entered into employment contracts with our Chief Executive Officer, John Sperzel, our Chief Operating Officer, Sharon Klugewicz, and our Chief Scientist & Technology Officer, Javan Esfandiari. Due to the specific knowledge and experience of these executives regarding the industry, technology and market, the loss of the services of any one of them could have a material adverse effect on the Company. The contract with Mr. Sperzel has a term of three years ending March 2017. The contract with Ms. Klugewicz has a term of two years ending May 2017. The contract with Mr. Esfandiari has a term of three years ending March 2019. The Company has obtained a key man insurance policy on Mr. Esfandiari. The Company and Mr. Sperzel currently are discussing terms for renewal of his employment agreement.

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 WHO, CDC, 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.

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, 2015 and 2016 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, 2015 and 2016, 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 19,300 shares per day over the three months ended December 31, 2016 as compared with approximately 21,600 shares per day over the three months ended December 31, 2015. The liquidity of our stock depends on several factors, including but not limited to the financial results of the Company and overall market conditions, so it is not possible to predict whether this level of liquidity will continue, be sustained, or decrease.

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

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

As of December 31, 2016, our named executive officers, directors and 5% stockholders beneficially owned approximately 38.43% of our voting power, which includes four large investors that beneficially own approximately 10.36%, 9.36%, 9.00% and 5.02%, 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 1B. Unresolved Staff Comments.

Not Applicable

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 $28,688 per month. The space is utilized for research and development activities (approximately 5,440 square feet), offices (approximately 2,640 square feet) and production (approximately 31,580 square feet). The lease term expires on April 30, 2017. The lease provides for annual increases of two and one-half percent each year starting May 1, 2015. We lease approximately 21,450 square feet of industrial space in Holbrook for $15,550 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 listed on the NASDAQ Global Select Market of the NASDAQ Stock Market LLC under the symbol "CEMI." The table below sets forth the high and low prices per share of our common stock for each quarter of our two most recently completed fiscal years.

Fiscal Year 2016	**High**	**Low**
First Quarter	$ 6.10	$ 4.03
Second Quarter	$ 9.40	$ 5.87
Third Quarter	$ 8.48	$ 5.08
Fourth Quarter	$ 7.45	$ 6.10
Fiscal Year 2015	**High**	**Low**
First Quarter	$ 4.20	$ 3.47
Second Quarter	$ 5.25	$ 4.00
Third Quarter	$ 5.20	$ 3.33
Fourth Quarter	$ 5.53	$ 3.90

Holders

As of March 3, 2017, there were approximately 2,030 record owners of our common stock (including nominee holders such as banks and brokerage firms who hold shares for beneficial owners).

Dividends

The Company has never paid cash dividends on its common stock and has no plans to do so in the foreseeable future. Any future declaration of dividends will be determined by our Board of Directors in its sole discretion and will depend on, among other things, our earnings, capital requirements, financial condition, prospects and any other factors the Board of Directors may deem relevant.

Recent Sales of Unregistered Securities

There were no sales of unregistered securities during the year ended December 31, 2016 that were not previously reported on a Quarterly Report on Form 10-Q or a Current Report on Form 10-K.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the fourth quarter of the fiscal year ended December 31, 2016.

ITEM 6. SELECTED FINANCIAL DATA

The Following selected financial data should be read in connection with Item 7 - "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and notes that are included in this Annual Report on Form 10-K.

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

Statement of Operations Data:

	December 31, 2016		December 31, 2015		December 31, 2014		December 31, 2013		December 31, 2012	
TOTAL REVENUES	$ 17,868,841		$ 24,255,485		$ 27,645,284		$ 29,549,609		$ 25,610,595	
GROSS MARGIN(1)	8,451,336	47%	10,486,827	43%	10,814,023	39%	12,300,159	42%	10,789,991	42%
OPERATING COSTS:										
Research and development expenses(1)	8,427,554	47%	6,377,839	26%	4,832,537	17%	5,834,249	20%	4,486,302	18%
Selling, general and administrative expenses(1)	7,595,559	43%	7,663,035	32%	7,531,739	27%	5,461,083	18%	4,851,587	19%
	16,023,113		14,040,874		12,364,276		11,295,332		9,337,889	
INCOME (LOSS) FROM OPERATIONS	(7,571,777)		(3,554,047)		(1,550,253)		1,004,827		1,452,102	
OTHER INCOME (EXPENSES):	25,548		(3,238)		132		12,943		(1,584)	
INCOME (LOSS) BEFORE INCOME TAXES(1)	(7,546,229)	(42)%	(3,557,285)	(15)%	(1,550,121)	(6)%	1,017,770	3%	1,450,518	6%
Income tax provision (benefit)	5,800,818		(1,160,243)		(412,918)		486,952		509,237	
NET INCOME (LOSS)	$ (13,347,047)		$ (2,397,042)		$ (1,137,203)		$ 530,818		$ 941,281	
Basic income (loss) per share	$ (1.26)		$ (0.25)		$ (0.12)		$ 0.06		$ 0.12	
Diluted income (loss) per share	$ (1.26)		$ (0.25)		$ (0.12)		$ 0.06		$ 0.11	
Weighted average number of shares outstanding, basic	10,622,331		9,626,028		9,530,320		8,994,080		7,986,030	
Weighted average number of shares outstanding, diluted	10,622,331		9,626,028		9,530,320		9,519,968		8,614,944	
Balance Sheet Data:										
Working capital	$ 14,707,876		$ 9,479,968		$ 12,372,169		$ 14,221,011		$ 7,630,368	
Total assets	20,575,236		20,816,344		25,010,192		24,486,592		17,335,150	
Total liabilities	3,405,650		3,154,838		5,286,030		4,309,490		3,460,630	
Shareholders' equity	17,169,586		17,661,506		19,724,162		20,177,102		13,874,520	

(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. These products are currently marketed under Chembio's label (DPP® HIV 1/2 Screening Assay and DPP® HIV 1/2 –Syphilis Assay), or which may be marketed pursuant to private label license or distribution agreements such as those with the Oswaldo Cruz Foundation ("FIOCRUZ"), and Bio-Rad.

Research and development ("R&D"), milestone, and grant and royalty revenues for the years ended December 31, 2016, 2015 and 2014 were $4.19 million, $2.37 million and $1.70 million, respectively, which was the result of grants awarded in 2016, 2015 and 2014. R&D expenses in the years ended December 31, 2016, 2015 and 2014 were $8.43 million, $6.38 million and $4.83 million, respectively.

Research & Development Activities

Sexually Transmitted Disease

DPP® HIV-Syphilis Assay: The DPP® HIV-Syphilis Assay is a rapid, point-of-care (POC), multiplex test for the simultaneous detection of antibodies to HIV and to Treponema Pallidum (TP) bacteria (the causative agent of syphilis). This novel combination assay was developed to address the growing concern among public health officials regarding the rising co-infection rates of HIV and syphilis as well as mother-to-child transmission (MTCT) of HIV and syphilis. The product received approval by the Mexican regulatory agency (Cofepris) in 2014, received approval by the Brazilian regulatory agency, Agência Nacional de Vigilância Sanitária (ANVISA) in 2015, and received CE mark approval in 2017. We are developing a U.S. version of the DPP® HIV-Syphilis Assay, designed to meet the performance requirements for the "reverse" algorithm that is currently in clinical use for syphilis testing in the United States. The DPP® HIV-SYP Assay clinical trial is on schedule; initiated in the first quarter of 2016 and, at the current enrollment rate, we expect to complete the trial in the first quarter of 2017. Following the completion of the clinical trial, we will file a Premarket Approval Application with the U.S. Food and Drug Administration.

Fever & Tropical Disease

DPP® Malaria Assay: The DPP® Malaria Assay is a rapid, POC, multiplex test for the simultaneous detection of plasmodium falciparum and other plasmodium infections. In January 2015, we received a grant from the Bill & Melinda Gates Foundation to expedite the development and feasibility testing of a POC DPP® Malaria Assay. The Company completed this project, which compared the new DPP® Malaria Assay to the world's leading currently-available POC malaria assay with favorable results: a ten-fold improvement in sensitivity. In April 2016, we received a second Malaria grant from the Bill & Melinda Gates Foundation to expedite the feasibility testing and development of the world's first oral fluid/saliva POC diagnostic test to simply and accurately identify individuals infected with all species of malaria. We recently completed the feasibility and plan to deliver DPP® Malaria Assays to a partner of the Bill & Melinda Gates Foundation in March 2017, to commence field evaluation.

DPP® Zika Assay: The DPP® Zika Assay is a rapid POC stand-alone test for the simultaneous detection of IgM/IgG antibodies. In February 2016, we received a grant from The Paul G. Allen Family Foundation to initiate development of the DPP® Zika Assay. During 2016, Chembio announced collaborations with Bio-Manguinhos, the unit of the Oswaldo Cruz Foundation (Fiocruz) responsible for the development and production of vaccines, diagnostics and biopharmaceuticals, primarily to meet the demands of Brazil's national public health system, related to the DPP® Zika Assay. In August 2016, the Company received an award from the U.S. Government (HHS/ASPR/BARDA), granting the Company up to $13.2 million ($5.9 million to develop DPP® Zika Assay and obtain U.S. regulatory approval). The Company filed the following regulatory submissions: U.S. Food and Drug Administration Emergency Use Authorization (EUA), World Health Organization EUA, Brazil's regulatory agency ANVISA, Mexico's regulatory agency Cofepris, and CE mark. The Company obtained CE mark in July 2016, and then began selling in the Caribbean region via its distribution partner, Isla Lab, LLC. In September 2016, the Company received a contract award from CDC to initiate a Zika surveillance program in India, Peru, Guatemala and Haiti, and we began selling the DPP® Zika IgM/IgG Assay to CDC for field testing purposes during the first quarter of 2017. The Company received ANVISA approval (Brazil) for the DPP® Zika IgM/IgG Assay in November 2016 and is working with our Brazilian partner, Bio-Manguinhos, to obtain ANVISA approval for the DPP® Micro Reader.

DPP® Dengue Fever Assay: The DPP® Dengue Fever Assay is a rapid, POC, multiplex test for the simultaneous detection of IgG/IgM and NS1 antigens. During 2016, Chembio announced collaborations with Bio-Manguinhos, the unit of the Oswaldo Cruz Foundation (Fiocruz) responsible for the development and production of vaccines, diagnostics and biopharmaceuticals, primarily to meet the demands of Brazil's national public health system related to the DPP® Dengue Fever Assay. We completed verification and validation studies, and production of pilot lots, to support preclinical studies. Also during 2016, we initiated registration to begin initial commercialization in Southeast Asia, and we believe initial DPP® Dengue Assay sales will occur in Southeast Asia during Q1 2017.

DPP® Chikungunya Assay: The DPP® Chikungunya Assay is a rapid, POC, multiplex test for the simultaneous detection of IgG/IgM antibodies. During 2016, Chembio announced collaborations with Bio-Manguinhos, the unit of the Oswaldo Cruz Foundation (Fiocruz) responsible for the development and production of vaccines, diagnostics and biopharmaceuticals, primarily to meet the demands of Brazil's national public health system, related to the DPP® Chikungunya Assay.

