CHEMBIO DIAGNOSTICS, INC.

FORM 10-K
(Annual Report)

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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, 2013

or

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

Commission File No. 0-30379

CHEMBIO DIAGNOSTICS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

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

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

Accelerated filer [ ]
Smaller reporting company [X]

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

As of the last business day of the Company's most recently completed second fiscal quarter, the aggregate market value of voting and non-voting common equity held by non-affiliates* was $38,000,000.

As of March 4, 2014, the registrant had 9,324,783 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.

TABLE OF CONTENTS

PART I

ITEM 1. BUSINESS

FORWARD-LOOKING STATEMENTS

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

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

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

Our Business

General

The Company (Chembio Diagnostics, Inc. and its wholly-owned subsidiary, Chembio Diagnostic Systems, Inc., are collectively referred to herein as the "Company") develops, manufactures, markets and licenses rapid point-of-care diagnostic tests (POCTs) that detect infectious diseases. The Company's main products presently commercially available are four rapid tests for the detection of HIV 1/2 antibodies, two rapid tests for the detection of syphilis antibodies, and a multiplex rapid test for the detection of HIV and Syphilis antibodies. Three of 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 and are exclusively distributed by Alere, Inc. ("Alere") in the United States and by Chembio outside the United States. As discussed below (see Partners Involved in Marketing Our Products), we are considering changes to our exclusive agreements with Alere based on Alere's introduction of a competitive product, which introduction has triggered provisions in those agreements, permitting us to make certain changes. Our fourth 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 on December 19, 2012. We anticipate launching it in the United States under Chembio's brand in 2014.

Our product pipeline, which currently includes a multiplex rapid test for earlier detection of HIV by detecting P-24 antigen as well as antibodies, a test for Hepatitis-C, and a multiplex test that detects HIV and Syphilis specific antibodies (which we are already selling internationally), is based on this DPP® technology for which we were issued a United States patent in 2007 and for which additional patent protection has issued or is pending in a number of other countries. With the patented DPP® and the lateral flow platform, we participate in the estimated $8-10 billion point-of-care market segment of the estimated nearly $50 billion global in-vitro diagnostic market that has an overall growth rate exceeding 5% per annum. POCTs, by providing prompt and early diagnosis, can reduce patient stays, lower overall costs, improve therapeutic interventions and improve patient outcomes. POCTs can also prevent needless hospital admissions, simplify testing procedures, avoid delays from central lab batching, and eliminate the need for return visits.

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

PRODUCTS

Lateral Flow Rapid HIV Tests

All three of our lateral flow rapid HIV antibody detection tests are qualitative "yes/no" tests for the detection of antibodies to HIV 1 & 2 with visually interpreted results (one line "negative"; two lines "positive") available within approximately 15 minutes. The tests are simple to use, have a shelf life of 24 months, and do not require refrigeration. The tests differ principally only in the method of test procedure, convenience and cost. One of our FDA-approved lateral flow HIV tests incorporates a proprietary plastic "barrel" device that houses the lateral flow strip. This barrel format enables collection of samples directly (usually from a finger-stick whole blood sample) into the barrel's capillary tip. A sealed unitized buffer vial, assembled onto the top of the barrel, is removed and seated into a stand; the seal is then pierced by the barrel's capillary tip, thereby initiating the upward flow of the resulting sample-buffer solution through a filter, up into the vertical device's chamber and onto the lateral flow strip. This results in a unique unitized and closed device system that can reduce the chance of exposure to potentially infectious samples. Our other FDA-approved lateral flow HIV test uses a more conventional rectangular plastic cassette format that houses the lateral flow strip. In this case, a sample is transferred by use of a separately provided transfer device ("loop") into a sample well or port of the cassette that houses the lateral flow strip, which is positioned horizontally or flat.

Both of the above-described products are marketed exclusively in the United States by Alere (see Partners Involved in Marketing Our Products) as Clearview® Complete HIV 1/2 (the barrel format as governed by the Barrel Agreement) and Clearview® HIV 1/2 STAT PAK® (the cassette format as governed by the Cassette Agreement), and in all other markets by Chembio under the names Chembio SURE CHECK® HIV 1/2 and Chembio HIV 1/2 STAT PAK®. Alere has non-exclusive rights to the barrel product outside the United States. In addition to the above-referenced agreements for Alere to market our products, Alere also licensed their lateral flow technology patents to Chembio for our international rapid HIV test sales and certain other Chembio lateral flow product sales. Also this license would extend to sales by Chembio of the cassette and barrel products in the United States should we decide to exercise certain rights now exercisable by us based on Alere's notice to us of their having a Permitted Competing Product (see Partners Involved in Marketing Our Products).

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

Regulatory Status of the lateral flow HIV tests

The FDA approved our Pre-Market Applications (hereinafter "PMA"; see "Governmental Regulations" and Glossary) in April 2006 for our SURE CHECK HIV 1/2 (and also now Alere Clearview® Complete HIV 1/2) and for our HIV 1/2 STAT-PAK® (now Alere' Clearview® HIV 1/2 STAT-PAK® in the United States only) 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® product received a CE Mark in July 2013 and the CE Markings for the HIV 1/2 STAT-PAK® (as well as the DPP® HIV 1/2 Assay described below) are expected in 2014. 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"). Both the cassette and dipstick versions of the STAT-PAK® are also 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 24 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: Due to the low HIV prevalence in the U.S., clinical trials are performed on known HIV-positive patients, and more and more of these individuals are on more highly active anti-retroviral treatments (known as "HAART") for much longer periods than when we and our competitors Orasure and Trinity performed their clinical trials ten to fifteen years ago. We believe that this fact, combined with our product's superior performance in a direct comparative evaluation that was conducted by the United States CDC Global AIDS Program, together with analytical studies that confirm earlier detection with our DPP® product than our main competitors on well characterized serum samples, all combine to provide us with a significant market opportunity with this product.

Regulatory Status of the DPP® HIV 1/2 Assay

In April 2012 we completed a 3,000 patient clinical study with our DPP® HIV 1/2 Assay in the United States which we had begun in 2010. In June 2012 we submitted the third of three modules required for a modular PMA application to the FDA. On December 19, 2012 we received FDA approval of our Pre-Marketing Approval. During 2013, we completed a 1,000 patient clinical study in order to submit a CLIA waiver application to the FDA, which was submitted at the end of November 2013. In February 2014 we received a letter from the FDA on the current status of review of our CLIA waiver application. The FDA determined that additional information is needed to complete their review of the Company's DPP® HIV 1/2 Assay CLIA waiver application. During the blinded prospective clinical study, a disproportionate number of new infections were found at one clinical site due to the lower than expected prevalence at two other sites. We are currently in discussion with the FDA to finalize the protocol to collect additional data. Upon receiving guidance on our proposed protocol, we anticipate that we will be able to update the timeline of activities for the CLIA waiver of the DPP HIV1/2 Assay.

The DPP® HIV 1/2 Assay product is qualified for procurement under the President's Emergency Plan for AIDS Relief ("PEPFAR") for use with all sample matrices, and we are pursuing WHO qualification in order to enable procurement of this product by the Global Fund and United Nations agencies, including programs underwritten by them. We are also pursuing CE Marking, anticipated during 2014, as stated above.

In June 2010, ANVISA approved the DPP® HIV 1/2 Assay that is being marketed in Brazil through our collaboration with the Oswaldo Cruz Foundation, Brazil's leading public health institute (see Oswaldo Cruz Foundation OEM DPP® Agreements).

DPP® HIV-Syphilis Multiplex Test

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

Regulatory Status of the DPP® HIV-Syphilis Test

The DPP® HIV-Syphilis multiplex test development was completed in 2013, and commercialization activities commenced in 2013 and are moving well as stated above. Also as mentioned above, a unitized version of this product was approved and launched in Mexico during the fourth quarter of 2013, and the product has been well received. In addition, this product is the first such product to have been approved by the USAID for procurement with U.S. foreign aid program funds (such as PEPFAR). We are pursuing pre-qualification of this product with the World Health Organization (WHO) in order to allow procurement through programs such as the Global Fund. Simultaneously we are pursuing registration of this product in a number of foreign jurisdictions where we believe there is an opportunity for this product.

In 2013, and 2014 year to date, we have made significant efforts on pursuing an FDA submission for this product. However, FDA has advised thus far that performance specifications for this product must be substantially equivalent both in comparison to the traditional algorithm and the "reverse" algorithms that are both now in use in the United States for syphilis testing, as well as meet the requirements for HIV sensitivity and specificity. It is possible to that other pathways to receiving FDA approval may be available by limiting the performance claims and/or the settings in which the tests could be used. We are conducting further studies now, and we are in dialog with the FDA and others, to see whether and how we may be able to meet their requirements without making changes to this product, which would result in further delays.

OTHER DPP® PRODUCTS

Our product pipeline includes a multiplex test that detects P24 HIV antigen as well as HIV 1/2 antibodies, and a rapid test for the detection of Hepatitis-C antibodies. These products are still in a development stage and have not been commercialized in any markets. The Company has a robust research and development department that is involved in a number of ongoing collaborations, some of which are sponsored, with public and private organizations. During 2013 we conduct sponsored research and development activities for two programs sponsored by agencies of the United States government; One is for the development of a 9-band influenza immune status test and the other is for a multiplex febrile illness test that could help identify and differentiate, in remote settings, symptoms that could be attributable to a variety of tropical diseases, including malaria, dengue, and the bubonic plague. We have also continued to conduct research and development activities on a serological test for tuberculosis pursuant to a Phase II SBIRR grant from the National Institutes of Health (NIH). All of these projects are based on our patented DPP® technology.

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

In late July 2013, we received notice from Alere that they intend to commercialize their 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 is being pursued and anticipated during 2014), in the United States. Under the Barrel Agreement and the Cassette Agreement such product is considered to be a Permitted Competing Product (PCP). Each of the two aforementioned agreements provides that, in the case of notice of a PCP, Chembio may make certain elections (jointly with SDS in the case of the Barrel Agreement), or elect to continue each agreement without taking any further action. Under the Cassette Agreement, Chembio may, at any time, terminate such agreement, which termination would become effective 60 days after the date notice was made. Under the Barrel Agreement, Chembio and SDS may jointly issue a non-exclusivity notice, which notice shall be effective immediately. In the event that Chembio (and SDS) makes this election with respect to either (or both) of these products, Chembio could sell that respective (or both) product(s) in the United States market under Chembio/SDS brands and in such case, the lateral flow license that Chembio has from Alere for international sales would be expanded to include sales in the United States, which would require the payment of a royalty to Alere at the time of any sales. See *Lateral Flow Technology and Reagent Licenses.*

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

OEM DPP® Products

Oswaldo Cruz Foundation OEM DPP® Agreements

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

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

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

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

- Each agreement states: "the object of this Agreement is for the Transfer of Technology from Chembio to Bio-Manguinhos, the license by Chembio to Bio-Manguinhos [of] the Chembio Patents applied or granted in Brazil or other Mercosur countries for the term of the patents and the transfer of all the technical information related to the DPP technology and the process to obtain the product by the DPP® technology. This Agreement contemplates the scientific and technological co-operation between Chembio and Bio-Manguinhos for such activities so that Bio-Manguinhos will be able to manufacture the Product in Brazil."
- Each agreement provides that Chembio will supply free of charge to Bio-Manguinhos prototypes of the product to demonstrate performance characteristics that are necessary for evaluation by the Brazilian Ministry of Health and for registration with ANVISA. ANVISA is the Agencia Nacional de Vigliancia Sanitaria, or the National Sanitary Vigilance Agency. The number of prototypes ranges from 15,000 to 45,000 in the various agreements.
- Each agreement provides that the prototypes will be utilized both for a performance study that follows a protocol prepared and approved by Bio-Manguinhos and the Brazilian Ministry of Health, and also will be used for studies in Brazil for the registration procedures at ANVISA. Bio-Manguinhos will then apply to ANVISA to register the product. Within 120 days of the registration of the product with ANVISA, Bio-Manguinhos will make an advance technology transfer payment to Chembio (the "Advance Payment"), in an amount specified in that particular agreement. All five of the Advance Payments provided for in the agreements were made in 2010 and 2011.
- At such time, if any, that the product for a particular agreement has been successfully registered with ANVISA, then Bio-Manguinhos has the right to qualify for the full technology transfer for that product by purchasing the amount of the product, and at the price, specified in the agreement.
- Bio-Manguinhos is not required to purchase any amount of any product. For each product, it only needs to purchase that product, in the amount specified in the agreement, only if it desires to be able to complete the technology transfer process in order to manufacture and sell that product on its own. Chembio does not have recourse against Bio-Manguinhos if Bio-Manguinhos does not purchase the qualifying purchase amount of any product. In that case, Chembio can only suspend further phases of the technology transfer, attempt to renegotiate the agreement, and/or retain any amounts previously paid by Bio-Manguinhos. Chembio cannot force Bio-Manguinhos to purchase any amount of any product.

- As a result of the terms of these agreements, Bio-Manguinhos has never been required to, and is not now required to, purchase any amount of any of the products.
- As of December 31, 2013 Bio-Manguinhos had earned the status described below with respect to each of the five products:
    1. With respect to Chembio's DPP® HIV1/2 Screen test, Bio-Manguinhos had qualified to request the technology transfer. It has requested, and has received, the technology transfer information. Bio-Manguinhos purchased $880,175 of this product in 2011, and $4,990,840 in 2012, all of which applied to the qualifying amount to obtain the right to the technology transfer (the "Qualifying Amount") for this product. In 2013, Bio-Manguinhos made $291,235 of purchases that applied to the Qualifying Amount for this product, and $3,320,010 of purchases in excess of the Qualifying Amount.
    2. With respect to Chembio's Canine Leishmania test, Bio-Manguinhos had qualified to request the technology transfer and did so request. Submission of the technology transfer information is in process at this time. Bio-Manguinhos purchased $2,000,817 of this product in 2011 and $99,183 of this product in 2012 that applied to the Qualifying Amount. In addition, Bio-Manguinhos made purchases in excess of the Qualifying Amount equal to $1,314,117 in 2012 and $1,736,700 in 2013.
    3.
        a. With respect to the three variations of Chembio's DPP® Syphilis test, all of which are covered by a single agreement, Bio-Manguinhos had qualified to request the technology transfer with respect to Trep only, and intends to do so in the near future. Bio-Manguinhos purchased $1,194,250 of this product in 2011 and $165,750 of this product in 2012 that applied to the Qualifying Amount. In addition, Bio-Manguinhos made purchases in excess of the Qualifying Amount equal to $2,817,750 in 2012, and equal to an estimated $646,340 in 2013.
        b. With respect to the two variations of Chembio's Screen & Confirm Test, Bio-Manguinhos had not made any purchases in 2011, 2012, or 2013, and therefore had not qualified to request the technology transfer for either of them. In order to qualify, Bio-Manguinhos would need to purchase an additional $2.2 million of one of these tests, and an additional $2.08 million of the other test.
    4. With respect to Chembio's DPP® Confirmatory test, Bio-Manguinhos had not qualified to request the technology transfer. Bio-Manguinhos made purchases of $560,000 of this product in 2011, $819,000 in 2012, and $390,000 in 2013, all of which applied to the Qualifying Amount. In order to qualify for the technology transfer, Bio-Manguinhos would need to purchase an additional $585,000 of this product.
    5. With respect to Chembio's DPP® Leptospirosis test, Bio-Manguinhos had not qualified to request the technology transfer. Bio-Manguinhos made purchases of $135,000 of this product in 2011, and it made -0- purchases in 2012 and $45,000 in 2013. In order to qualify for the technology transfer, Bio-Manguinhos would need to purchase an additional $225,000 of this product.

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

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

Other OEM And License Agreements Related to DPP® Technology

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

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

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

Our strategy with respect to our DPP® technology has evolved as the Company has evolved. Initially, following the issuance of our DPP® patent in the United States in 2007, our strategy was necessarily limited to developing third-party-funded OEM research and development contracts and grants. This strategy enabled us to conserve capital resources, while at the same time acquiring know-how and experience with the platform and developing third-party references and implicit endorsements of the technology. As our capabilities to develop and manufacture DPP® products expanded, and as our financial position has improved, so have our strategic options expanded and improved. Although we have employed and may continue to employ the strategy of seeking OEM development and manufacturing agreements as a way to participate in markets that we cannot and/or choose not to serve with Chembio-branded products, we believe that we can also develop our own branded line of products, and we plan to do this in the public health area. We plan to launch this brand with our DPP® HIV 1/2 Assay in the United States market in 2014, to be followed by the other products in our pipeline in 2015 and beyond.

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 1.2 million individuals in the U.S. are living with HIV, with an estimated 250,000 of these U.S. individuals, or more than 20%, unaware that they are infected. It is transmissions from these 250,000 infected people that are reported to account for 54% of all new infections per year. Part of the reason for this is that even those individuals that do get tested in public health settings will often not return or call back for their test results if their blood samples have to be sent out to and tested in a laboratory and then reported back, a process which can take up to several days to complete. Making more people aware of their HIV status at the point-of-care reduces the number of HIV transmissions.

Rapid HIV testing in the United States has now developed into an estimated 7.5 million test market at an average price of $10, or a total of $75 million. Public health programs, currently funded by grants distributed to states by the CDC, account for an estimated 45% of the market, with hospitals (40%) and doctor's offices (15%) comprising the other estimated market segments. Chembio's lateral flow rapid HIV tests, the cassette and barrel, together represent approximately a 25% share of this market. Orasure Technologies, Inc., which was the first FDA-approved rapid HIV test, has lost nearly half its market share, now estimated to be approximately 55%. Trinity Biotech has an estimated 15% market share and Biolytical Laboratories, Medmira and Bio-Rad share the remaining 5%.

We believe that the US professional HIV rapid test market has the potential to increase to 15-18 million tests over the next several years, which would represent 40-50% of all HIV tests done today in the United States for clinical purposes. Assuming an average price to the manufacturers of $8.00 per test, a total potential U.S. market of nearly $120-$145 million is implied.

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

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

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

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

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

There is also now an over-the-counter market for HIV self-testing in the United States. Orasure Technologies Inc. received FDA approval for an over-the-counter (self-testing) version of its previously professional-market-approved (test performed on an individual by a health care professional) HIV test. The FDA approval was granted in July 2012, and Orasure has been investing heavily in developing this market. Initial results after over a year 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. In any case, Orasure is likely to spend heavily on this for some time, and if it appears that there is an attractive market, we believe we are very well positioned versus any other competitors.

Rapid Syphilis Tests

Recent data indicate that approximately 70,000-100,000 new cases of syphilis are occurring annually in the U.S. Syphilis can be treated with antibiotics, but if untreated, it can cause pelvic inflammatory disease, infertility, ectopic pregnancy and can infect newborns. Treatment cannot be provided without a confirmed diagnosis of an active case of syphilis. Current testing algorithms in the United States require two different laboratory tests (called non-treponemal and treponemal), as neither test alone has the required specificity to rule out certain other conditions (i.e., other infection or past infection), but in combination they can provide reasonably reliable results. However each requires trained personnel in laboratory settings and can take several days to receive results, in order to confirm an active, previously untreated case.

Development of the POC market for syphilis testing is expected to be comparable to the development of the POC market for HIV testing, as there is a significant public health value to being able to provide results at the point-of-care. There are several ways to assess the market opportunity for this unique rapid test, although we believe the U.S. rapid test market opportunity may exceed 8 million tests, which is approximately 20% of the total number of syphilis tests performed in the United States for clinical use today.