DPP® Zika/Dengue/Chikungunya Assay: The DPP® Zika/Dengue/Chikungunya Assay is a rapid, POC, multiplex test for the simultaneous detection of IgM/IgG antibodies. In February 2016, we received a grant from The Paul G. Allen Family Foundation to initiate development of the DPP® Zika/Dengue/Chikungunya Assay. During 2016, Chembio announced collaborations with Bio-Manguinhos, the unit of the Oswaldo Cruz Foundation (Fiocruz) responsible for the development and production of vaccines, diagnostics and biopharmaceuticals, primarily to meet the demands of Brazil's national public health system, related to the DPP® Zika/Dengue/Chikungunya Assay. In August 2016, the Company received an award from the U.S. Government (HHS/ASPR/BARDA), granting the Company up to $13.2 million (including an option of $7.3 million to develop DPP® Zika/Dengue/Chikungunya Assay and obtain U.S. regulatory approval). In September 2016, the Company received a contract award from CDC, to initiate a Zika, Dengue, and Chikungunya surveillance program in India, Peru, Guatemala and Haiti and we began selling the DPP® Zika/Dengue/Chikungunya IgM/IgG Assay to CDC for field test purposes during the first quarter of 2017.

DPP® Fever Panel Assay: The DPP® Fever Panel Assay is a rapid, POC, multiplex test for the simultaneous detection of Malaria, Dengue, Chikungunya, Zika, Ebola, Lassa, and Marburg. In October 2015, we received a $2.1 million grant from the Paul G. Allen Ebola Program, to develop the DPP® Fever Panel Assay and a $0.55 million follow-on grant to add a test for the detection of Zika virus. We completed the development of the DPP® Fever Panel Assay in 2016, including the addition of Zika, and we supplied 10,000 tests to FIND, who will initiate evaluation in Peru and Nigeria.

DPP® Ebola Assay and DPP® Malaria-Ebola Assay: The DPP® Ebola Assay is a rapid POC test for the detection of Ebola, and the DPP® Malaria-Ebola Assay is a rapid, POC, multiplex test for the simultaneous detection of Malaria and Ebola. In October 2014, we announced plans to develop, validate, and commercialize POC DPP® Assays for Ebola and Febrile Illness. We completed the development of the DPP® Ebola Assay and submitted it for Emergency Use Authorization (EUA) with the Food & Drug Administration (FDA) and World Health Organization (WHO), and we are actively engaged with these regulatory agencies. During the third and fourth quarters of 2015, we sold DPP® Ebola and DPP® Malaria-Ebola Assays to the Centers for Disease Control & Prevention (CDC) for field studies in West Africa, which is ongoing.

Technology Collaboration

DPP® Cancer Assay: The DPP® Cancer Assay is a rapid, POC, multiplex test for the early detection and monitoring of a specific type of cancer. In October 2014, we entered into collaboration with an international diagnostics company to develop a POC diagnostic test for a specific type of cancer. This program is fully funded by this partner. However, under the terms of the agreement, neither Chembio's partner nor the specific type of cancer is being disclosed. The cancer project represents an application of the DPP® technology outside of the infectious disease field, and the scope of the agreement involves product development of a quantitative, reader-based cancer assay for two cancer markers, utilizing Chembio's DPP® technology and its DPP® Micro Reader. During the third quarter of 2015, we completed successful feasibility, and our partner agreed to fund continued development of the DPP® Cancer Assay, which development and verification is ongoing.

DPP® Traumatic Brain Injury Assay: The DPP® Traumatic Brain Injury Assay is a rapid POC test for the detection of traumatic brain injury (TBI) and sports-related concussion. In January 2015, we entered into an agreement with the Concussion Science Group (CSG) Division of Perseus Science Group LLC, to combine CSG's patented biomarker with our proprietary DPP® platform and DPP® Micro Reader, to develop a semi-quantitative or quantitative POC test, to diagnose TBI. The DPP® Traumatic Brain Injury Assay is in the feasibility and pre-clinical stage. Under institutional review board (IRB) agreements with multiple hospitals, we are conducting pre-clinical studies of the prototype DPP® Traumatic Brain Injury Assay using patient samples.

DPP® Bovine Tuberculosis: The DPP® BovidTB Assay is a rapid POC test for the detection of bovine tuberculosis (TB). In September 2016, the Company was awarded a $600,000 grant from the United States Department of Agriculture (USDA) to develop the DPP® BovidTB Assay. The grant will be managed by the Small Business Innovation Research Program (SBIR) of the National Institute of Food and Agriculture (NIFA), a federal agency within the USDA and the assay will be developed in collaboration with National Animal Disease Center (NADC) and Infectious Disease Research Institute (IDRI). Under the two-year grant, Chembio will use its patented DPP® technology to undertake to develop a simple, rapid, accurate and cost-effective test for bovine TB in cattle. The DPP® BovidTB Assay will be designed to provide results within 20 minutes, thereby significantly improving on the time-consuming, tedious and inadequate diagnostic methods currently in use.

Regulatory Activities

DPP® HIV-Syphilis Assay: We have developed a U.S. version of the DPP® HIV-Syphilis Assay, designed to meet the performance requirements for the "reverse" algorithm that is currently in clinical use for syphilis testing in the United States. The clinical trial to support the FDA application for approval of the DPP® HIV-Syphilis Assay was initiated during first quarter of 2016 and is expected to be completed in the first quarter of 2017. Following the completion of the clinical trial, we will file a Premarket Approval Application with the U.S. Food and Drug Administration. In January 2017, we received CE mark approval for the DPP® HIV-Syphilis Assay.

DPP® Zika IgM/IgG System: In July of 2016 Chembio obtained a CE Mark for the DPP® Zika IgM/IgG Assay. The DPP® Zika IgM/IgG System, which includes an assay utilizing the patented DPP® technology as well as a digital reader (DPP® Micro Reader), are now cleared for commercialization in European countries as well as the majority of the Caribbean nations, not including U.S. territories. In November of 2016, we received approval from ANVISA, Brazil's regulatory Agency and we are working with our Brazilian partner, Bio-Manguinhos, to obtain ANVISA approval for the DPP® Micro Reader. We have also filed regulatory submissions to U.S. Food and Drug Administration (Emergency Use Authorization), the World Health Organization (Emergency Use Assessment and Listing), and Cofepris (Mexico), and we are actively engaged with these organizations.

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 9, 2017, the Company announced it completed the acquisition of RVR Diagnostics Sdn Bhd, a Malaysia corporation ("RVR"), pursuant to the previously reported Amended And Restated Stock Purchase Agreement, dated as of December 7, 2016 (the "Stock Purchase Agreement"), by and among Chembio, RVR, Avijit Roy and Magentiren Vajuram. See footnote 16 to Chembio's Consolidated Financial Statements included in this Form 10-K for more information.

RESULTS OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2016 AS COMPARED WITH THE YEAR ENDED DECEMBER 31, 2015

Income:

For the year ended December 31, 2016, Loss before income taxes was $7,546,000 compared to Loss before income taxes of $3,557,000 for the year ended December 31, 2015. Net Loss for the year ended December 31, 2016 consists not only of the $7,546,000 Loss before income tax described above, but also of the $5,801,000 non-cash income tax provision described below under "Income tax provision (benefit)". Net Loss for the year ended December 31, 2015 consists not only of the $3,557,000 Loss before income tax described above, but also of the $1,160,000 non-cash income tax benefit described below under "Income tax provision (benefit)". The change in Loss before income taxes is primarily attributable to decreased revenue and gross margin, and increased operating expenses. Gross margin decreased in the year ended December 31, 2016 as compared with the year ended December 31, 2015, by $2,035,000, or (19.4)%. The increased operating expenses, the most significant of which were an increase materials and supplies for R&D of $1,512,000, increased clinical trial expenses of $412,000, and an increase in wages and related expenses of $633,000, partially offset by decreased commission expenses of $611,000, accounted for most of the change in Loss before income taxes.

Revenues:

Selected Product Categories:	For the years ended December 31, 2016	December 31, 2015	$ Change	% Change
Lateral Flow HIV Tests and Components	$ 7,943,224	$ 9,957,882	$ (2,014,658)	-20.23%
DPP® Tests and Components	5,400,893	11,265,876	(5,864,983)	-52.06%
Other	335,990	662,930	(326,940)	-49.32%
Net Product Sales	13,680,107	21,886,688	(8,206,581)	-37.50%
License and royalty revenue	449,685	52,753	396,932	752.43%
R&D, milestone and grant revenue	3,739,049	2,316,044	1,423,005	61.44%
Total Revenues	$ 17,868,841	$ 24,255,485	$ (6,386,644)	-26.33%

Revenues for our lateral flow HIV tests and related components during the year ended December 31, 2016 decreased by approximately $2,015,000 from the same period in 2015. This was primarily attributable to decreased sales to Africa of approximately $1,436,000, decreased sales to Europe of $40,000, decreased sales to the U.S. of $1,580,000, partially offset by increased sales to Mexico of $123,000. Revenues for our DPP® products during the year ended December 31, 2016 decreased by approximately $5,865,000 over the same period in 2015, primarily for decreases in sales in Brazil to FIOCRUZ of $5,340,000. The increase in R&D, and in milestone and grant revenue, was primarily due to revenues from certain development projects that were awarded during the period. R&D revenues include funds, recognized on an "as expenses are incurred" basis or on a proportonial performance basis, from various grants, see footnote 14 of our financial statements.

Gross Margin:

Gross Margin related to Net Product Sales:	For the years ended December 31, 2016	December 31, 2015	$ Change	% Change
Gross Margin per Statement of Operations	$ 8,451,336	$ 10,486,827	$ (2,035,491)	-19.41%
Less: R&D, milestone, grant, license and royalties	4,188,734	2,368,797	1,819,937	76.83%
Gross Margin from Net Product Sales	4,262,602	8,118,030	$ (3,855,428)	-47.49%
Product Gross Margin %	$ 31.16%	$ 37.09%		

The overall gross margin dollar decrease of 2,035,000 consisted of a $3,855,000 decrease in gross margin from net product sales and a $1,820,000 increase in non-product revenues. The decrease in net product sales gross margin of $3,855,000 is primarily attributable to the change in product sales compared to 2015. The net product sales gross margin decrease is comprised of two components, one is the decrease in product sales of $8,207,000, which at the 37.1% margin contributed $3,044,000 to the decrease, and the other is the decreased change in margin percentage of 5.9% which contributed the balance of $812,000. The 5.9% decrease in the percentage, from 37.1% in 2015 to 31.2% in 2016, was primarily due to increased overhead as a percentage of products produced, due to the lower volume of sales.

Research and Development:

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

Selected expense lines:	For the years ended			
	December 31, 2016	December 31, 2015	$ Change	% Change
Clinical and Regulatory Affairs:				
Wages and related costs	$ 569,664	$ 490,802	$ 78,862	16.07%
Consulting	40,974	44,135	(3,161)	-7.16%
Stock-based compensation	-	-	-	100.00%
Clinical trials	778,921	366,469	412,452	112.55%
Other	54,851	80,960	(26,109)	-32.25%
Total Regulatory	1,444,410	982,366	462,044	47.03%
R&D Other than Regulatory:				
Wages and related costs	2,951,456	2,896,226	55,230	1.91%
Consulting	143,321	128,117	15,204	11.87%
Stock-based compensation	89,246	62,713	26,533	42.31%
Materials and supplies	3,290,868	1,779,046	1,511,822	84.98%
Other	508,253	529,371	(21,118)	-3.99%
Total other than Regulatory	6,983,144	5,395,473	1,587,671	29.43%
Total Research and Development	**$ 8,427,554**	$ 6,377,839	$ 2,049,715	32.14%

Expenses for Clinical and Regulatory Affairs for the year ended December 31, 2016 increased by $462,000 as compared to the same period in 2015. This was due to an increase of $412,000 in clinical trial expenses and increased wages and related costs of $79,000.