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:

- Depending on our decision based on Alere's introduction of a PCP:
    - If we remain status quo: Support, review and assess the marketing and distribution efforts of our rapid HIV tests by Alere in the U.S., as well as our distributors worldwide, and to engage in sales and marketing activities that allow us to engage with our target markets and customers. Alere, which is a leading marketer of point-of-care diagnostic products, has significantly expanded its distribution footprint and product portfolio since we signed our agreement with them, and although we believe that this will enhance opportunities for Alere to market our rapid HIV tests, our product line is a very small one for them, notwithstanding the strong growth they have enjoyed with respect to our products. In this case we would not have to bear the expense of establishing our own sales and marketing organization and we would continue to share a substantial portion of the net sales proceeds of the products with Alere as we have been. However, since Alere now has their own product to sell, they are likely to have a greater financial incentive to sell that product depending upon the market acceptance of that product and other factors. Therefore this could have a material and adverse effect on the sales Alere makes of our products.
    - If we decide to make certain elections available to us now such as to assume direct sales by Chembio under Chembio brands of the lateral flow products that we developed and that we manufacture but have been and continue to be marketed by Alere under their brands, then we will need to establish a commercial organization that is capable of assuming the distribution of these products. In this case Chembio would not have to share any portion of the net sales proceeds with Alere, except for the 8.5% lateral flow royalties applicable to the sales of the products, which royalty is only applicable until February 2015 at which time the applicable lateral flow patent of Alere's expires. This will immediately result in higher gross margins than if we continue with the status quo . However this decision will involve 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 product is indeed successful, our ability to retain a significant share of the market that has been established for our products may be enhanced by our having control of the marketing of our products, rather than having Alere sell our products. We have been developing contingency plans so that we can activate this strategy in a timely manner, including the possibility of ultimately utilizing the same sales force that we would use for U.S. Sales of DPP® HIV 1/2 Assay.
- Leverage our DPP® intellectual property and product development and manufacturing experience to continue creating new collaborations where Chembio can be the exclusive development and manufacturing partner supporting leading marketing organizations.
- Establish strong distribution relationships for our Chembio-branded products in the U.S and abroad, and establish a direct sales and marketing organization that is focused in the public health market segment, and that utilizes distributors for other market segments, primarily the acute care market which, together with public health, are the main market segments for rapid HIV tests in the United States. We believe that creation of a Chembio public health brand and marketing organization is fundamental to the creation of shareholder value over the long term.

During 2013 we increased our commercial activities and efforts in Africa and Europe for our HIV tests by establishing a sales representative in each of these markets. We believe the sales representative in Africa will enable us to be more closely engaged with opportunities to participate in the national testing algorithms that are established and revised from time to time by countries that are beneficiaries of PEPFAR, Global Fund and/or other bilateral or multilateral donor funding. In Europe, where there are a larger percentage of HIV positive people unaware of their status than in the United States, we believe that there is an emerging public health outreach opportunity, and there are relatively few strong competitors that are CE marked. Most recently we have established new sales and marketing positions in the Company to support our efforts to increase brand awareness globally and to lead our direct sales effort in the U.S. market.

Competition

The diagnostics industry is a multi-billion dollar international industry and is intensely competitive. Many of our competitors are substantially larger and have greater financial, research, manufacturing and marketing resources.

Industry competition in general is based on the following:

- Scientific and technological capability;
- Proprietary know-how;
- The ability to develop and market products and processes;

- The ability to obtain FDA or other required regulatory approvals;
- The ability to manufacture products that meet applicable FDA requirements, (i.e. FDA's Quality System Regulations) (see Governmental Regulation section);
- The ability to manufacture products cost-effectively;
- Access to adequate capital;
- The ability to attract and retain qualified personnel; and
- The availability of patent protection.

We believe our scientific and technological capabilities and our proprietary know-how relating to our in-licensed lateral flow technology rapid tests and to our proprietary know-how related to our patented dual path platform® 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 Dual Path Platform® (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 Dual Path Platform® (DPP®) 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 plan to introduce our FDA-approved DPP® oral fluid HIV test, which test also can be used with blood samples, in the U.S. market under a Chembio brand. Until it is CLIA-waived, this product will serve a very small market segment. Orasure Technologies manufactures the only other 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 by Chembio and marketed by Alere, are priced lower and/or are as or more accurate than the performance of Orasure's product on blood samples. Orasure has primarily retained those customers for whom the oral fluid sample feature is a strong preference, and this is an estimated $35 million business for Orasure. Although we believe we can capture a meaningful portion of this Orasure market share, we also anticipate that Orasure will defend this business aggressively.

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

The so-called "3 rd 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 "4 th 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 4 th 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 "4thgeneration" tests, but they are of course neither rapid nor point-of-care.

The initial "4 th 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 4 th 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 Alere is seeking CLIA-waiver for it. Alere is also aggressively pursuing development of the market for this product in anticipation of receiving CLIA waiver. Although the product can now be sold to moderate complexity certified laboratories, there is very limited supply of the product thus far, and there is no assessment thus far concerning the actual performance of this product in the hands of customers. We believe the price that Alere is charging for this product is substantially higher than our and our competitors' antibody tests, as the antigen claim avails some customers of an additional reimbursement code. Moreover there is support by a number of key opinion leaders for the public health value of such 4th generation tests, and if Alere is able to successfully launch this product, it represents a significant competitive threat to Chembio as well as to each of the other rapid HIV test manufacturers (Orasure and Trinity primarily).

During 2011 Biolytical, Inc. of Vancouver, Canada received FDA approval and in 2012 received CLIA waiver of a flow-through rapid HIV test called "INSTI". The technology used in the INSTI test, flow-through, is older than lateral flow, and it requires handling of multiple components (3 vials of solution) to perform the test in multiple steps. However, these steps can be accomplished in less than ten minutes, and the actual test results occur in only one minute after those steps are completed. Therefore sample-to-result time is shorter than any of the competitive products. 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.

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 2013 and 2012, $5.8 million and $4.5 million, respectively, were spent on research and development (including regulatory activities). These expenses were in part underwritten by funding from R&D and milestones revenues of $2.0 million in 2013 and $1.3 million in 2012. All of our new product development activities involve employment of our Dual Path Platform® (DPP®) technology. These activities include completing development of certain products and making significant progress toward the development of additional products.

Employees

At December 31, 2013, we employed 206 people. We have entered into employment contracts with our President, Lawrence Siebert, our Chief Operating Officer Sharon Klugewicz and our Senior Vice President of Research and Development, Javan Esfandiari. Due to the specific knowledge and experience of these executives regarding the industry, technology and market, the loss of the services of either one of them would likely have a material adverse effect on the Company. The contract with Ms. Klugewicz, has a term of two years ending May 2015. The contract with Mr. Esfandiari has a term of three years ending March 2016. We have obtained a key man insurance policy for Mr. Esfandiari. The contract with Mr. Siebert provides that Mr. Siebert will serve as the Chief Executive Officer and President of the Company through May 11, 2014, and Mr. Siebert has advised the Company that he intends to retire from the Company on or before that date. Upon Mr. Siebert's announcement in 2013, of his retirement plans, the Company began a search for a new CEO.

Governmental Regulation

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

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

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

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

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

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

Environmental Laws

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

Intellectual Property

Intellectual Property Strategy

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

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

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

The Company also licenses a group of lateral flow technology patents from Alere. Our lateral flow products, which are primarily our STAT-PAK®, SURE CHECK®, and DIPSTICK® product lines, may incorporate methods that are claimed under one of the patents licensed from Alere that we use in our tests. That U.S. Patent #6,485,982 is also referred to as the Charlton patent, which patent expires on February 3, 2015. This patent describes a test device and method for a colored particle immunoassay that determines the presence of an analyte in a sample

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

Trademarks

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

Trade Secrets and Know-How

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

Lateral Flow Technology and Reagent Licenses

As part of the agreements executed in 2006 with Alere for the marketing of our HIV tests, we were granted non-exclusive licenses to certain lateral flow patents for certain products manufactured and marketed by Chembio including but not limited to our lateral flow HIV tests. This license allows us to produce, market and sell assays using lateral flow technologies specifically including our STAT-PAK®, SURE CHECK®, DIPSTICK®, and veterinary product lines. Under this license agreement, we pay royalties to Alere ranging from 5% to 8½%, depending upon the country in which the products are sold. Even though the relevant patent has expired in most other jurisdictions, or were never issued in markets where we have sold these products, our manufacture of the products in the United States has required that we pay royalties under this license, which has been a substantial expense. In 2013 our lateral flow royalty expense to Alere was $822,000, and since 2007 we have incurred a total of $2.65 million in lateral flow royalty expenses. As of February 3, 2015 this royalty expense will no longer be payable as the applicable patent expires at that time. The license we have from Alere to their lateral flow patents will expand to include the barrel and cassette products in the United States, if we elect to sell those products under Chembio brands prior to the expiration of the applicable patent; that is until February of 2015.

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

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

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

Corporate History

On May 5, 2004, we completed a merger with Trading Solutions, Inc. through which Chembio Diagnostic Systems Inc. became our wholly-owned subsidiary, and through which the management and business of Chembio Diagnostic Systems Inc. became our management and business. As part of this transaction, we changed our name to Chembio Diagnostics, Inc.

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

On March 12, 2004, we implemented a 1-for-17 reverse split of our common stock. All references in this Form 10-K to shares of our common stock have been adjusted to reflect this reverse split.

In February 2010, Crestview Capital Master, L.L.C. ("Crestview Master"), a Delaware limited liability company that held 18,907,431 shares of Chembio's common stock, spun off all these shares, constituting approximately 30.5% of Chembio's outstanding shares, to its three equity holders. One of the three equity holders of Crestview Master immediately spun off, to its approximately 126 equity holders, all of the 12,990,569 shares of Chembio stock that it received in this distribution. As a result, as of February 24, 2010, Crestview Master no longer owned any shares. The former direct and indirect equity holders of Crestview Master owned all these shares, with none of these individual stockholders having beneficial ownership of more than 5.61% of the outstanding common stock of Chembio.

On May 30, 2012, the Company effected a 1-for-8 reverse split of its common stock. This was done to allow the Company to move to the NASDAQ trading market from the OTCQB market, which occurred on June 7, 2012. As a result of the stock split, the outstanding 63,967,263 common shares were reduced to 7,995,918 outstanding common shares on May 30, 2012. The effect of the reverse stock split has been retroactively reflected for all periods in these financial statement.

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	Anti-Retroviral Treatments for AIDS 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.
EITF	Emerging Issues Task Force
FASB	Financial Accounting Standards Board
FIOCRUZ	The Oswaldo Cruz Foundation of Brazil
FDA	United States Food and Drug Administration
FDIC	Federal Deposit Insurance Corporation
FAS	Financial Accounting Standard
IgG	IgG or Immunoglobulin are proteins found in human blood. This protein is called an "antibody" and is an important part of the body's defense against disease. When the body is attacked by harmful bacteria or viruses, antibodies help fight these invaders.
NGO	Non-Governmental Organization
OTC	Over-the-Counter
PEPFAR	The President's Emergency Plan for AIDS Relief
PMA	Pre-Marketing Approval –FDA approval classification for a medical device that is not substantially equivalent to a legally marketed device or is otherwise required by statute to have an approved application. Rapid HIV tests must have an approved PMA application before marketing of such a product can begin.
PROTOCOL	A procedure pursuant to which an immunodiagnostic test is performed on a particular specimen in order to obtain the desired reaction.
REAGENT	A chemical added to a sample under investigation in order to cause a chemical or biological reaction which will enable measurement or identification of a target substance.
RETROVIRUS	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.
SAB	Staff Accounting Bulletin
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 Annual Report. We currently believe that the risks described below may materially affect us. An investment in our Common Stock involves a high degree of risk, and should be considered only by persons who can afford the loss of their entire investment.

Risks related to our industry, business and strategy

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

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

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

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

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

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

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

The diagnostic industry is focused on the testing of biological specimens in a laboratory or at the point-of-care and is highly competitive and rapidly changing. Our principal competitors often 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 than ours.

Alere's planned introduction of a competing product in the U.S., as well as other competitors, could significantly reduce our U.S. sales.

We have granted Alere exclusive rights to market our SURE CHECK® HIV 1/2 in the United States and non-exclusive rights in the rest of the world and exclusive rights to market our HIV 1/2 STAT PAK® in the U.S. only. However Alere now has a "Permitted Competing Product" which, if it becomes CLIA waived and successfully launched, will be a significant competitive threat. While we have the option to terminate the Cassette Agreement and to convert Alere's rights under the Barrel Agreement to becoming non-exclusive, there are costs, risks and uncertainties associated with our doing this, particularly because we have not had a commercial organization in the U.S. market. If we were to assume the marketing of these products, we would retain that portion of the selling price of these products that Alere is now receiving, and we would have a potentially significant base of customers in the United States that are familiar with our products (although under Alere's trade names) and that could be introduced to Chembio and potentially to additional products to be marketed to them by Chembio. However, in that case we will incur costs not previously incurred related tos sales, marketing, distribution, and customer/technical support, and these costs are likely to be substantial. In addition, we would face the risk that a significant portion of these customers would not open accounts with us and would instead purchase competing products from Alere or other competitors.

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

The so-called "3 rd 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 "4 th 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 4 th 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 "4 th 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 4 th 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 is seeking CLIA-waiver for it. Alere is also aggressively pursuing development of the market for this product in anticipation of receiving CLIA waiver. Although the product can now be sold to moderate complexity certified laboratories, there is very limited supply of the product thus far, and there is no assessment thus far concerning the actual performance of this product in the hands of customers. We believe the price that Alere is charging for this product is substantially higher than our and our competitors' antibody tests, as the antigen claim avails some customers of an additional reimbursement code. Moreover there is support by a number of key opinion leaders for the public health value of such 4th generation tests, and if Alere is able to successfully launch this product, it represents a significant competitive threat to Chembio as well as to each of the other rapid HIV test manufacturers (Orasure and Trinity primarily).

During 2011 Biolytical, Inc. of Vancouver, Canada received FDA approval and in 2012 received CLIA waiver of a flow-through rapid HIV test called "INSTI". The technology used in the INSTI test, flow-through, is older than lateral flow, and it requires handling of multiple components (3 vials of solution) to perform the test in multiple steps. However, these steps can be accomplished in less than ten minutes, and the actual test results occur in only one minute after those steps are completed. Therefore sample-to-result time is shorter than any of the competitive products. 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 of approximately 30%, 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 product, or that will render our products obsolete, if we fail to maintain and enhance our competitive position or fail to introduce new products and product features, our customers may decide to use products developed by our competitors, which could result in a loss of revenues and cash flow.

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

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

We believe that our Dual Path Platform® is outside of the scope of currently issued patents in the field of lateral flow technology, thereby offering the possibility of a 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.

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 have been profitable for five consecutive years. Nevertheless, prior to 2009 we sustained significant operating losses since 2004, and we have incurred operating losses during certain quarterly periods, as recently as the fourth quarter of 2013. At December 31, 2013, we had a stockholders' equity of $20.3 million and a working capital surplus of $14.0 million. The Company estimates that its resources are sufficient to fund its needs through the end of 2014 and beyond, particularly due to the fact that it issued new common shares in 2013 in an equity financing that resulted in net proceeds to the company of approximately $5.4 million. Nevertheless we may have to make significant financial commitments to invest in a sales and marketing organization, regulatory approvals, research and development including new technologies, and production capacity.

The Company's liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenues; (2) the extent to which, if any, that revenue level improves operating cash flows; (3) the Company's investments in research and development, facilities, marketing, regulatory approvals, and other investments it may determine to make; and (4) the Company's investment in capital equipment and the extent to which it improves cash flow through operating efficiencies. There are no assurances that the Company will remain profitable or generate positive cash flow in 2014 or, in the alternative, be successful in raising sufficient capital to fund its needs after 2014.

We experienced an increase in revenues in 2013, though this increase was primarily attributable to a single purchase order in the approximate amount of $5.3 million that we received from a leading international procurement organization on behalf of a large screening initiative that was being undertaken by one country. Increased sales to Alere and increased non-product revenues attributable to sponsored research and development programs also contributed to our increased revenues in 2013.

In order for our 2014 revenues to be at the same level as in 2013, or increase from that level, we would need for the large international purchase order to be renewed, or to be able to replace this purchase order with other revenues from other customers. There can be no assurance that this will occur. A similar situation occurred in 2013 when we experienced a significant decrease in our revenues from FIOCRUZ, and we were able to more than offset this decrease with the above-mentioned purchase order. Nevertheless there can be no assurance that we will have a repeat in 2014 of the large order received in 2013, or that we will be able to replace it with other revenues from other sources.

Moreover, our U.S. market sales will be difficult to predict in 2014 given the anticipated introduction of a new rapid test by Alere, and the uncertainty as to whether or to what extent it will be successful in cannibalizing sales of our products, regardless of whether we modify or terminate our agreements with Alere. If we terminate our cassette agreement with Alere and/or if we convert the barrel agreement to a non-exclusive agreement with Alere, we would expect to experience higher average revenue per unit for the associated products due to the fact that, under the Cassette Agreement and the Barrel Agreement, we currently sell these products to Alere at a significantly lower price than the price at which Alere then resells to customers (including re-sellers and distributors) in the United States. However this could only occur after any inventory that Alere has accumulated of our products is run off, which may take several months. Moreover, Alere could heavily discount these products, although we don't believe it is in Alere's interest to do so. In addition, if we are marketing either or both of these products we will incur substantial costs associated with establishing a sales and marketing organization for these products and in establishing channel distribution partners. Finally, we would need to pay a royalty of 8.5% to Alere on sales of these products in the United States for the duration of the relevant lateral flow patent, which is until February 2015.

We believe that underlying demand for HIV rapid testing in the United States remains strong, and that the restoration of some of the funding cutbacks from sequestration and the implementation of the Affordable Care Act and of the United States Preventive Services Task Force recommendations will have a positive impact on the development of the market. Further, Chembio's 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 upon attainment of CLIA waiver, of which there can be no assurance, that our DPP® HIV 1/2 Assay for use with oral fluid or bloods samples will be able to address new customers that were previously not available to Chembio with its lateral blood tests marketed by Alere. However the timing of the CLIA waiver has been delayed and it cannot be assured, and development of new customers with this product is costly and time-consuming. Finally, we believe that short-term reductions in sales attributable to sales by Alere of inventory already purchased from Chembio will eventually be offset by stocking orders placed by certain distributors, although there can be no assurance of this.

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 for many years, the nature of our international business is such that it can be volatile from period to period, depending on ordering patterns of donor-funded programs.

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

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

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

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

Chembio has a policy in place prohibiting its employees, distributors and agents from engaging in corrupt business practices, including activities prohibited by the United States Foreign Corrupt Practices Act (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, those programs that our products are or may be deployed in are all funded by the Brazilian Ministry of Health. Although FIOCRUZ is affiliated with the Brazilian Ministry of Health, and is its sole customer, FIOCRUZ is not the exclusive supplier for the Ministry of Health. However because each of our collaborations with FIOCRUZ incorporates a technology transfer aspect, we believe we have a competitive advantage versus other suppliers to the Brazilian Ministry of Health, assuming other aspects of our product offering through FIOCRUZ are otherwise competitive in comparison. We have no knowledge or reason to know of any activities by our employees, distributors or sales agents of any actions which could be in violation of the FCPA, although there can be no assurance of this.

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

We believe that factors such as the technological and creative skills of our personnel, strategic relationships, new product developments, frequent product enhancements and name recognition are essential to our success. All 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 efforts we make to protect our confidential information, such as entering 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 and President, Lawrence Siebert, our Chief Operating Officer Sharon Klugewicz and our Senior Vice President of Research and Development, 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 Ms. Klugewicz has a term of two years ending May 2015. The contract with Mr. Esfandiari has a term of three years ending March 2016. The Company has obtained a key man insurance policy on Mr. Esfandiari. The contract with Mr. Siebert provides that Mr. Siebert will serve as the Chief Executive Officer and President of the Company through May 11, 2014, and Mr. Siebert has advised the Company that he intends to retire from the Company on or before that date. Upon Mr. Siebert's announcement in 2013, of his retirement plans, the Company began a search for a new CEO.

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

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

In December 2013 President Obama signed into law the PEPFAR Stewardship and Oversight Act, which is the most recent reauthorization of PEPFAR. However, unlike the 2008 PEPFAR authorization, which authorized approximately $45 billion, 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 has $6 billion for global HIV/AIDS assistance, including $4 billion for PEPFAR.

Although we were profitable in 2009, 2010, 2011, 2012 and 2013, we cannot be certain that we will be able to sustain profitability in 2014.

From the inception of Chembio Diagnostic Systems, Inc. in 1985 through the period ended December 31, 2008, we incurred net losses, and we have only become profitable during the last five years. In 2014, we expect to make substantial expenditures for sales and marketing, regulatory submissions, product development, and production and warehouse capacity and other purposes. Without a substantial increase in revenues, this will impact profitability at least in the short term. Our ability to continue 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 usage. 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 50 ,000 shares per day over the three months ended March 1, 2014 as compared to less than 44,000 shares per day over the three months ended March 1, 2013. Therefore, there has been consistency in the liquidity of our stock based on this comparison, and our stock began trading on NASDAQ in early June, 2012. However, improvements in 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 there can be no assurance that this improvement will continue, or even be maintained.

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 our Company.