R&D expenses other than Clinical & Regulatory Affairs increased by $1,588,000 in the year ended December 31, 2016, as compared with the same period in 2015. 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, 2016	December 31, 2015	$ Change	% Change
Wages and related costs	$ 3,559,482	$ 3,060,407	$ 499,075	16.31%
Consulting	128,992	311,488	(182,496)	-58.59%
Commissions	680,545	1,291,453	(610,908)	-47.30%
Stock-based compensation	214,913	271,674	(56,761)	-20.89%
Marketing materials	375,739	223,445	152,294	68.16%
Investor relations/investment bankers	298,675	204,198	94,477	46.27%
Legal, accounting and compliance	1,086,212	879,887	206,325	23.45%
Travel, entertainment and trade shows	446,541	448,599	(2,058)	-0.46%
Bad debt allowance (recovery)	-	-	-	100.00%
Other	804,460	971,884	(167,424)	-17.23%
Total S, G &A	**$ 7,595,559**	**$ 7,663,035**	**$ (67,476)**	**-0.88%**

Selling, general and administrative expenses for the year ended December 31, 2016, decreased by $67,000 as compared with the same period in 2015, a 0.9% decrease. This decrease resulted primarily from decreases in consulting, commissions (due to decreased sales to Brazil), and stock-based compensation, which were partially offset by increases in wages and related costs and travel expenses which for 2016 included the continued development of a sales and marketing team over 2015, marketing materials, professional fees and in investor relations/investment bankers.

Other Income and Expense:

	For the years ended December 31, 2016	December 31, 2015	$ Change	% Change
Other income (expense)	$ -	$ (4,814)	$ 4,814	-100.00%
Interest income	25,548	2,412	23,136	959.20%
Interest expense	-	(836)	836	-100.00%
Total Other Income and (Expense)	$ 25,548	$ (3,238)	$ 28,786	889.01%

Other income (expense) for the year ended December 31, 2016 increased approximately $29,000, primarily due to interest income, compared to the same period in 2015.

Income tax provision (benefit):

For the year ended December 31, 2016 the Company recognized a $5,801,000 non-cash income tax provision and decreased its deferred tax assets by $5,801,000 as the Company took a full valuation allowance against its carryforward losses in the second quarter. For the year ended December 31, 2015, the Company recognized a $1,160,000 non-cash income tax benefit and increased its deferred tax assets by $1,160,000. The effective tax rate used to recognize the benefit in 2015 was 32.0% to record the amount charged. In the 2015 year, non-deductible expenses for tax purposes accounted for most of the difference from the standard 34% U.S. tax rate. The Company still maintains a full valuation allowance on research and development tax credits

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

Income:

For the year ended December 31, 2015, Loss before income taxes was $3,557,000 compared to Loss before income taxes of $1,550,000 for the year ended December 31, 2014. Net Loss for the year ended December 31, 2015 consists not only of the $3,557,000 Loss before income tax described above, but also of the $1,160,000 non-cash income tax benefit described below under "Income tax provision (benefit)". Net Loss for the year ended December 31, 2014 consists not only of the $1,550,000 Loss before income tax described above, but also of the $413,000 non-cash income tax benefit described below under "Income tax provision (benefit)". The change in Loss before income taxes is primarily attributable to decreased revenue and gross margin, and increased operating expenses. Gross margin decreased in the year ended December 31, 2015 as compared with the year ended December 31, 2014, by $327,000, or 3.0%. The increased operating expenses, the most significant of which were an increase in wages and related expenses of $779,000, an increase in materials and supplies for R&D of $758,000, and increased clinical trial expenses of $161,000, partially offset by decreased commission expenses of $141,000, accounted for most of the change in Loss before income taxes.

Revenues:

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

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

Gross Margin:

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

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

Research and Development:

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

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

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

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

Selling, General and Administrative Expense:

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

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

Other Income and Expense:

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

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

Income tax provision (benefit):

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

MATERIAL CHANGES IN FINANCIAL CONDITION

Selected Changes in Financial Condition	As of December 31, 2016	As of December 31, 2015	$ Change	% Change
Cash and cash equivalents	$ 10,554,464	$ 5,376,931	$ 5,177,533	96.29%
Accounts receivable, net of allowance for doubtful accounts of $52,000 and $52,000 at December 31, 2016 and 2015, respectively	3,383,729	2,422,971	960,758	39.65%
Prepaid expenses and other current assets	840,145	1,256,879	(416,734)	-33.16%
Fixed assets, net of accumulated depreciation	1,709,321	2,374,308	(664,987)	-28.01%
Deferred tax asset, net of valuation allowance	-	5,467,143	(5,467,143)	-100.00%
Deposits and other assets	720,489	209,169	511,320	244.45%
Accounts payable and accrued liabilities	3,013,133	2,801,432	211,701	7.56%
Deferred revenue	392,517	353,406	39,111	11.07%
Additional paid-in capital	60,721,783	47,890,642	12,831,141	26.79%

Cash increased by $5,178,000 from December 31, 2015, primarily due to net cash provided by financing activities for the year of 2016. The Company raised, net of expenses, approximately $12,500,000 which was partially offset by cash used in operating activities for the year of 2016. In addition there were increases in accounts receivable, net of allowance, of $961,000, deposits, accounts payable and accrued liabilities of $212,000 and other assets of $511,000, deferred revenue of $39,000, and decreases in fixed assets of $665,000 after depreciation, prepaid expenses of $417,000, non-current deferred tax asset of $5,467,000, and an increase in additional paid-in-capital of $12,831,000.

The accounts receivable increase from December 31, 2015, is primarily due to an increase in December 2016 versus December 2015 sales of approximately $1.50 million, partially offset by lower sales in prior months. The decrease in fixed assets is primarily due to depreciation for the year ending December 2016 versus December 2015. Deferred tax asset decrease is related to recording of a full valuation allowance.

LIQUIDITY AND CAPITAL RESOURCES

	For the years ended December 31, 2016	For the years ended December 31, 2015	$ Change	% Change
Net cash provided by (used in) operating activities	$ (6,704,734)	$ 1,792,978	$ (8,497,712)	-473.94%
Net cash used in investing activities	(668,706)	(1,030,585)	361,879	35.11%
Net cash provided by financing activities	12,550,973	-	12,550,973	100.00%
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	$ 5,177,533	$ 762,393	$ 4,415,140	579.12%

The Company's cash increased as of December 31, 2016 by $5,178,000 from December 31, 2015, primarily due to net cash provided by operating activities and partially offset by cash used in investing activities for 2016.

The cash used in operations in 2016 was $6,705,000, primarily due to the net loss net of non-cash items of $6,103,000 and with an increase in accounts receivable of $961,000, increase in prepaid and other current assets of $136,000, and a decrease in accounts payable and other accrued liabilities of $212,000, partially offset by a decrease in inventories of $243,000, decrease in deposits and other assets of $1,000, and an increase in deferred revenue of $39,000. Net loss net of non-cash items includes net loss of $13,347,000 partially offset by $5,801,000 in income tax provision, $1,139,000 in depreciation and amortization, and $304,000 in share-based compensation. The use of cash from investing activities is primarily the purchase of fixed assets and acquisition of licenses.

Fixed Asset Commitments

As of December 31, 2016, the Company had paid deposits on various pieces of equipment aggregating $31,900 which is reflected in Deposits on manufacturing equipment on the balance sheet. As of December 31, 2016, the Company was not committed to additional equipment-purchase obligations.

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

During 2016, Chembio took three important strategic steps which management believes will position the Company for growth. First, the Company continued to expand its product portfolio, leveraging its patented DPP® technology platform. Second, the Company expanded its global sales and marketing infrastructure, strengthening its U.S. sales leadership and building its first international sales team. Third, the Company expanded its operational capabilities, acquiring a Malaysia-based operation.

Expanding Chembio's Product Portfolio

For nearly fifteen years, Chembio was primarily focused on POC HIV testing and succeeded in commercializing multiple FDA-approved and CLIA-Waived POC HIV tests. In 2014, the Company made the strategic decision to expand its product portfolio and focus on three initiatives: 1) strengthening its core sexually transmitted disease business, 2) building a highly-differentiated fever and tropical disease business, and 3) establishing technology collaborations to further leverage its patented DPP® technology platform.

1. Strengthening the Company's core sexually transmitted disease business began with the decision to terminate its U.S. distribution agreements for HIV 1/2 Stat-Pak® Assay in 2014 and SURE CHECK HIV® 1/2 Assay in 2016, which provided the Company with worldwide commercial control of its legacy POC HIV tests, which are FDA-approved, CLIA-waived, WHO Prequalified and CE marked. The Company leveraged its DPP® technology platform to develop a DPP® HIV 1/2 Assay, which became FDA-Approved and CLIA-Waived in October 2014 for use with blood and oral fluid, the second such entrant in the U.S. market. Finally, following the introduction of its DPP® HIV-Syphilis Assay in Latin America, the Company has prioritized the development of a DPP® HIV-Syphilis Assay for the U.S. market to address the rise in HIV and Syphilis co-infection.

2. Building a highly-differentiated fever and tropical disease business began as a response to the 2014-2015 Ebola outbreak in West Africa, which led to the Company's decision to enter the fever and tropical disease market. Today, the Company is developing eight POC fever and tropical disease tests, specifically the following: DPP® Malaria Assay, DPP® Zika Assay, DPP® Dengue Fever Assay, DPP® Chikungunya Assay, DPP® Zika/Dengue/Chikungunya Assay, DPP® Fever Assay (Malaria, Zika, Dengue, Chikungunya, Ebola, Lassa, Marburg), DPP® Ebola Assay, and DPP® Ebola-Malaria Assay. The Company's fever and tropical disease products are being developed through collaborations and/or funding's from the Bill & Melinda Gates Foundation, the Paul G. Allen Family Foundation, the Centers for Disease Control and Prevention (CDC), the U.S. Department of Health and Human Services (HHS), the Office of the Assistant Secretary for Preparedness and Response, and the Biomedical Advanced Research and Development Authority (BARDA).

3. Establishing technology collaborations to further leverage the Company's patented DPP® technology platform has allowed the Company to advance the development of novel POC tests in areas with unmet medical needs, such as traumatic brain injury (concussion), a specific form or cancer, and bovine tuberculosis in cattle. The collaborations and external funding can be attributed to the unique characteristics of the Company's DPP® technology platform as compared to traditional lateral flow technology, such as enhanced sensitivity and specificity, the ability to multiplex, and the ability to provide a semi-quantitative result when combined with Chembio's DPP® Micro Reader.

Expanding Chembio's Sales & Marketing Infrastructure

Prior to 2014, Chembio's HIV products were sold through a single, exclusive distribution partner in the U.S. market, the majority of the Company's international sales were limited to a few countries, and the Company had no internal commercialization infrastructure. Between 2014 and 2016, Chembio took important steps to gain control of its HIV products in the U.S. market, ending the longstanding relationship with its previous distribution partner and building its own U.S. sales and marketing team to sell its DPP® HIV, STAT-PAK® HIV, and SURE CHECK® HIV products in the U.S. market. In addition, the Company has partnered with professional distributors such as Fisher, McKesson/PSS, Henry Schein and Medline to establish a geographic coverage model in the U.S. market.

To lead this growing infrastructure, Chembio recently appointed two senior executives to direct the expansion of the Company's global commercial operations. Robert Passas, Ph.D., joined the Company in October 2016 as President, EMEA and APAC regions, and is responsible for commercial operations in Europe, the Middle East, Africa, and Asia. Prior to joining the Company, Dr. Passas held positions of increasing responsibility at Abbott, Quidel, The Binding Site, and Trinity Biotech. In his most recent position, he was responsible for worldwide marketing and international sales at Trinity Biotech.