As of March 3, 2014, our named executive officers, directors and 5% stockholders beneficially owned approximately 14.6 % of our voting power. In addition, we have two large institutional investors that beneficially owned 7.2% and 4.8%, respectively of the stock. For the foreseeable future, and assuming these ownership percentages continue to pertain, 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 be different from, the interests of each other or the interests of the other stockholders.

ITEM 2. PROPERTIES

Our manufacturing, administrative offices and research facilities are located in Medford, New York. In addition we have warehousing space as well as some additional administrative offices located in Holbrook, New York. We lease approximately 39,660 square feet of industrial space in Medford for $27,305 per month. The space is utilized for research and development activities (approximately 4,160 square feet), offices (approximately 3,100 square feet) and production (approximately 32,400 square feet). The lease term expires on April 30, 2017. The lease provides for annual increases of two and one half percent each year starting May 1, 2015. We lease approximately 21,450 square feet of industrial space in Holbrook for $14,657 per month. The space is utilized for offices (approximately 2,500 square feet) and warehousing (approximately 18,950 square feet). The lease term expires on April 30, 2018. The lease provides for annual increases of three percent each year starting March 1, 2015. The Company believes this space should be sufficient for its needs in the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

PART II

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

Market Information

Our stock is quoted on the NASDAQ, under the symbol "CEMI." Prior to June 8, 2012, our stock was quoted on the OTCQB and prior to February 24, 2011 on the OTC Bulletin Board. On May 30, 2012, a reverse split was effected at a ratio of 8 for 1. The table below sets forth the high and low bid prices per share of our common stock for each quarter of our two most recently completed fiscal years. Quarters prior to June 2012 were adjusted for the split. These prices represent inter-dealer quotations without retail markup, markdown, or commission and may not necessarily represent actual transactions.

Fiscal Year 2013	**High Bid**	**Low Bid**
First Quarter	$ 5.75	$ 4.61
Second Quarter	$ 5.10	$ 4.10
Third Quarter	$ 5.32	$ 3.00
Fourth Quarter	$ 3.95	$ 3.19
Fiscal Year 2012	**High Bid**	**Low Bid**
First Quarter	$ 4.08	$ 3.12
Second Quarter	$ 4.96	$ 3.52
Third Quarter	$ 5.30	$ 4.11
Fourth Quarter	$ 5.80	$ 3.61

On May 30, 2012, the Company undertook an 8-for-1 reverse stock split in order to have a stock price sufficient to qualify for listing on NASDAQ, which occurred on June 7, 2012.

Holders

As of March 1, 2014, there were approximately 149 record owners of our common stock.

Dividends

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

Recent Sales of Unregistered Securities

Not applicable.

ITEM 6. SELECTED FINANCIAL DATA

Presented in this table are selected financial data for the past five years ended December 31, 2013.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES

SELECTED HISTORICAL FINANCIAL DATA

As of and For the Years Ended

Statement of Operations Data:	December 31, 2013		December 31, 2012		December 31, 2011		December 31, 2010		December 31, 2009	
TOTAL REVENUES	$29,549,609		$25,610,595		$19,388,036		$16,704,703		$13,834,248	
GROSS MARGIN	12,300,159	42%	10,789,991	42%	9,390,303	48%	8,100,699	48%	5,860,405	42%
OPERATING COSTS:										
Research and development expenses	5,834,249	20%	4,486,302	18%	4,878,119	25%	2,586,308	15%	2,883,696	21%
Selling, general and administrative expenses	5,461,083	18%	4,851,587	19%	3,424,297	18%	2,940,721	18%	2,659,382	19%
	11,295,332		9,337,889		8,302,416		5,527,029		5,543,078	
INCOME FROM OPERATIONS	1,004,827		1,452,102		1,087,887		2,573,670		317,327	
OTHER INCOME (EXPENSES):	12,943		(1,584)		(12,325)		(14,503)		(8,267)	
INCOME BEFORE INCOME TAXES	1,017,770	3%	1,450,518	6%	1,075,562	6%	2,559,167	15%	309,060	2%
Income tax (benefit) provision	486,952		509,237		(5,133,229)		-		-	
NET INCOME	$ 530,818		$ 941,281		$ 6,208,791		$ 2,559,167		$ 309,060	
Basic income per share	$ 0.06		$ 0.12		$ 0.79		$ 0.33		$ 0.04	
Diluted income per share	$ 0.06		$ 0.11		$ 0.73		$ 0.29		$ 0.03	
Weighted average number of shares outstanding, basic	8,994,080		7,986,030		7,874,807		7,762,858		7,743,304	
Weighted average number of shares outstanding, diluted	9,519,968		8,614,944		8,556,284		8,865,114		9,380,242	
Balance Sheet Data:										
Working capital	$14,221,011		$ 7,630,368		$ 6,133,956		$ 4,560,277		$ 1,493,970	
Total assets	24,486,592		17,335,150		15,485,744		9,086,174		6,315,250	
Total liabilities	4,309,490		3,460,630		2,991,110		3,277,230		3,227,336	
Shareholders' equity	20,177,102		13,874,520		12,494,634		5,808,944		3,087,914	

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

Overview

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

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

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

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

The Company has had very active research and development programs and has significantly increased its spending on research and development during the last three years. Third-party funding from research and development contracts and grants have offset a significant portion of these increased research and development expenses. Moreover these collaborations have resulted in significant third party validations of our DPP® technology and an increasing capability to develop, manufacture, validate, and improve current and future DPP® products and product features.

The Company has a number of products under development that employ the DPP® technology. These product development activities are further described below.

DPP® HIV Multiplex Antigen-Antibody "Fourth Generation" Test - Development work continues on a DPP® HIV multiplex test that is being designed to detect acute (early stage) HIV infection by means of detecting P24 antigen, as well as antibodies, to HIV1/2, in whole blood samples. Recently the FDA approved the first point-of-care test that claims to detect acute HIV infection, and there are also two FDA-approved laboratory tests with such claims. The point-of-care test approved by the FDA, manufactured in Israel by a subsidiary of Alere, is called Determine® HIV Ag/Ab Combo. This test, which Alere has reported is now undergoing CLIA waiver studies, claims earlier detection due to the ability to detect unbound p24 antigen. We believe that our development of such a test, combined with our patented DPP® point-of-care platform may better help identify HIV infections that cannot be identified by any of the currently FDA-approved rapid HIV tests, including the new Alere Determine test. Such a test may serve an unmet market need, and may help to maintain and potentially grow the already strong position Chembio's products have in the U.S. rapid HIV test market. We are in an early stage of design development of this product including feasibility to meet or exceed the target specifications of product that is commercially available on the market.

DPP® Hepatitis-C (HCV) – Development work on our DPP® HCV point-of-care rapid test continues. Our development activity has been focused on creating a differentiated product that is at least capable of identifying antibody response in a more comprehensive manner than the currently available point-of-care test is able to do.

In July 2012, the U.S. Centers for Disease Control finalized the recommendations for testing all individuals in the United States born between the years of 1945 and 1965 for HCV, which age cohort represents a substantial portion of the estimated over three million individuals in the United States that are infected with HCV infection, but unaware of their status. With a number of new anti-retroviral therapies approved, and even more anticipated pending approval in the years ahead by the FDA, we believe that over time, these new recommendations will be implemented. In fact, in May the United States Preventive Services Task Force revised its November 2012 recommendations to endorse the CDC recommendations by giving both hepatitis-C (HCV) screening for at-risk individuals and age-cohort screening a 'B' grade; under the Affordable Care Act, preventive services that have received an 'A' or 'B' grade from the USPSTF must be covered by insurance policies without cost-sharing, and be part of the essential health benefits for those individuals eligible for Medicare.

We plan to complete development activities of the antibody detection assay in 2014, and to begin activities to commercialize product, including regulatory submission, in the US by the end of 2015 or early 2016.

International Distribution & Manufacturing Agreements –

Labtest

In 2013 the Company entered into an international assembly and distribution agreement with Labtest Diagnostica SA (Labtest), a leading diagnostics manufacturer and marketing organization based in Brazil, for products based upon Chembio's patented Dual Path Platform® (DPP ®) in Brazil and potentially other markets outside the U.S.

Pursuant to the agreement, upon receipt of an order from, Chembio will manufacture and sell certain specialized test components to Labtest and also will receive a royalty based on sales by Labtest of DPP ® products. Labtest will produce certain reagents and perform assembly and packaging operations in a dedicated space at Labtest's manufacturing facilities near Belo Horizonte, Brazil. Chembio will provide Labtest with the training necessary to perform the operations specific to the DPP ® products. Labtest will also have responsibility for marketing, promotion and distribution of the products in Brazil.

All products will be marketed under brand names that will include Chembio's DPP ® trademark together with trade names selected by Labtest, and each test kit will state that Chembio Diagnostic Systems, Inc. is the licensor of the DPP ® trademark and technology. The products selected for inclusion in this agreement will address both private as well as public health markets, and will enable Chembio to participate in significant market opportunities in Brazil. This agreement addresses market opportunities that are independent of those addressed by Chembio's ongoing collaboration with the Oswaldo Cruz Foundation.

Labtest is installing the assembly equipment that it received during the fourth quarter so that it can begin product validation and registration activities for an initial group of infectious disease products with sales expected to commence in 2015. The agreement contemplates additional products and territories to be added by mutual agreement. In addition, the agreement offers the possibility for Labtest to assemble products for other global Chembio customers as a contract manufacturer.

Sponsored Research & Development

Multiplex Influenza Immunity Test –

As a result of pandemic planning activities, the United States Department of Health and Human Services and the CDC have identified POC and high-throughput testing as a gap in influenza diagnostics. Rapid responses in the field — such as the vaccination, prophylactic treatment or isolation of patients — require POC diagnostic tests for influenza infection and immunity. Ideally, these tests should be fast, portable, self-contained and non-technical. Development of this test is especially critical for the military, as evidenced by previous influenza outbreaks that spread rapidly through densely populated barracks and killed thousands of soldiers.

Further to this identified gap in influenza diagnostics, in 2013 the Company entered into a follow-on, milestone-based development agreement with the private contracting organization that is engaged to enter into, implement and provide technical oversight of agreements relating to pandemic influenza preparedness on behalf of its client, the United States Centers for Disease Control and Prevention (CDC), for a multiplex, rapid, POC influenza immunity test utilizing Chembio's patented Dual Path Platform® (DPP®) technology. The objective of this follow-on project is to further develop a rapid influenza immunity test that can determine a person's influenza immunity status in the field or in an outpatient setting, while incorporating certain additional subunits of influenza virus proteins. The follow-on agreement was for up to approximately $472,000 and was completed during the first quarter of 2014. New prototypes have been delivered to our customer and we are waiting for next steps.

DPP® Febrile Illness Multiplex test – During 2013 we entered into a cooperative research project agreement with a U.S. government agency for up to $750,000 for an eight-month development project. The project is to develop a rapid POC diagnostic test for five infectious diseases associated with febrile illness and to multiplex them into one assay. The project also contemplates that the test would be optimized for use with a mobile reader that incorporates cell phone technology to enable the results to be recorded, transmitted and monitored remotely via a cloud system, in real-time. This research project supports our efforts in developing multiplex products using our proprietary DPP ® technology. Our DPP ® technology, when combined with the mobile reader being used in the project, will enable real time data collection and monitoring capabilities. As these infectious diseases can all exhibit similar clinical symptoms, a rapid multiplex test that could distinguish them would be very useful, particularly in field conditions, so that correct diagnosis and treatment could be provided on a timely basis. We completed R&D activities for this project during 2013, including supplying the U.S. government agency that this test was developed for with approximately 10,000 prototype devices for clinical trials.

DPP® Tuberculosis – In 2011, we were awarded a three-year, $2.9 million, Small Business Innovative Research (SBIR) Phase II grant from the United States National Institutes of Health (NIH) to continue our successful Phase I grant work to develop a simple, rapid, accurate, and cost-effective serological test for active tuberculosis that can be utilized in resource-limited settings. During 2012, several additional antigens were identified to enhance antibody detection by the DPP® test prototype designed in our Phase I studies. Antigen reagents have been finalized and test prototype evaluation using well-characterized clinical specimens is in progress. Funding for the third and final year of this Phase II grant was confirmed with a reduction of approximately 1%. Chembio's work to finalize DPP assay design using various fusion proteins has been completed and production of an evaluation lot is in progress; these tests will be used for verification studies, internal and external evaluations at the selected collaborative sites (see below), QC protocol validation, and accelerated stability study. The target sensitivity is 80% and specificity is 95%. Study sites for external evaluations of DPP assay include Bangladesh, Brazil, China, Haiti, Peru, Venezuela, and South Africa. The grant is expected to be completed by early July 2014.

In addition to the above-mentioned research and development work sponsored by governmental agencies and/or their contractors for the influenza, febrile illnesses, and tuberculosis projects, we are discussing additional opportunities for sponsored research and development activity. We endeavor to select sponsored research projects where we believe there is an identifiable commercial opportunity and/or where other benefits to the Company are anticipated in connection with these projects.

In general, we are considering certain new DPP® product opportunities, either as OEM development projects and/or as Chembio-branded products. These products are being identified based upon our assessment of opportunities in the market and upon whether they can be addressed with our proprietary technology, along with our development and manufacturing capabilities and experience. We are also identifying and assessing additional technologies that we believe can enhance or expand our current product portfolio, and thereby provide additional revenue streams, although there is no assurance that we will be able to obtain or utilize any of them profitably.

Regulatory Activities

CE Mark for FDA-Approved HIV Tests – The Company's SURE CHECK® HIV 1/2 Assay has received CE Mark approval from European regulators and is therefore now cleared for commercialization within the European Union (EU) for rapid, point-of-care detection of HIV. Chembio is currently working with commercialization partners in Europe. We expect that our HIV 1/2 STAT PAK® lateral flow HIV test will receive the CE mark during the first quarter of 2014. We anticipate that the DPP® HIV 1/2 test will receive CE Mark approval in early 2014.

FDA Approval for DPP® HIV 1/2 Assay for Use with Oral Fluid or Blood Samples – We received FDA approval of our Pre-Marketing Application (PMA) for this product on December 19, 2012 as we previously announced. The CLIA waiver application was submitted at the end of November 2013. In February 2014 we received a letter from the FDA on the current status of review of our CLIA waiver application. The FDA determined that additional information is needed to complete their review of the Company's DPP® HIV 1/2 Assay CLIA waiver application. During the blinded prospective clinical study, a disproportionate number of new infections were found at one clinical site due to the lower than expected prevalence at two other sites. We are currently in discussion with the FDA to finalize the protocol to collect additional data. Upon receiving guidance on our proposed protocol, we anticipate that we will be able to update the timeline of activities for the CLIA waiver of the DPP HIV1/2 Assay.

DPP® HIV-Syphilis – We have developed this product for international and US marketing. For the international market, the product has been registered in Mexico. We have submitted this product both for evaluation by the CDC, acting on behalf of the United States Agency of International Development, and the WHO, which has accepted this product to be evaluated for pre-qualification in its global procurement scheme.

The FDA review timeline for this product, which we originally anticipated would be in mid-2014, has now been shifted to late 2014, with CLIA waiver now anticipated in 2015. This development is due to this product being characterized by FDA as a PMA, not a 510(K), as the syphilis component performance will be compared to actual patient infection status, as compared to a predicate device allowed in 510(K). This change will be more time consuming due to the increased statutory review time, and potentially more costly. We collected and completed phase I of the clinical study and found that the patient infected status varied dependent on the comparator assay used for the serological clinical diagnosis of syphilis. Due to the complex nature of the disease state of syphilis as well as the varying algorithms used for diagnosis, the original requirement discussed with the FDA may not be appropriate. FDA has requested the submission of preliminary data collected during the clinical study, which we did in February 2014, to further the discussion regarding the requirement for the DPP HIV-Syphilis Assay.

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.

RESULTS OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2013 AS COMPARED WITH THE YEAR ENDED DECEMBER 31, 2012

Income :

Income before income taxes for the year ended December 31, 2013 decreased to $1,018,000 from $1,451,000 for the year ended December 31, 2012. Net Income decreased from $941,000 for 2012 to $531,000 for 2013. The decrease in net income is primarily attributable to a $695,000 increase in clinical trial expenses, along with other increased operating expenses, offset by a higher gross margin. In 2013, as a result of a 13.1% increase in Net Product sales and a 58.5% increase in non-product revenues, the Company had a $1,510,000, or 14.0%, increase in its gross margin, to $12,300,000. This increased gross margin funded most of the increased operating expenses, the most significant of which was an increase in clinical trial expenses of $695,000, due to the CLIA trials for our DPP HIV 1/2 product.

Revenues:

Selected Product Categories:	For the years ended December 31, 2013	December 31, 2012	$ Change	% Change
Lateral Flow HIV Tests and Components	$ 20,248,364	$ 13,505,849	$ 6,742,515	49.92%
DPP Tests and Components	6,592,660	10,086,459	(3,493,799)	-34.64%
Other	674,762	735,047	(60,285)	-8.20%
Net Product Sales	**27,515,786**	**24,327,355**	**3,188,431**	**13.11%**
License and royalty revenue	4,906	-	4,906	100.00%
R&D, milestone and grant revenue	2,028,917	1,283,240	745,677	58.11%
Total Revenues	**$ 29,549,609**	**$ 25,610,595**	**$ 3,939,014**	**15.38%**

Revenues for our lateral flow HIV tests and related components during the year ended December 31, 2013 increased by $6.7 million over the same period in 2012. This was primarily attributable to increased sales in South America, of $4.6 million, in Africa of $1.7 million, and in the U.S. of $1.1 million; and was partially offset by decreased sales in other regions. Partially offsetting these increases were decreased other sales, which decreased by 8.2%, or $60,000. Sales of our DPP® products in 2013 decreased by $3,494,000, or 34.6%, compared to levels in 2012 as Brazil reduced purchases for the five ANVISA-approved DPP® products. The increase in R&D, milestone and grant revenue was primarily due to an increase in grants and other development projects of $746,000 along with an increase in royalty income of $5,000. R&D revenues in 2013 include funds, recognized on an "as expenses are incurred" basis, from a Phase II NIH grant for Leptospirosis, which was effective as of June 1, 2009, and from a Phase II grant for Tuberculosis which was effective March 1, 2011 as well as from two milestone based projects.

Gross Margin:

Gross Margin related to Net Product Sales:	For the years ended December 31, 2013	December 31, 2012	$ Change	% Change
Gross Margin per Statement of Operations	$ 12,300,159	$ 10,789,991	$ 1,510,168	14.00%
Less: R&D, milestone, grant, license and royalties	2,033,823	1,283,240	750,583	58.49%
Gross Margin from Net Product Sales	**$ 10,266,336**	**$ 9,506,751**	**$ 759,585**	**7.99%**
Product Gross Margin %	**37.31%**	**39.08%**		

The gross margin dollar increase of $1,510,000 included a $760,000 increase in gross margin from product sales and a $751,000 increase in non-product revenues. The increase in product gross margin dollars is primarily attributable to the higher product sales compared to the 2012 period which resulted in $1,246,000 (this is calculated by taking the increase in sales times the gross margin percentage from 2012)and was partially offset by the 1.8% decrease in our product gross margin percentage, from 39.1% in 2012 to 37.3% in 2013, accounting for the $486,000 balance, which was primarily due to increased costs of royalties from 7.4% of product sales in 2012 to 9.0% in 2013.

Research and Development:

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

Selected expense lines:	For the years ended December 31, 2013	December 31, 2012	$ Change	% Change
Clinical and Regulatory Affairs:				
Wages and related costs	$ 436,088	$ 436,668	$ (580)	-0.13%
Consulting	53,493	61,664	(8,171)	-13.25%
Stock-based compensation	19,478	28,278	(8,800)	-31.12%
Clinical trials	1,515,212	820,083	695,129	84.76%
Other	82,852	46,217	36,635	79.27%
Total Regulatory	**2,107,123**	**1,392,910**	**714,213**	**51.27%**
R&D Other than Regulatory:				
Wages and related costs	2,224,882	1,956,536	268,346	13.72%
Consulting	106,155	137,789	(31,634)	-22.96%
Stock-based compensation	86,023	41,838	44,185	105.61%
Materials and supplies	975,503	646,271	329,232	50.94%
Other	334,563	310,958	23,605	7.59%
Total other than Regulatory	**3,727,126**	**3,093,392**	**633,734**	**20.49%**
Total Research and Development	**$ 5,834,249**	**$ 4,486,302**	**$ 1,347,947**	**30.05%**

Expenses for Clinical & Regulatory Affairs increased by $714,000 for the year ended December 31, 2013, as compared to the same period in 2013. This was primarily due to an increase of $695,000 in clinical trial expenses which in 2013 are mostly associated with CLIA waiver studies for our DPP® HIV 1/2 Assay.