Sharon Klugewicz, who most recently served as Chembio's Chief Operating Officer, was promoted to President, Americas region in October 2016, with responsibility for commercial operations in the United States, Latin America, and Canada. Ms. Klugewicz is responsible for sales, marketing, customer support, clinical and regulatory affairs, and quality systems in the Americas, and will be tasked with leading the U.S. commercial team and expanding commercial operations throughout Latin America, the U.S. and Canada. Prior to joining the Company in 2012, she spent 20 years at Pall Corporation where she held positions of increasing responsibility, including Senior Vice President, Scientific and Laboratory Services.

In addition, Chembio has recently hired three international sales executives to oversee commercial expansion in specific regions. Javier Gutman was named Regional Director, Latin America; Kenneth Burns was named Regional Director, Africa; and Mohan Anasalam was named Regional Director, Asia Pacific. Each of these sales executives brings considerable experience to Chembio, and each will focus on increasing product sales, strengthening and expanding the Company's distribution channels, and providing local support to customers and commercial partners in their respective areas of Latin America, Africa and Asia Pacific.

Today, led by experienced executives with extensive experience in global diagnostic sales, Chembio is building a world-class commercialization organization with focus on the U.S., Europe, Africa, Asia Pacific and Latin America.

Expanding Chembio's Operational Capabilities

In November 2016, Chembio announced plans to acquire Malaysia-based RVR Diagnostics ("RVR"), a strategic decision to expand the Company's operational capabilities, increasing manufacturing capacity and establishing a physical presence in Southeast Asia.

Previously, in 2014, Chembio entered into two agreements with RVR, a privately-held company in Malaysia. The agreements were intended to build a Chembio presence in Asia and establish RVR as a licensee, distributor and contract manufacturer. Through these agreements, RVR acquired rights to license, manufacture and distribute certain Chembio products in Southeast Asia. Between 2014 and 2016, RVR achieved a number of important milestones under the agreements, including the following:

- completed a manufacturing facility capable of producing DPP® Assays and obtained ISO 13485 certification;
- provided funding to accelerate the development of Chembio's DPP® Dengue Assay;
- received regulatory approval to market and sell products in certain Southeast Asia countries;
- obtained RVR Dengue tender award in Malaysia, which resulted in 2016 revenue in excess of US$1 million.

In light of the considerable progress made by RVR, and to further support Chembio's global product and commercialization strategies, Chembio acquired RVR in January 2017. As a subsidiary of Chembio, RVR provides an important base of operations, providing additional revenue, a strategically located and cost-effective manufacturing facility, and a path to regulatory access in Southeast Asia that management believes will be an important growth driver.

Overview of Chembio's Business

Sexually Transmitted Disease:

Chembio's sexually transmitted disease product sales decreased during 2016, primarily due to the Company's loss of ongoing DPP® HIV and DPP® Syphilis product sales as a result of a previously disclosed tender offer in Brazil having been awarded to a competitor at an extremely low price point as well as lower sales of HIV products in Africa. Despite the loss of the HIV and Syphilis tender in Brazil, Chembio continues to supply other novel DPP® products to Bio-Manguinhos/Fiocruz, and the Ministry of Health in Brazil. These products include DPP® HIV Confirmatory Assay and DPP® Leishmania Assay. Given Chembio's product portfolio in sexually transmitted disease, coupled with the expansion of our global commercial resources, the Company believes the Unites States, Latin America, Africa, and Asia Pacific will be important current and future markets for its sexually transmitted disease products.

In the U.S., sales of the Company's POC HIV Assays showed positive trends. During 2016, U.S. sales of the HIV 1/2 STAT-PAK® Assay increased 34.7% as compared to 2015. We are also seeing very encouraging U.S. sales of the SURE CHECK® HIV 1/2 Assay. During the fourth quarter of 2016, U.S. sales of the SURE CHECK® HIV 1/2 Assay increased by approximately $516,000 or 230.5% as compared to the third quarter of 2016. Our U.S. HIV sales are bolstered by a receipt of a two-year HIV tender for the state of Florida, which the Company was awarded during the fourth quarter of 2016 and of a two-year HIV tender for another state, which the Company was awarded subsequent to the end of 2016. This growth provides evidence that we are effectively rebuilding the U.S. HIV STAT-PAK® and SURE CHECK® HIV business, after we took back the U.S. distribution rights to these products in June 2014 and June 2016 respectively.

Looking toward 2017 sales of Chembio's sexually transmitted disease products, the Company recently received CE Mark for the DPP® HIV-Syphilis Assay, clearing the product to be marketed and sold within the member states of the European Union and the Caribbean region, except for Puerto Rico and the U.S. Virgin Islands. The Company continued to advance the clinical trial for its DPP® HIV-Syphilis Assay for the U.S. market during 2016, which is expected to be completed as planned, in the first quarter of 2017. As we've stated previously, we are striving to be the first-to-market in the U.S. with an HIV-Syphilis combination test.

Fever Disease:

During 2016, Chembio significantly advanced the development of its fever disease products, including: DPP® Malaria Assay, DPP® Dengue Assay, DPP® Zika Assay, DPP® Chikungunya Assay, DPP® Zika/Dengue/Chikungunya Assay, DPP® Fever Panel Assay, DPP® Ebola Assay, and DPP® Malaria/Ebola Assay. Also during 2016, the Company pursued and received numerous grants which fund much of the fever disease development initiatives, including funding from the Paul G. Allen Family Foundation, the Bill & Melinda Gates Foundation, and the U.S. Government (HHS/ASPR/BARDA and CDC). In addition, during the first quarter of 2016, the Company also entered into a collaboration with Bio-Manguinhos/Fiocruz for the development of POC Zika diagnostic tests for Brazil.

Of particular note is the Company's work to develop a much-needed alternative to currently available molecular tests for the Zika virus that have limited utility as they are accurate only during a narrow window of time, approximately one week, between initial Zika virus exposure and the patient's development of detectable antibodies to the virus, a process known as seroconversion. Following seroconversion, antibody tests are recommended to accurately identify Zika virus infections. The DPP® Zika IgM/IgG Assay is an antibody test that will provide timely results, during the patient consultation. The DPP® Zika System, which includes the DPP® Zika IgM/IgG Assay and DPP® Micro Reader, detects both IgM and IgG antibodies, uses a 10uL fingerstick blood sample, and provides semi-quantitative results in 15 minutes. Though Chembio's Zika program was only initiated in February 2016, by September 2016, the Company was awarded a contract by the CDC for the purchase of POC surveillance diagnostic assays for Zika, Dengue and Chikungunya. Under the terms of the contract, during the first quarter of 2017 Chembio will supply its DPP® Zika IgM/IgG Assay, DPP® Zika/Chikungunya/Dengue IgM/IgG Combination Assay, and DPP® Micro Reader to the CDC, for a surveillance testing pilot program in India, Peru, Guatemala and Haiti.

Concurrent with this important development work, Chembio is moving expeditiously to complete regulatory filings that will ultimately determine the availability of our products to the regions in need. In July 2016, a CE Mark was obtained that allowed the Company to begin commercializing the DPP® Zika IgM/IgG System, which includes an assay utilizing the patented DPP® technology, as well as a digital reader, the DPP® Micro Reader, in 17 European countries, including the United Kingdom, Germany, and France, as well as a majority of the Caribbean nations. During the fourth quarter of 2016, Chembio initiated sales of the DPP® Zika system via its exclusive Caribbean distribution partner, Isla Labs.

In November 2016, the Company received approval for commercial use of its DPP® Zika IgM/IgG Assay by the Brazilian health regulatory agency, Agência Nacional de Vigilância Sanitária (ANVISA), and during the first quarter 2017, the Company was notified of the successful evaluation of the DPP® Zika system by INCQS, Brazil's National Institute for Quality Control in Health. Brazil has been hardest hit by the Zika virus, where it is estimated that 1.5 million people have been infected with Zika virus and approximately 2,000 babies have been born with microcephaly, a devastating birth defect linked to the Zika virus. For this reason the Company is particularly pleased to receive approval from Brazil's health regulatory agency, and we look forward to initiating sales of our DPP® Zika IgM/IgG Assay, following ANVISA approval of the DPP® Micro Reader. There is no assurance of the timing of this approval or that it will occur at all.

Beyond these approvals, the Company made multiple other regulatory filings during 2016 for the DPP® Zika IgM/IgG Assay, including an Emergency Use Authorization (EUA) submission with the U.S. Food and Drug Administration (FDA), an Emergency Use Assessment and Listing (EUAL) with the World Health Organization (WHO), and a submission with Cofepris in Mexico. Supplementing these filings, the Company is engaged fully with these agencies in the hope of facilitating the earliest possible approvals.

Technology Collaborations:

Chembio currently has the following ongoing technology collaborations: DPP® Cancer Assay for a specific form of cancer, DPP® Traumatic Brain Injury Assay, and DPP® BovidTB Assay. We are pleased to report that we made progress with each of these programs in 2016.

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

We also made important advances with our DPP® Traumatic Brain Injury Assay program during 2016. This project, which is funded by Perseus Science Group, LLC, is in the feasibility phase. We recently finalized institutional review board (IRB) agreements with several hospitals and began conducting initial studies of the DPP® Traumatic Brain Injury Assay using patient samples.

The DPP® BovidTB Assay is a rapid POC test for the detection of bovine tuberculosis (TB). In September 2016, the Company was awarded a $600,000 grant from the United States Department of Agriculture (USDA) to develop the DPP® BovidTB Assay. Under the two-year grant, Chembio will use its patented DPP® technology in an effort to develop a simple, rapid, accurate and cost-effective test for bovine TB in cattle. The DPP® BovidTB Assay will be designed to provide results within 20 minutes, thereby significantly improving on the time-consuming, tedious and inadequate diagnostic methods currently in use.

Conclusion

During 2016, the Company made significant advances to expand its product portfolio, its sales and marketing infrastructure, and its operational capabilities.

The product strategy includes three strategic initiatives: strengthening the Company's core sexually transmitted disease, building a highly-differentiated fever and tropical disease, and establishing technology collaborations to further leverage the Company's patented DPP® technology platform. Though the Company only initiated its fever disease program in late 2014, sales of two fever disease products were initiated in 2015 (DPP® Ebola, DPP® Malaria-Ebola) and expanded in late 2016 (DPP® Zika Assay). The efficiency with which these products were developed, and regulatory clearances were obtained, speaks to the versatility of the Company's patented DPP® technology platform, the Company's scientific expertise, and its commitment to fever disease. It further highlights Chembio's ability to succeed with a range of new product opportunities.

The commercial strategy shifted from a product supply model, in which the Company relied on others to market and sell its products, to taking critical steps to build a global sales and marketing organization. Prior to 2014, the Company had no sales infrastructure. Today, Chembio has experienced sales leadership guiding the Company's global commercialization plan, with focus on the U.S., Europe, the Middle East, Africa, Asia, and Latin America. The new sales and marketing leadership joined Chembio starting in Q4 of 2016 with 2017 goals of increasing product sales, strengthening and expanding the Company's distribution channels, and providing local support to customers and commercial partners around the world. With several fever and HIV products receiving regulatory approvals in late 2016, there is great optimism for 2017 sales.

And the operational strategy was significantly expanded beyond Medford, NY to incorporate Malaysia-based RVR Diagnostics. The acquisition, of RVR provides Chembio with an important base of operations, providing additional revenue, a strategically located and cost-effective manufacturing facility, and a path to regulatory access in Southeast Asia that management believes will be an important growth driver.

2016 was an important year for Chembio, but it was merely a starting point for this new global organization.

Contractual Obligations and Commercial Commitments

The following sets forth our approximate aggregate obligations as of December 31, 2016 for future payments under contracts and other contingent commitments, for the year 2017 and beyond:

		Payments due by period			
Contractual Obligations	**Total**	**Less than one year**	**1 - 3 years**	**3-5 years**	**More than 5 years**
Operating leases[1]	$ 370,085	$ 306,018	$ 64,067	$ -	$ -
Employment contracts[2]	907,000	516,200	390,800	-	-
Purchase obligations[3]	694,725	694,725	-	-	-
Minimum commitments under contracts[4]	532,627	333,627	92,000	77,000	30,000
Total contractual obligations	$ 2,504,437	$ 1,850,570	$ 546,867	$ 77,000	$ 30,000

[1] Represents payments required under our operating leases. See Note 13 of the Notes to the consolidated financial statements included herein.
[2] Represents salary payments payable under the terms of employment agreements executed by us with certain executives. See Note 13 of the Notes to the consolidated financial statements included herein.
[3] Represents payments required by non-cancellable purchase orders related to inventory, capital expenditures and other goods or services.
[4] Represents payments required pursuant to certain licensing agreements executed by the Company. These agreements are cancellable within a specified number of days after communication by the Company of its intent to terminate.

Off-Balance Sheet Arrangements.

We do not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K under the Securities Exchange Act of 1934, as amended.

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, and 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 $35,000.

Allowance for doubtful accounts –

Our policy is to review our accounts receivable on a periodic basis, no less than monthly. On a quarterly basis an analysis is made of the adequacy of our allowance for doubtful accounts and adjustments are made accordingly. The current allowance is approximately 2% of accounts receivable. For example each additional 1% of accounts receivable that becomes uncollectible would reduce such balance of accounts receivable by approximately $32,000.

Income Taxes –

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

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

Recent Accounting Pronouncements –

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

The standard is effective for annual periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients; or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our consolidated financial statements and have not yet determined the method by which we will adopt the standard in 2018. The Company has conducted a preliminary analysis of its sales contracts which are based on the shipment of goods to the customer, and currently this new accounting standard will not have a material impact on its consolidated financial statement for our sales contracts. The Company has conducted a preliminary analysis of its current R&D contracts which are currently based on "as expenses are incurred" basis, and currently this new accounting standard will not have a material impact on its consolidated financial statement for our current R&D contracts.

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

In February 2016, the FASB issued Accounting Standards Update ("ASU") 2016-02, which amends the ASC and creates Topic 842, Leases. Topic 842 will require lessees to recognize lease assets and lease liabilities for those leases classified as operating leases under previous US GAAP on the balance sheet. This guidance is effective for annual periods beginning after December 15, 2018 and early adoption is permitted. We are in the initial stages of evaluating the effect of the standard on our financial statements and will continue to evaluate. While not yet in a position to assess the full impact of the application of the new standard, the Company expects that the impact of recording the lease liabilities and the corresponding right-to-use assets will have a significant impact on its total assets and liabilities with a minimal impact on equity.

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-09, Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, which will change certain aspects of accounting for share-based payments to employees. ASU 2016-09 is effective for fiscal years (and interim reporting periods within those years) beginning after December 15, 2016. The Company is currently in the initial stages of evaluating the impact of the provisions of ASU 2016-09. We are still evaluating this standard and currently the Company does not believe this new accounting standard will have a material impact on its consolidated financial statement.

ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk.

We do not hold any amounts of derivative financial instruments or derivative commodity instruments and, accordingly, we have no material derivative risk to report under this Item.

As of December 31, 2016, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. Sales for the year ended December 31, 2016 are in U.S. Dollars (USD).

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.

Management's Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15(f).

The Company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) 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 (iii) 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 can only provide reasonable assurance and may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including the Chief Executive Officer (CEO) and the Chief Financial Officer (CFO), we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2016, based on the framework and criteria in the 2013 *Internal Control – Integrated Framework*, issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on management's evaluation and those criteria, the CEO and CFO concluded that its system of internal control over financial reporting was effective as of December 31, 2016.

The Company's independent registered public accounting firm has issued an attestation report on the Company's internal control over financial reporting.

Dated: March 7, 2017 /s/ John J. Sperzel
John J. Sperzel III
Chief Executive Officer

Dated: March 7, 2017 /s/ Richard J. Larkin
Richard J. Larkin
Chief Financial Officer

Report of Independent Registered Public Accounting Firm
Board of Directors and Stockholders of
Chembio Diagnostics, Inc.
Medford, New York

We have audited the internal control over financial reporting of Chembio Diagnostics, Inc. and subsidiaries (the "Company") as of December 31, 2016, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting ("Management's Report"). Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 (3) 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. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Chembio Diagnostics, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Chembio Diagnostics, Inc. and subsidiary as of December 31, 2016 and 2015, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2016 and our report dated March 7, 2017 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP
Melville, New York
March 7, 2017

(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

The information required in response to this Item 10 is incorporated herein by reference to our Definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A of the Exchange Act not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

The information required in response to this Item 11 is incorporated herein by reference to our Definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A of the Exchange Act not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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

The information required in response to this Item 12 is incorporated herein by reference to our Definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A of the Exchange Act not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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

The information required in response to this Item 13 is incorporated herein by reference to our Definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A of the Exchange Act not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required in response to this Item 14 is incorporated herein by reference to our Definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A of the Exchange Act not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

PART IV

ITEM 15.

EXHIBITS INDEX

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

1	Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on July 29, 2010.
2	Incorporated by reference to the Registrant's registration statement on Form SB-2 (File No. 333-85787) filed with the Commission on August 23, 1999 and the Registrant's Forms 8-K filed on May 14, 2004, December 20, 2007 and April 18, 2008.
3	Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on August 3, 2012.
4	Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on May 8, 2014.
5	Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on April 29, 2014.
6	Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on August 7, 2014.
7	Incorporated by reference to the Registrant's registration statement on Form 8-A filed with the Commission on April 7, 2016.
8	Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on March 14, 2016.
9	Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on June 17, 2015.
10	Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on October 5, 2006.
11	Incorporated by reference to the Registrant's Annual Report on Form 10-K filed with the Commission on March 5, 2015.
12	Incorporated by reference to the Registrant's Annual Report on Form 10-KSB filed with the Commission on March 30, 2006.
13	Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on April 7, 2016.

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

ITEM 16. Form 10-K Summary

None.

SIGNATURES

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

CHEMBIO DIAGNOSTICS, INC.

March 7, 2017

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

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

Signatures	Title	Date
/s/ John J. Sperzel John J. Sperzel III	Chief Executive Officer, President and Member Of The Board (Principal Executive Officer)	March 7, 2017
/s/ Richard J. Larkin Richard J. Larkin	Chief Financial Officer (Principal Financial & Accounting Officer)	March 7, 2017
/s/ Gary Meller Gary Meller	Director	March 7, 2017
/s/ Katherine L. Davis Katherine L. Davis	Director & Chair of the Board	March 7, 2017
/s/ Peter T. Kissinger Peter T. Kissinger	Director	March 7, 2017

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

Index to Consolidated Financial Statements

—INDEX—

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of Chembio Diagnostics, Inc. and Subsidiary (the "Company") as of December 31, 2016 and 2015 and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2016. In connection with our audits of the consolidated financial statements, we have also audited the financial statement schedule as listed in the accompanying index. These consolidated financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements and schedule, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements and schedule. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Chembio Diagnostics, Inc. and Subsidiary as of December 31, 2016 and 2015, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2016 in conformity with accounting principles generally accepted in the United States of America.

Also, in our opinion the financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, present fairly, in all material respects, the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Chembio Diagnostics, Inc.'s internal control over financial reporting as of December 31, 2016, based on criteria established in *Internal Control – Integrated Framework 2013* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 7, 2017 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Melville, New York
March 7, 2017

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

- ASSETS -

	December 31, 2016	December 31, 2015
CURRENT ASSETS:		
Cash and cash equivalents	**$ 10,554,464**	$ 5,376,931
Accounts receivable, net of allowance for doubtful accounts of $52,000 and $52,000 at December 31, 2016 and 2015, respectively	**3,383,729**	2,422,971
Inventories	**3,335,188**	3,578,025
Prepaid expenses and other current assets	**840,145**	1,256,879
TOTAL CURRENT ASSETS	**18,113,526**	12,634,806
FIXED ASSETS, net of accumulated depreciation	**1,709,321**	2,374,308
OTHER ASSETS:		
Deferred tax asset, net of valuation allowance	**-**	5,467,143
License agreements, net of current portion	**-**	100,000
Deposits on manufacturing equipment	**31,900**	30,918
Deposits and other assets	**720,489**	209,169
TOTAL ASSETS	**$ 20,575,236**	$ 20,816,344
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	**$ 3,013,133**	$ 2,801,432
Deferred revenue	**392,517**	353,406
TOTAL CURRENT LIABILITIES	**3,405,650**	3,154,838
TOTAL LIABILITIES	**3,405,650**	3,154,838
COMMITMENTS AND CONTINGENCIES (Note 13)		
STOCKHOLDERS' EQUITY:		
Preferred stock – 10,000,000 shares authorized, none outstanding	**-**	-
Common stock - $.01 par value; 100,000,000 shares authorized, 12,026,847 and 9,628,248 shares issued and outstanding for 2016 and 2015, respectively	**120,268**	96,282
Additional paid-in capital	**60,721,783**	47,890,642
Accumulated deficit	**(43,672,465)**	(30,325,418)
TOTAL STOCKHOLDERS' EQUITY	**17,169,586**	17,661,506
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 20,575,236**	$ 20,816,344

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the years ended		
	December 31, 2016	December 31, 2015	December 31, 2014
REVENUES:			
Net product sales	**$ 13,680,107**	$ 21,886,688	$ 25,949,769
License and royalty revenue	**449,685**	52,753	23,257
R&D, milestone and grant revenue	**3,739,049**	2,316,044	1,672,258
TOTAL REVENUES	**17,868,841**	24,255,485	27,645,284
Cost of product sales	**9,417,505**	13,768,658	16,831,261
GROSS MARGIN	**8,451,336**	10,486,827	10,814,023
OPERATING EXPENSES:			
Research and development expenses	**8,427,554**	6,377,839	4,832,537
Selling, general and administrative expenses	**7,595,559**	7,663,035	7,531,739
	16,023,113	14,040,874	12,364,276
LOSS FROM OPERATIONS	**(7,571,777)**	(3,554,047)	(1,550,253)
OTHER INCOME (EXPENSE):			
Other expense	**-**	(4,814)	(5,707)
Interest income	**25,548**	2,412	5,839
Interest expense	**-**	(836)	-
	25,548	(3,238)	132
LOSS BEFORE INCOME TAXES (BENEFIT)	**(7,546,229)**	(3,557,285)	(1,550,121)
Income tax provision (benefit)	**5,800,818**	(1,160,243)	(412,918)
NET LOSS	**$ (13,347,047)**	$ (2,397,042)	$ (1,137,203)
Basic loss per share	**$ $ (1.26)**	$ (0.25)	$ (0.12)
Diluted loss per share	**$ $ (1.26)**	$ (0.25)	$ (0.12)
Weighted average number of shares outstanding, basic	**10,622,331**	9,626,028	9,530,320
Weighted average number of shares outstanding, diluted	**10,622,331**	9,626,028	9,530,320