R&D expenses other than Clinical & Regulatory Affairs increased by $634,000 in the year ended December 31, 2013, as compared with the same period in 2012. 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, 2013	December 31, 2012	$ Change	% Change
Wages and related costs	$ 2,068,173	$ 1,534,440	$ 533,733	34.78%
Consulting	279,688	261,054	18,634	7.14%
Commissions	902,393	1,208,946	(306,553)	-25.36%
Stock-based compensation	169,502	174,462	(4,960)	-2.84%
Marketing materials	112,326	65,249	47,077	72.15%
Investor relations/investment bankers	214,786	282,058	(67,272)	-23.85%
Legal, accounting and compliance	621,429	559,569	61,860	11.05%
Travel, entertainment and trade shows	190,698	163,704	26,994	16.49%
Bad debt allowance (recovery)	(33,450)	28,000	(61,450)	-219.46%
Other	935,538	574,105	361,433	62.96%
Total S, G &A	**$ 5,461,083**	**$ 4,851,587**	**$ 609,496**	**12.56%**

Selling, general and administrative expenses for the year ended December 31, 2013, increased by $609,000 as compared with the same period in 2012. The primary factor of this increase was a $534,000 increase in wages and related expenses, primarily attributable to the hiring of a COO and a VP of sales and marketing, and a new Medical Device tax of $72,000, along with other increases. These increases were partially offset by decreases in commissions due to decreased sales to Brazil, bad debt allowance and other decreases.

Other Income and Expense:

	For the years ended December 31, 2013	December 31, 2012	$ Change	% Change
Gain on sale of fixed asset	$ 7,500	-	7,500	100%
Interest income	$ 5,778	$ 7,911	$ (2,133)	-26.96%
Interest expense	(335)	(9,495)	9,160	-96.47%
Total Other Income and (Expense)	**$ 12,943**	**$ (1,584)**	**$ 14,527**	**-917.11%**

Other income for the year ended December 31, 2013 increased approximately $15,000 from an expense of $2,000 in the same period in 2012, primarily as a result of a gain on the sale of fixed assets and a decrease in interest expense due on the term loan with HSBC.

Income tax (benefit) provision:

For the years ended December 31, 2013 and 2012, the Company charged $487,000 and $509,000, respectively to income tax expense and reduced the deferred tax asset by $458,000 and $471,000, respectively . The Company still 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, 2013	December 31, 2012	$ Change	% Change
Cash and cash equivalents	$ 9,650,275	$ 2,951,859	$ 6,698,416	226.92%
Accounts receivable, net of allowance for doubtful accounts of $24,000 and $58,000 at December 31, 2013 and 2012, respectively	4,592,121	4,821,357	(229,236)	-4.75%
Inventories	3,188,726	2,488,071	700,655	28.16%
Fixed assets, net of accumulated depreciation	1,978,232	1,427,646	550,586	38.57%
Deferred tax asset, net of valuation allowance	3,590,207	4,233,194	(642,987)	-15.19%
Accounts payable and accrued liabilities	4,309,490	3,303,923	1,005,567	30.44%

Cash increased by $6,698,000 from December 31, 2012, primarily due to the common stock funding completed in April 2013 which added $5,409,000. Excluding the common stock funding, the cash increased by $1,289,000. In addition there were decreases in accounts receivable, net of allowance, of $229,000 and deferred taxes of $643,000. We experienced increases in inventories of $701,000, fixed assets of $551,000 and accounts payable and accrued expenses of $1,006,000.

The increase in inventories is due to production for orders received to be shipped in the first quarter of 2014, which partially explains the increase in accounts payable and other accrued expenses. The increase in fixed assets is due in part to delivery of equipment for which we had made deposits, this equipment included vial filling equipment, a reel-to-reel printer for R&D, some leasehold improvements, and other pieces of equipment. Deferred tax asset decrease is related to the provision for income tax expense.

LIQUIDITY AND CAPITAL RESOURCES

	For the years ended			
	December 31, 2013	December 31, 2012	$ Change	% Change
Net cash provided by operating activities	$ 2,243,164	$ 761,084	$ 1,667,862	223.99%
Net cash used in investing activities	(851,159)	(872,442)	(148,020)	16.97%
Net cash provided by financing activities	5,306,411	52,263	5,237,669	7619.31%
(DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	**$ 6,698,416**	**$ (59,095)**	**$ 6,757,511**	**-11435.00%**

The Company's cash increased by $6,698,000 from December 31, 2012, primarily due to the common stock funding completed in April 2013 which added $5,409,000 and was slightly offset by other uses of cash from financing activities, compared to a decrease in cash of $59,000 in the 2012 period.

The cash provided from operations in 2013 was $2,243,000, primarily due to net income plus non-cash expenses of $1,898,000, along with a decrease in accounts receivable of $650,000 and an increase of $1,006,000 in accounts payable and other accrued liabilities which were partially offset by an increase of $701,000 in inventory. The $1,898,000 of net income plus non-cash expenses includes net income of $531,000, plus $611,000 in depreciation and amortization, $332,000 in share-based compensation, $458,000 in provision for deferred taxes and a reduction for the change in the provision for doubtful accounts of $34,000. The use of cash from investing activities is primarily the purchase of fixed assets.

The increase in cash from operations in 2012 was $761,000, primarily due to net income plus non-cash expenses of $2,282,000 and an increase of $514,000 in accounts payable and accrued liabilities and other items aggregating $24,000, which were partially offset by an increase in accounts receivable of $1,851,000, and an increase of $188,000 in inventory and other items aggregating $20,000. The $2,282,000 net income plus non-cash expenses includes net income of $941,000, plus $523,000 in depreciation and amortization, $318,000 in share-based compensation, $471,000 in provision for deferred taxes and a change in the provision for doubtful accounts of $28,000. The use of cash from investing activities is primarily the purchase of fixed assets.

Fixed Asset Commitments

As of December 31, 2013, the Company had paid deposits on various pieces of equipment aggregating $16,410 which is reflected in Other Assets on the balance sheet. The Company is further committed to additional equipment-purchase obligation of $31,990 as various milestones are achieved by the various vendors.

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

With over 10 consecutive years of double-digit revenue growth and five consecutive years of profitability, and with our strongest balance sheet ever, Chembio is well positioned for continued growth. A growing number of markets are now available to and being actively pursued for our products in North America (including significant near term new business opportunities in Mexico), South America and Africa. We are now also entering the European and Asian markets as a result of investments begun in 2013. Chembio is addressing the global health market mor than ever.

Having received, in December 2012, FDA approval of our Pre-Marketing Application for our DPP® HIV 1/2 Assay for use with oral fluid or blood samples, one of our priorities is to complete the requirements for a Clinical Laboratory Improvement Act (CLIA) waiver for this product. Receipt of a CLIA waiver will enable the product to be sold in the U.S. professional point-of-care market segments where these tests are primarily used. We anticipate this process to be completed in 2014. We believe the availability of an alternative oral fluid HIV rapid test, which test also performs very well on all blood matrices, will enable Chembio to participate in market segments not currently addressed by the lateral flow blood POCT products that have been sold through Alere.

While we continue to pursue and develop successful private label license and distribution agreements in a number of markets such as we have done with FIOCRUZ and Labtest in Brazil, Alere in North America and, as recently announced, RVR in Asia, we believe our long-term success will be primarily driven by providing our customers with the best value and the most direct relationship with our high quality organization and products and by doing so through further development of a Chembio brand in the United States and other key markets. This is fundamental to the strategic plan that we developed last year.

We intend to sell, under the Chembio brand, our DPP® HIV 1/2 Assay for use with oral fluid or blood samples. While we have a robust pipeline of products that will complement this initial offering, we may also seek to distribute additional products that we can license or acquire.

We believe 2014 will be a transformative year for Chembio, as we both bring in a new chief executive and we establish a commercial sales organization for the first time. Our commitment to provide our customers the best value and support under a Chembio brand in the U.S. will require not only investing in a commercial sales organization, but also ensuring that the commercial organization will have a growing pipeline of products to sell, whether they are developed in-house, in-licensed or acquired. Investments will need to be made in sales and marketing, research and development, regulatory submissions, and manufacturing in order to realize our long-term strategic plan. We are committed to doing that. These investments were one of the primary reasons we raised capital in 2013.

We are optimistic that, with a strong track record, and an ongoing business and financial position in place, an outstanding organization, the support of our board of directors, and strong leadership, this transformation will be successful.

Critical Accounting Policies and Estimates

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

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

Revenue Recognition –

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

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

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

Stock-Based Compensation –

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

Research & Development Costs –

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

Valuation of Inventories –

Inventories are stated at the lower of cost or market, using the first-in, first-out method (FIFO) to determine cost. Our policy is to periodically evaluate the market value of the inventory and the stage of product life cycle, and record a reserve for any inventory considered slow moving or obsolete. For example, each additional 1% of obsolete inventory would reduce such inventory by approximately $32,000.

Allowance for doubtful accounts –

Our policy is to review our accounts receivable on a periodic basis, no less than monthly. On a quarterly basis an analysis is made of the adequacy of our allowance for doubtful accounts and adjustments are made accordingly. The current allowance is approximately 1% of accounts receivable. For example each additional 1% of accounts receivable that becomes uncollectible would reduce such balance of accounts receivable by approximately $46,000.

Income Taxes –

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

The Guidance also requires that a valuation allowance be established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence needs to be considered, including a company's current and past performance, the market environment in which the company operates, length of carryback and carryforward periods and existing contracts that will result in future profits. Prior to 2011 and through September 30, 2011, the Company had a full valuation allowance recorded against deferred tax assets since it was not more likely than not that the Company would realize the benefits of such deferred tax assets. During 2011, the Company determined based upon the guidance under ASC 740 that it was more likely than not that it would realize the benefit of such deferred tax assets. As result, the Company reversed the valuation allowance previously recorded against the deferred tax assets. The Company still maintains a full valuation allowance on research and development tax credits

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

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

Not Applicable.