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2016, 2015 AND 2014

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount	Amount	Amount	Amount
Balance at December 31, 2013	**9,324,783**	**$ 93,248**	**$ 46,875,027**	**$ (26,791,173)**	**$ 20,177,102**
Options:					
Exercised	**286,356**	**2,864**	**234,299**	**-**	**237,163**
Stock option compensation	**-**	**-**	**447,100**	**-**	**447,100**
Net loss				**(1,137,203)**	**(1,137,203)**
Balance at December 31, 2014	**9,611,139**	**$ 96,112**	**$ 47,556,426**	**$ (27,928,376)**	**$ 19,724,162**
Options:					
Exercised	**17,109**	**170**	**(170)**	**-**	**-**
Stock option compensation	**-**	**-**	**334,386**	**-**	**334,386**
Net loss	**-**	**-**	**-**	**(2,397,042)**	**(2,397,042)**
Balance at December 31, 2015	**9,628,248**	**$ 96,282**	**$ 47,890,642**	**$ (30,325,418)**	**$ 17,661,506**
Common Stock:					
New stock from offering	**2,300,000**	**23,000**	**12,470,398**	**-**	**12,493,398**
Options:					
Exercised	**98,599**	**986**	**56,589**	**-**	**57,575**
Stock option compensation	-	-	**304,154**	-	**304,154**
Net loss	**-**	**-**	**-**	**(13,347,047)**	**(13,347,047)**
Balance at December 31, 2016	**12,026,847**	**$ 120,268**	**$ 60,721,783**	**$ (43,672,465)**	**$ 17,169,586**

See accompanying notes to consolidated financial statements

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

	December 31, 2016	December 31, 2015	December 31, 2014
CASH FLOWS FROM OPERATING ACTIVITIES:			
Cash received from customers and grants	**$ 16,947,194**	$ 30,174,083	$ 23,898,516
Cash paid to suppliers and employees	**(23,677,476)**	(28,382,681)	(27,724,654)
Interest received	**25,548**	2,412	5,839
Interest paid	**-**	(836)	-
Net cash provided by (used in) operating activities	**(6,704,734)**	1,792,978	(3,820,299)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Acquisition of license	**-**	(550,000)	-
Deposit for investment in RVR	**(550,000)**	-	-
Acquisition of and deposits on fixed assets	**(118,706)**	(480,585)	(1,452,601)
Net cash used in investing activities	**(668,706)**	(1,030,585)	(1,452,601)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from option and warrant exercises	**57,575**	-	237,163
Proceeds from credit line	**-**	700,000	-
Repayment of credit line	**-**	(700,000)	-
Proceeds from sale of common stock, net	**12,493,398**	-	-
Net cash provided by financing activities	**12,550,973**	-	237,163
(DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	**5,177,533**	762,393	(5,035,737)
Cash and cash equivalents - beginning of the period	**5,376,931**	4,614,538	9,650,275
Cash and cash equivalents - end of the period	**$ 10,554,464**	$ 5,376,931	$ 4,614,538
RECONCILIATION OF NET LOSS TO NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES:			
Net Loss	**$ (13,347,047)**	$ (2,397,042)	$ (1,137,203)
Adjustments:			
Depreciation and amortization	**1,139,228**	1,372,563	739,297
Provision for (benefit from) deferred taxes	**5,800,818**	(1,170,969)	(403,375)
Provision for (recovery of) doubtful accounts	**-**	-	28,000
Share based compensation	**304,154**	334,386	447,100
Changes in assets and liabilities:			
Accounts receivable	**(960,758)**	5,915,918	(3,774,768)
Inventories	**242,837**	60,274	(449,573)
Prepaid expenses and other current assets	**(136,258)**	(190,960)	32,906
Deposits and other assets	**1,480**	-	(279,223)
Accounts payable and accrued liabilities	**211,701**	(2,144,598)	636,540
Customer deposits and deferred revenue	**39,111**	13,406	340,000
Net cash provided by (used in) operating activities	**$ (6,704,734)**	$ 1,792,978	$ (3,820,299)
Supplemental disclosures for non-cash investing and financing activities:			
Deposits on manufacturing equipment transferred to fixed assets	**$ -**	$ 20,017	$ 603,627

See accompanying notes to condensed consolidated financial statements

NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. and its subsidiary, Chembio Diagnostic Systems, Inc. (collectively, the "Company" or "Chembio"), develop, manufacture, and market rapid diagnostic tests that detect infectious diseases. The Company's main lateral flow products are three rapid tests for the detection of HIV antibodies in whole blood, serum and plasma samples, two of which were approved by the FDA in 2006; the third is sold for export only. Lateral Flow Rapid HIV tests represented nearly 58% of the Company's product revenues in 2016. The Company's products based on its patented DPP® platform represented approximately 40% of the Company's product revenues in 2016. The Company also has other rapid tests that together represented approximately 2% of sales in 2016. The Company's products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments both domestically and internationally. Chembio's products are sold under the Company's STAT-PAK®, SURE CHECK®, STAT VIEW® or DPP® registered trademarks, or under the private labels of its marketing partners. All of the Company's products that are currently being developed are based on its patented Dual Path Platform (DPP®), which is a unique diagnostic point-of-care platform that has certain advantages over lateral flow technology. In December 2012, the Company received FDA approval for its DPP® HIV 1/2 Assay for the detection of HIV antibodies in saliva, whole blood, serum and plasma samples, which was CLIA-Waived in October 2014.

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES:

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

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

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

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

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

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

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

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

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

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of temporary cash investments and trade receivables. The Company places its temporary cash instruments with well-known financial institutions and, at times, may maintain balances in excess of the FDIC insurance limit. The Company monitors the credit ratings of the financial institutions to mitigate this risk. Concentration of credit risk with respect to trade receivables is principally mitigated by the Company's ability to obtain letters of credit from certain foreign customers, and its diverse customer base both in number of customers and geographic locations.

(f) ***Inventories:***

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

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

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

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

In February 2008, the Company entered into a sublicense agreement for which it had initially recorded an asset of $1,000,000. This asset is being expensed over an estimated economic life of ten years, based on the expected lifespan of our then current HIV products. The current portion of this asset is $100,000 as of December 31, 2016 and 2015 and is reported in prepaid expenses and other current assets. The long-term portion as of December 31, 2016 and 2015 is $- and $100,000, respectively and is reflected in other assets on the consolidated balance sheet.

In January 2015, the Company entered into a sublicense agreement for which it had initially recorded an asset of $400,000. This asset is being expensed over the life of the patent of 22 months. The current portion of this asset is $- and $181,818 as of December 31, 2016 and 2015, respectively and is reported in prepaid expenses. The long-term portion as of December 31, 2016 and 2015 is $- and $-, respectively and is reflected in other assets on the consolidated balance sheet.

In August 2015, the Company entered into a sublicense agreement for which it had initially recorded an asset of $100,000. This asset is being validated and will be expensed over the estimated economic life of the product(s) which will utilize this sublicense. The current portion of this asset is $100,000 as of December 31, 2016 and 2015 and is reported in prepaid expenses and other current assets. The long-term portion of this asset is $- as of December 31, 2016 and 2015.

Amortization expenses for the licenses above for the years ended December 31, 2016, 2015 and 2014 were $357,000, $479,000 and $122,000.

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

Long-lived assets to be held and used are analyzed for impairment whenever events or changes in circumstances indicate that the related carrying amounts may not be recoverable. The Company evaluates at each balance sheet date whether events and circumstances have occurred that indicate possible impairment. If there are indications of impairment, the Company uses future undiscounted cash flows of the related asset or asset grouping over the remaining life in measuring whether the assets are recoverable. In the event such cash flows are not expected to be sufficient to recover the recorded asset values, the assets are written down to their estimated fair value. We believe that the carrying values of our long-lived tangible and intangible assets were realizable at December 31, 2016 and 2015, respectively.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

	For the years ended		
	December 31, 2016	December 31, 2015	December 31, 2014
Basic	**10,622,331**	9,626,028	9,530,320
Diluted	**10,622,331**	9,626,028	9,530,320

Basic loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted loss per share for the year ended December 31, 2016, 2015 and 2014 reflects the potential dilution from the exercise or conversion of other securities into common stock, if dilutive.

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

	For the years ended		
	December 31, 2016	December 31, 2015	December 31, 2014
1999, 2008 and 2014 Plan Stock Options	**-**	-	-

There were 600,549, 658,631 and 798,475 options and warrants outstanding as of December 31, 2016, 2015 and 2014, respectively, which were not included in the calculation of diluted income per share for the years ended because their effect would have been anti-dilutive.

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

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

The standard is effective for annual periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients; or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our consolidated financial statements and have not yet determined the method by which we will adopt the standard in 2018. The Company has conducted a preliminary analysis of its sales contracts which are based on the shipment of goods to the customer, and currently this new accounting standard will not have a material impact on its consolidated financial statement for our sales contracts. The Company has conducted a preliminary analysis of its current R&D contracts which are currently based on "as expenses are incurred" basis, and currently this new accounting standard will not have a material impact on its consolidated financial statement for our current R&D contracts.

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

In February 2016, the FASB issued Accounting Standards Update ("ASU") 2016-02, which amends the ASC and creates Topic 842, Leases. Topic 842 will require lessees to recognize lease assets and lease liabilities for those leases classified as operating leases under previous US GAAP on the balance sheet. This guidance is effective for annual periods beginning after December 15, 2018 and early adoption is permitted. We are in the initial stages of evaluating the effect of the standard on our financial statements and will continue to evaluate. While not yet in a position to assess the full impact of the application of the new standard, the Company expects that the impact of recording the lease liabilities and the corresponding right-to-use assets will have a significant impact on its total assets and liabilities with a minimal impact on equity.

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-09, Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, which will change certain aspects of accounting for share-based payments to employees. ASU 2016-09 is effective for fiscal years (and interim reporting periods within those years) beginning after December 15, 2016. The Company is currently in the initial stages of evaluating the impact of the provisions of ASU 2016-09. We are still evaluating this standard and currently the Company does not believe this new accounting standard will have a material impact on its consolidated financial statement.

NOTE 3 — INVENTORIES:

Inventories consist of the following at:

	December 31, 2016	December 31, 2015
Raw materials	**$ 1,824,248**	$ 2,248,371
Work in process	**535,320**	370,340
Finished goods	**975,620**	959,314
	$ 3,335,188	$ 3,578,025

NOTE 4 — FIXED ASSETS:

Fixed assets consist of the following at:

	December 31, 2016	December 31, 2015
Machinery and equipment	**$ 3,962,051**	$ 3,862,698
Furniture and fixtures	**437,962**	436,588
Computer and telephone equipment	**343,167**	326,170
Leasehold improvements	**2,012,945**	2,012,945
	6,756,125	6,638,401
Less accumulated depreciation and amortization	**(5,046,804)**	(4,264,093)
	$ 1,709,321	$ 2,374,308

There were no capital leases at the end of December 31, 2016. Fixed assets at December 31, 2016 also include $199,921 in equipment, which has been delivered and set-up but is undergoing validation and as such is currently not being depreciated. Depreciation expense for the 2016, 2015 and 2014 years aggregated $782,711, $893,305 and $616,943, respectively.

As of December 31, 2016 and 2015, the Company had paid deposits on various pieces of equipment aggregating $31,900 and $30,918, respectively.

NOTE 5 — ACCOUNTS PAYABLE AND ACCRUED LIABILITIES:

Accounts payable and accrued liabilities consist of the following at:

	December 31, 2016	December 31, 2015
Accounts payable – suppliers	**$ 1,437,290**	$ 1,260,520
Accrued commissions	**221,982**	129,192
Accrued royalties / license fees	**352,660**	732,301
Accrued payroll	**167,575**	146,962
Accrued vacation	**289,587**	244,810
Accrued bonuses	**282,500**	177,700
Accrued expenses – other	**261,539**	109,947
TOTAL	**$ 3,013,133**	$ 2,801,432

NOTE 6 — DEFERRED RESEARCH AND DEVELOPMENT REVENUE:

The Company recognizes income from R&D milestones when those milestones are reached and non-milestone contracts and grants when earned. Grants are invoiced after expenses are incurred. Any projects or grants funded in advance are deferred until earned. As of December 31, 2016 and 2015, there were $392,517 and $353,406 unearned advanced revenues, respectively.

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

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

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

The Company currently maintains its operating, payroll, and primary cash accounts at HSBC.

NOTE 8 — INCOME TAXES:

The (benefit from) provision for income taxes for the years ended December 31, 2016 and 2015, is comprised of the following:

	2016	2015	2014
Current			
Federal	**$ -**	$ -	$ (16,119)
State	**-**	10,726	6,576
Total current (benefit) provision	**-**	10,726	(9,543)
Deferred			
Federal	**5,778,185**	(1,171,865)	(449,452)
State	**22,633**	896	46,077
Total deferred (benefit) provision	**5,800,818**	(1,170,969)	(403,375)
Total (benefit) provision	**$ 5,800,818**	$ (1,160,243)	(412,918)

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

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

After applying the above limitations, at December 31, 2016, the Company has post-change net operating loss carry-forwards of approximately $21,960,362 which expire between 2020 and 2036. In addition the Company has research and development tax credit carryforwards of approximately $1,461,351 for the year ended December 31, 2016, which expire between 2025 and 2036.

	2016	2015
Current assets		
Inventory reserves	**$ 253,380**	$ 242,532
Accrued expenses	**53,140**	91,143
Current deferred tax assets	**306,520**	333,675
Less valuation allowances	**(306,520)**	-
Net current deferred asset	**$ -**	$ 333,675
Noncurrent assets		
Net operating loss carry-forwards	**$ 7,487,937**	$ 5,365,401
Research and development credit	**1,461,351**	1,518,414
Other credits	**97,339**	97,339
Depreciation	**31,285**	(206,150)
Other	**292,556**	210,553
Noncurrent deferred tax assets	**9,370,468**	6,985,557
Less valuation allowances	**(9,370,468)**	(1,518,414)
Net noncurrent deferred tax assets	**$ -**	$ 5,467,143

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

	Year Ending December 31,		
	2016	2015	2014
Federal income tax at statutory rates	**(34.00)%**	(34.00)%	(34.00)%
State income taxes, net of federal benefit	**.21%**	0.23%	0.28%
Nondeductible expenses	**.57%**	1.38%	4.54%
Change in valuation allowance	**114.81%**	9.46%	9.47%
Tax credits	**.00%**	(9.46)%	(9.47)%
Change in tax rates	**.00%**	0.00%	1.96%
Other	**.04%**	0.34%	0.58%
Income tax (benefit)	**81.63%**	(32.05)%	(26.64)%

Interest and penalties, if any, related to income tax liabilities are included in income tax expense. As of December 31, 2016, the Company does not have a liability for uncertain tax positions.

The Company files Federal and state income tax returns. Tax years for fiscal 2013 through 2015 are open and potentially subject to examination by the federal and state taxing authorities.

NOTE 9 — STOCKHOLDERS' EQUITY:

(a) ***Common Stock***

In August of 2016, the Company closed on an underwritten public offering of 2,300,000 shares of its common stock at $6.00 per share. The net proceeds of the offering, after deducting the underwriters' discounts and other offering expenses payable by the Company, was approximately $12,493,000. The Company intends to use the net proceeds for business expansion and working capital.

During 2016, options to purchase 191,804 shares of the Company's common stock were exercised on a cashless basis into 98,599 shares of common stock at exercise prices ranging from $2.80 to $5.56 by surrendering options and shares of common stock already owned.

During 2015, options to purchase 41,141 shares of the Company's common stock were exercised, either for cash or cashless, into 17,109 shares of common stock at exercise prices ranging from $2.16 to $3.60 by paying cash or surrendering options already owned.

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

(b) ***Preferred Stock***

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

(c) Options

During the fourth quarter of 2016, the Company issued options to purchase 36,000 shares of common stock to a newly-hired president of the EMEA and APAC regions. The options are exercisable in three equal annual installments starting on the first anniversary of the date of issue. The options issued have an exercise price of $7.15 per share, which was the last traded price of the common stock on the day issued. The options expire five years from date of issue.

During the second quarter of 2016 the Company issued options to purchase 46,875 shares of common stock to one of its directors pursuant to the Company's compensation policy for directors. The options become exercisable in five equal annual installments starting on the date of issue. The options issued have an exercise price of $8.860 per share, which was the last traded price of the common stock on the day issued. The options expire five years from date of issue.

The Company entered into an employment agreement, effective as of March 5, 2016 (the "Employment Agreement"), with Javan Esfandiari to serve as the Company's Chief Scientific and Technical Officer, for an additional term of three years through March 5, 2019. Pursuant to the Employment Agreement, the Company issued to Mr. Esfandiari incentive and non-qualified stock options to purchase 60,000 shares of the Company's common stock. Of these stock options, options to purchase 20,000 shares vest on each of the first three anniversaries of March 11, 2016 which is the date on which the Employment Agreement was entered into. The exercise price for these options was to be equal to the trading price for the Company's common stock on March 11, 2016, which was $5.64 per share. Each option granted will expire and terminate, if not exercised sooner, upon the earlier to occur of (a) 30 days after termination of Mr. Esfandiari's employment with the Company or (b) the fifth anniversary of the effective date of the grant.

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

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

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

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

(d) ***Warrants***

As of December 31, 2016 and 2015, the Company had no warrants outstanding to purchase shares of common stock.

NOTE 10 — RIGHTS AGREEMENT:

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

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

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

NOTE 11 — EMPLOYEE STOCK OPTION PLAN:

Effective June 3, 2008, the Company's stockholders voted to approve the 2008 Stock Incentive Plan ("SIP"), with 625,000 shares of Common Stock available to be issued. At the Annual Stockholder meeting on September 22, 2011 the Company's stockholders voted to approve an increase to the shares of Common Stock issuable under the SIP by 125,000 to 750,000. Under the terms of the SIP, the Compensation Committee of the Company's Board has the discretion to select the persons to whom awards are to be granted. Awards can be stock options, restricted stock and/or restricted stock units. The awards become vested at such times and under such conditions as determined by the Compensation Committee. As of December 31, 2016, there were 467,685 options exercised, 275,931 options outstanding and 6,384 options still available to be issued under the SIP.

Effective June 19, 2014, the Company's stockholders voted to approve the 2014 Stock Incentive Plan ("SIP14"), with 800,000 shares of Common Stock available to be issued. Under the terms of the SIP14, the Compensation Committee of the Company's Board has the discretion to select the persons to whom awards are to be granted. Awards can be stock options, restricted stock and/or restricted stock units. The awards become vested at such times and under such conditions as determined by the Compensation Committee. As of December 31, 2016, there were 12,000 options exercised, 117,750 options outstanding and 670,250 options still available to be issued under the SIP14.

The Company's results for the years ended December 31, 2016, 2015 and 2014 include stock-based compensation expense totaling $304,100, $334,400, and $447,100 respectively. Such amounts have been included in the Consolidated Statements of Operations within cost of goods sold ($-, $-, and $700 respectively), research and development ($89,200, $62,700, and $44,500 respectively) and selling, general and administrative expenses ($214,900, $271,700, and $401,900 respectively). In accordance with ASC 718 the Company has not recorded a deferred tax asset related to the net operating losses resulting from the exercise of disqualifying stock options in the accompanying financial statements.

Stock option compensation expense in the years ended December 31, 2016, 2015 and 2014 represents the estimated fair value of options outstanding which is being amortized on a straight-line basis over the requisite vesting period of the entire award.

The weighted average estimated fair value of stock options granted in the year ended December 31, 2016 was $2.75 per share. The Company did not grant any stock options during the year ended December 31, 2015 . The weighted average estimated fair value of stock options granted in the year ended December 31, 2014 was $3.52 per share. The fair value of options at the date of grant was estimated using the Black-Scholes option pricing model. The expected volatility is based upon historical volatility of our stock and other contributing factors. The expected term is based on the Company's historical experience with similar type options.

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

For the year ended	December 31, 2016	December 31, 2015	December 31, 2014
Expected term (in years)	4.71	n/a	4.50-6.30
Expected volatility	45.78 %	n/a	61.50-96.10%
Expected dividend yield	n/a	n/a	n/a
Risk-free interest rate	0.92 %	n/a	.83-1.52%

The Company granted 142,875 new options during the year ended December 31, 2016 to employees and directors.

The following table provides stock options activity for the year ended December 31, 2016:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2013	**656,398**	**2.57**	**1.65 years**	**$ 801,888**
Granted	379,750	**3.52**		
Exercised	318,750	**1.04**		**341,729**
Forfeited/expired/cancelled	25,529	**3.17**		
Outstanding at December 31, 2014	**691,869**	**3.66**	**3.97 years**	**$ 334,636**
Exercisable at December 31, 2014	**265,619**	**3.67**	**1.94 years**	**$ 158,149**
Outstanding at December 31, 2014	**691,869**	**3.66**	**3.97 years**	**$ 334,636**
Granted	-	-		
Exercised	41,141	**2.25**		**65,449**
Forfeited/expired/cancelled	1,250	**4.30**		
Outstanding at December 31, 2015	**649,478**	**3.75**	**3.21 years**	**$ 1,032,362**
Exercisable at December 31, 2015	**359,228**	**3.89**	**2.03 years**	**$ 522,039**
Outstanding at December 31, 2015	**649,478**	**$ 3.75**	**3.21 years**	**$ 1,032,362**
Granted	142,875	$ 7.08		
Exercised	191,804	$ 3.73		**629,143**
Forfeited/expired/cancelled	-	$ -		
Outstanding at December 31, 2016	**600,549**	**$ 4.55**	**3.43 years**	**$ 1,463,052**
Exercisable at December 31, 2016	**267,549**	**$ 4.14**	**2.66 years**	**$ 731,997**

The following table summarizes information about stock options outstanding at December 31, 2016:

	Stock Options Outstanding				**Stock Options Exercisable**		
Range of Exercise Prices	**Shares**	**Average Remaining Contract Life (Year)**	**Weighted Average Exercise Price**	**Aggregate Intrinsic Value**	**Shares**	**Weighted Average Exercise Price**	**Aggregate Intrinsic Value**
1 to 2.79999	-	-	$ -	$ -	-	$ -	$ -
2.8 to 4.59999	419,719	3.30	3.60	1,342,788	220,219	3.71	681,333
4.6 to 6.39999	97,955	3.02	5.57	120,264	37,955	5.47	50,664
6.4 to 8.19999	36,000	4.78	7.15	-	-	-	-
8.2 to 10	46,875	4.44	8.86	-	9,375	8.86	-
Total	600,549	3.43	$ 4.55	$ 1,463,052	267,549	$ 4.14	$ 731,997

As of December 31, 2016, there was $386,000 of net unrecognized compensation cost related to stock options that are not vested, which is expected to be recognized over a weighted average period of approximately 2.32 years. The total fair value of shares vested during the year ended December 31, 2016, was $262,000.

NOTE 12 — GEOGRAPHIC INFORMATION AND ECONOMIC DEPENDENCY:

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

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

	For the years ended		
	December 31, 2016	December 31, 2015	December 31, 2014
Africa	**$ 2,363,944**	$ 3,673,199	$ 2,097,353
Asia	**227,564**	172,250	96,061
Europe	**1,131,193**	1,164,476	191,947
North America	**5,082,319**	6,525,951	11,134,691
South America	**4,875,087**	10,350,812	12,429,717
	$ 13,680,107	$ 21,886,688	$ 25,949,769

Sales to Africa decreased in 2016 primarily due to decreased sales in Uganda by approximately $1,122,400, and Nigeria by approximately $220,900. Sales in Asia increased slightly by $55,300. European sales decreased by $68,600. Sales decreased in 2016 to North America from decreased sales in the U.S by approximately $1,579,800 and partially offset by increased sales to Mexico of $123,200. Sales decreased in 2016 to South America were primarily from decreased sales in Brazil of approximately $5,340,250.

Sales to Africa increased in 2015 primarily due to increased sales in Uganda by approximately $1,344,500, and Nigeria by approximately $287,500. Sales in Asia increased slightly by $76,200. European sales increased by $972,500. Sales decreased in 2015 to North America from decreased sales to Mexico of $3,913,400 and by decreased sales in the U.S by approximately $1,545,000. Sales decreased in 2015 to South America were primarily from decreased sales in Brazil of approximately $2,111,700.

NOTE 13 — COMMITMENTS AND CONTINGENCIES:

Employment Contracts:

The Company has contracts with three key employees. The contracts call for salaries presently aggregating $975,000 per year. One contract expires in May 2017, one expires in March 2019 and one contract expires in March 2017. The following table is a schedule of future minimum salary commitments:

2017	$ 516,200
2018	335,000
2019	55,800

Pension Plan:

The Company has a 401(k) plan established for its employees. Effective January 1, 2011 the Company elected to match 40% of the first 5% (or 2% of salary) that an employee contributes to their 401(k) plan. Expenses related to this matching contribution aggregated $96,051, $90,915 and $82,750 for the years ended December 31, 2016, 2015, and 2014 respectively.

Obligations Under Operating Leases:

The Company leases industrial space used for office, R&D and manufacturing facilities, currently with a monthly rent of $28,688. The current lease expires on April 30, 2017. The lease provides for annual increases of 2.50% percent each year starting May 1, 2016. In February of 2014, the Company entered into a lease, effective March 1, 2014, for another facility located a short distance from its current facility currently with a monthly rent of $15,550. The space is used primarily for warehousing and provides for additional office space. The lease expires on April 30, 2018. The lease provides for annual increases of 3.00% percent each year starting March 1, 2016.

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

Years ending December 31,

2017	$ 306,018
2018	64,067
2019	-
	$ 370,085

Rent expense was $516,708, $511,900 and $476,000 for the years ended December 31, 2016, 2015, and 2014 respectively.

Economic Dependency:

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

	For the years ended						Accounts Receivable	
	December 31, 2016		December 31, 2015		December 31, 2014		December 31, 2016	December 31, 2015
	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales		
Customer 1	$ 4,801,577	35%	$ 10,132,512	46%	$ 12,253,526	47%	$ 828,848	$ 775,209
Customer 2	1,796,477	13%	4,526,908	21%	6,618,251	26%	-	700,656

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

	For the years ended						Accounts Payable	
	December 31, 2016		December 31, 2015		December 31, 2014		December 31, 2016	December 31, 2015
	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.		
Vendor 1	$ 652,273	11%	$ *	*	$ *	*	$ 26,984	$ *
Vendor 2	*	*	794,536	11%	1,331,647	14%	*	90,075

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

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

NOTE 14 — COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENTS:

In 2016, 2015, and 2014 the Company earned $3.7 million, $2.3 million, and $1.7 million, respectively, from research revenues and milestones. The Company is now involved in additional feasibility and development contracts related to its DPP® technology. The total expended on R&D, excluding regulatory, in 2016, 2015, and 2014, was approximately $6.9 million, $5.4 million, and $4.1 million, respectively.

a. RVR DPP® technology transfer agreement:

In February 2014, the Company entered into a technology transfer agreement with RVR Diagnostics for $1,500,000. The agreement was modified in September 2014 and September 2015. Per the agreement, as modified, the Company earned $-, $125,000 and $1,125,000 in milestone payments during 2016, 2015 and 2014. The Company has earned $1,250,000 from this grant from inception through December 31, 2016. See subsequent event note describing the Company's acquistion of RVR Diagnostics in January 2017.

b. Dengue agreement:

In October 2014, the Company entered into a development agreement with an international diagnostics company for $300,000. Revenue for this agreement is being recognized under a proportional performance method. For the years ended December 31, 2016, 2015 and 2014, the Company earned $-, $240,000 and $60,000, respectively from this grant. The Company has earned $300,000 from this grant from inception through December 31, 2016.

c. Brain Injury agreement:

In January 2015, the Company entered into a technology development agreement with Perseus Science Group LLC for $946,000 and a follow-on agreement in December 2016 for $350,000. Revenue for this agreement is being recognized under a proportional performance method. The Company earned $297,000 and $469,600 for the year ended December 31, 2016 and 2015, respectively from this agreement. The Company has earned $766,600 from this grant from inception through December 31, 2016.

d. Malaria agreement:

In January 2015, the Company was awarded a grant from The Bill & Melinda Gates Foundation for $307,000. Revenue for this agreement is being recognized under a proportional performance method. The Company earned $- and $307,000 for the year ended December 31, 2016 and 2015, respectively from this agreement. The Company has earned $307,000 from this grant from inception through December 31, 2016.

In April 2016, the Company was awarded a grant from the Bill & Melinda Gates Foundation for $677,944. The Company earned $518,761 for the year ended December 31, 2016 from this agreement, which is the total amount earned from this grant from inception through December 31, 2016.

e. Cancer agreement:

In October 2014, the Company entered into a technology development agreement with an international diagnostics company for $320,000. Revenue for this agreement is being recognized under a proportional performance method. For the years ended December 31, 2016, 2015 and 2014, the Company earned $65,000, $205,000 and $-, respectively from this grant. The Company has earned $270,000 from this grant from inception through December 31, 2016.

f. Fever panel agreement:

In October 2015, the Company entered into an agreement with Paul G. Allen Ebola Program for $2,118,265 and a follow-on agreement in February 2016 for $550,000. Revenue for this agreement is being recognized under a proportional performance method. The Company earned $2,259,800 and $408,500 for the year ended December 31, 2016 and 2015, respectively from this agreement. The Company has earned $2,668,265 from this grant from inception through December 31, 2016.

g. BARDA Zika agreement:

In August 2016, the Company was awarded a grant for $5,933,742 from BARDA, which is part of the U.S. Department of Health And Human Resources. The Company earned $472,700 for the year ended December 31, 2016 from this agreement. The Company earned $472,700 from this grant from inception through December 31, 2016.

h. USDA Bovid:

In September 2016, the Company entered into an agreement with the USDA for $669,423 to develop a Bovid TB assay. Revenue for this agreement is being recognized under a proportional performance method. The Company earned $121,500 for the year ended December 31, 2016 from this agreement.

Governmental Regulation:

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

NOTE 15 — QUARTERLY FINANCIAL DATA (UNAUDITED)

The sum of the earnings per common share may not equal the corresponding annual amounts due to interim quarter rounding.

For the Quarters Ended in Fiscal 2016	March 31	June 30	September 30	December 31
Total revenues	$ 6,601,099	$ 3,266,405	$ 3,746,461	$ 4,254,876
Gross profit	3,165,548	1,580,305	1,952,097	1,753,386
Net loss	(303,590)	(8,347,482)	(2,138,218)	(2,557,757)
Basic loss per share	(0.03)	(0.86)	(0.19)	(0.21)
Diluted loss per share	(0.03)	(0.86)	(0.19)	(0.21)

For the Quarters Ended in Fiscal 2015	March 31	June 30	September 30	December 31
Total revenues	$ 6,231,137	$ 6,716,158	$ 6,887,374	$ 4,420,816
Gross profit	2,686,618	3,019,132	2,910,534	1,870,543
Net loss	(646,817)	(664,085)	(437,157)	(648,984)
Basic loss per share	(0.07)	(0.07)	(0.05)	(0.07)
Diluted loss per share	(0.07)	(0.07)	(0.05)	(0.07)

NOTE 16 — SUBSEQUENT EVENTS:

On January 9, 2017, the Company, completed the acquisition of RVR Diagnostics Sdn Bhd, a Malaysia corporation ("RVR"), pursuant to the previously reported Amended And Restated Stock Purchase Agreement, dated as of December 7, 2016 (the "Stock Purchase Agreement"), by and among the Company, RVR, Avijit Roy and Magentiren Vajuram (Messrs. Roy and Vajuram, the "Sellers").

Pursuant to the Stock Purchase Agreement, the Company acquired all of the issued and outstanding common stock and other equity interests of RVR from the Sellers for (i) a cash payment of $1,400,000 and (ii) 269,236 shares of the Company's common stock, of which 7,277 shares are being held back to satisfy certain potential claims under the Stock Purchase Agreement and will become issuable to the Sellers, if at all, on the one-year anniversary of the closing.

In addition, the Stock Purchase Agreement provides that the Sellers may become entitled to receive certain milestone payments based on the achievement of performance goals related to sales by RVR during the 12 months ending December 31, 2017. Based on the actual sales achieved by RVR, the Sellers will be entitled to receive (i) a cash milestone payment equal to $100,000 multiplied by the Milestone Proration Amount, for a maximum cash milestone payment of $100,000, and (ii) a stock milestone payment equal to 21,830 shares of the Company's common stock multiplied by the Milestone Proration Amount, with a maximum stock milestone payment of 21,830 shares of the Company's common stock.

In connection with the closing of the transaction under the Stock Purchase Agreement, each of the Sellers entered into an employment agreement with RVR, pursuant to which, among other things, each of the Sellers agreed to serve as an employee of RVR for the one-year period following the closing in exchange for a monthly base salary of $10,000. In addition, at the closing, John J. Sperzel III, the Company's President, Chief Executive Officer and a member of the Company's board of directors, Richard J. Larkin, the Company's Chief Financial Officer and Executive Vice President, and Katherine L. Davis, the Company's Chairman of the Board and a member of the Company's board of directors, were appointed as the directors of RVR, with each of the Sellers continuing as the other two directors of RVR.

Schedule II
Valuation and Qualifying Accounts

Description	Balance at beginning of period	Additions		Deductions	Balance at end of period
		Charged to statement of income	Charged to other accounts		
Year ended December 31, 2016					
Allowance for doubtful accounts	$ 52,000	$ -	$ -	$ -	$ 52,000
Inventory Reserve	$ 218,000	$ 221,478	$ -	$ 194,478	$ 245,000
Year ended December 31, 2015					
Allowance for doubtful accounts	$ 52,000	$ -	$ -	$ -	$ 52,000
Inventory Reserve	$ 218,000	$ 256,302	$ -	$ 256,302	$ 218,000
Year ended December 31, 2014					
Allowance for doubtful accounts	$ 52,000	$ -	$ -	$ -	$ 52,000
Inventory Reserve	$ 218,000	$ 274,506	$ -	$ 274,506	$ 218,000