ITEM 9A. CONTROLS AND PROCEDURES

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

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

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

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

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

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

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

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

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

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

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors and Executive Officers

Lawrence A. Siebert (57), President, Chief Executive Officer and Chairman. Mr. Siebert was appointed President of Chembio Diagnostics, Inc. and a member of our board of directors upon consummation of the merger in 2004. Mr. Siebert has been Chairman of Chembio Diagnostic Systems Inc. for approximately thirteen years and its President since May 2002. Mr. Siebert's background is in private equity and venture capital investing. From 1982 to 1991, Mr. Siebert was associated with Stanwich Partners, Inc, which during that period invested in middle market manufacturing and distribution companies. From 1992 to 1999, Mr. Siebert was an investment consultant and business broker with Siebert Capital Corp. and Siebert Associates LLC, and was a principal investor in a privately held test and measurement company which was sold in 2002. Mr. Siebert received a JD from Case Western Reserve University School of Law in 1981 and a BA with Distinction in Economics from the University of Connecticut in 1978. Mr. Siebert as president and CEO is an integral part of the Chembio management team. His experience in the rapid test field and financing markets made him an excellent candidate for serving on the board and as its chairman. In September 2013, Mr. Siebert announced his retirement from his positions as CEO and President of Chembio, effective when his current employment agreement expires in May 2014.

Richard J. Larkin (57), Chief Financial Officer. Mr. Larkin was appointed as Chief Financial Officer of Chembio Diagnostics, Inc. upon consummation of the merger in 2004. Mr. Larkin oversees our financial activities and information systems. Mr. Larkin has been the Chief Financial Officer of Chembio Diagnostic Systems Inc. since September 2003. Prior to joining Chembio Diagnostic Systems Inc., Mr. Larkin served as CFO at Visual Technology Group ("VTG") from May 2000 to September 2003, and also led VTG's consultancy program that provided hands-on expertise in all aspects of financial service, including the initial assessment of client financial reporting requirements within an Enterprise Resource Planning (Manufacturing) environment through training and implementation. Prior to joining VTG, he served as CFO at Protex International Corporation from May 1987 to January 2000. Mr. Larkin holds a BBA in Accounting from Dowling College and is a member of the American Institute of Certified Public Accountants.

Javan Esfandiari (47), Executive VP of Research and Development. Mr. Esfandiari joined Chembio Diagnostic Systems, Inc, in 2000. Mr. Esfandiari co-founded, and became a co-owner of Sinovus Biotech AB where he served as Director of Research and Development concerning lateral flow technology until Chembio Diagnostic Systems Inc. acquired Sinovus Biotech AB in 2000. From 1993 to 1997, Mr. Esfandiari was Director of Research and Development with On-Site Biotech/National Veterinary Institute, Uppsala, Sweden, which was working in collaboration with Sinovus Biotech AB on development of veterinary lateral flow technology. Mr. Esfandiari received his B.Sc. in Clinical Chemistry and his M. Sc. in Molecular Biology from Lund University, Sweden. He has published articles in various veterinary journals and has co-authored articles on tuberculosis serology with Dr. Lyashchenko.

Sharon Klugewicz (46), Chief Operating Officer. Prior to joining the Company in September 2012, Ms. Klugewicz, served as Senior Vice President, Scientific & Laboratory Services at Pall Corporation (NYSE:PLL), a world leader in filtration, separation and purification technologies. Prior to that, Ms. Klugewicz held a number of positions at Pall Corporation over her 20-year tenure there, including in the Pall Life Sciences Division, in Marketing Product Management, and Field Technical Services, which included a position as Senior Vice President, Global Quality Operations. Ms. Klugewicz holds an M.S. in Biochemistry from Adelphi University and a B.S. in Neurobiology from Stony Brook University.

Tom Ippolito (51), VP of Regulatory Affairs, QA and QC. Mr. Ippolito joined Chembio in June 2005. He has over twenty years' experience with in vitro diagnostics for infectious diseases, protein therapeutics, vaccine development, Process Development, Regulatory Affairs and Quality Management. Over the years, Mr. Ippolito has held Vice President level positions at Biospecific Technologies, Corp. from 2000 - 2005, Director level positions in Quality Assurance, Quality Control, Process Development and Regulatory Affairs at United Biomedical, Inc. from 1987 - 2000. Mr. Ippolito is the Course Director for "drug development process" and "FDA Regulatory Process" for the BioScience Certificate Program at the New York State University of Stony Brook, a program he has been a part of since its inception in 2003.

Dr. Gary Meller M.D. (64), Director. Dr. Meller was elected to our Board of Directors in March 15, 2005, and currently serves on the Board's Audit, Compensation and Nominating And Corporate Governance Committees, including as Chairman of the Compensation Committee. Dr. Meller also served as Chairman of the Board's Special Committee for handling certain strategic opportunities. Dr. Meller has been the president of CommSense Inc., a healthcare business development company, since 2001. CommSense Inc. works with clients in Europe, Asia, North America, and the Middle East on medical information technology, medical records, pharmaceutical product development and financing, health services operations and strategy, and new product and new market development. From 1999 until 2001 Dr. Meller was the executive vice president, North America, of NextEd Ltd., a leading internet educational services company in the Asia Pacific region. Dr. Meller also was a limited partner and a member of the Advisory Board of Crestview Capital Master LLC, which at one time was our largest stockholder. Dr. Meller is a graduate of the University of New Mexico School of Medicine and has an MBA from the Harvard Business School. Dr. Meller's experience in the medical field both domestic and foreign (especially his experience with CommSense Inc.) as well as his financing experience made him an excellent candidate for serving on the board.

Kathy Davis (56), Director. Ms. Davis was elected to the Company's Board of Directors in May 2007, and currently serves on the Company's Audit, Compensation and Nominating And Corporate Governance Committees, including as Chairman of each of the Audit Committee and the Nominating And Corporate Governance Committee. She also is serving on the Company's CEO Search Committee. Since January 2007, Ms. Davis has been the owner of Davis Design Group LLC, a company that provides analytical and visual tools for public policy design. Previously, from February 2005 to December 2006, she served as the Chief Executive Officer of Global Access Point, a startup company with products for data transport, data processing, and data storage network and hub facilities. From October 2003 to January 2005, Ms. Davis was Lieutenant Governor of the State of Indiana, and from January 2000 to October 2003 was Controller of the City of Indianapolis. From 1989 to 2003, Ms. Davis held leadership positions with agencies and programs in the State of Indiana including State Budget Director, Secretary of Family & Social Services Administration, and Deputy Commissioner of Transportation. From 1982 to 1989 Ms. Davis held increasingly senior positions with Cummins Engine, where she managed purchasing, manufacturing, engineering, and assembly of certain engine product lines. Ms. Davis also led the startup of and initial investments by a $50 million Indiana state technology fund, Kathy serves as vice chair of the board of Noble of Indiana, director of Lumina Foundation for Education, Indiana University School of Public and Environmental Affairs Dean's Advisory Council, IU Public Policy Institute Advisory Council, WGU Indiana Advisory Council, Co-chair of the Shepherd Tech Arts Resource Team, columnist for Indianapolis Business Journal Forefront. She has a Masters of Business Administration from Harvard Business School and a Bachelor of Science in Mechanical Engineering from the Massachusetts Institute of Technology. Ms. Davis has varied experience in business, political and financial areas make her an excellent candidate for serving on the board.

Dr. Barbara DeBuono M.D., M.P.H., (58), Director **.** Dr. DeBuono, who was elected to the Company's Board of Directors in June 2011, serves on the Company's Compensation Committee and also as Chair of the CEO Search Committee. Dr. DeBuono is a renowned expert in public health innovation, health policy, education and research. She currently serves as Senior Vice President for Market Development at TREO Solutions, a data analytics and health system transformation company based in New York. Previously she held the post of President and CEO of ORBIS International, which is dedicated to saving sight and eliminating avoidable blindness worldwide. From 2009-2011, Dr. DeBuono was Chief Medical Officer, Partner and Global Director of Health and Social Marketing at Porter Novelli, and from 2000-2008 she was Executive Director, Public Health and Government at Pfizer Inc. Dr. DeBuono has served as Commissioner of Health for the state of New York and as Director of Health in Rhode Island and she was honored by the CDC Foundation in 2005 as one of five Public Health Heroes nationwide. She serves as adjunct professor at The George Washington University School of Public Health, and is a co-founder of The MAIA Foundation, a charity dedicated to women's health in sub-Saharan Africa. A Fellow of the American College of Physicians, Dr. DeBuono received her B.A. from the University of Rochester, her M.D. from the University of Rochester, School of Medicine, and a Masters in Public Health (M.P.H.) from Harvard University School of Public Health. Dr. DeBuono's experience in and knowledge of, both domestic and international, public health services, public health innovations, and the medical field make her an excellent candidate for serving on the board.

Dr. Peter Kissinger, Ph.D. (69), Director. Dr. Kissinger, who was elected to the Company's Board of Directors in June 2011 **,** serves on the Company's Audit Committee and is a member of the CEO Search Committee. Dr. Kissinger is a scientist, entrepreneur and academic, with a multi-faceted career in biotechnology and biomedical technologies. He is a Professor of Chemistry at Purdue University, West Lafayette, Indiana, and is the founder of Bioanalytical Systems, Inc. (NASDAQ: BASI), which he led from 1974-2007. Dr. Kissinger's academic research has involved the study of modern liquid chromatography techniques, and in vivo methodology for drug metabolism and the neurosciences. Dr. Kissinger has published more than 240 scientific papers and is a Fellow of the American Association of Pharmaceutical Scientists and the American Association for the Advancement of Science. In 2005, he became the Chairman of Prosolia, which markets mass spectrometry innovations for life science, industrial and homeland security applications. In 2007, he and Candice Kissinger founded Phlebotics, Inc., a medical device company focused on diagnostic information for intensive care medicine. He is a columnist for the trade publication Drug Discovery News. Dr. Kissinger received a B.S. in Chemistry from Union College, Schenectady, N.Y. and a Ph.D. in Analytical Chemistry from the University of North Carolina in Chapel Hill. Dr. Kissinger has knowledge of and experience in biotechnology and biomedical technologies as well as publicly-traded companies, all of which make him an excellent candidate for serving on the board.

Section 16(a) Beneficial Ownership Reporting Compliances

Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), requires the Company's directors, executive officers and beneficial owners of more than 10% of the Company's common stock to file with the Securities and Exchange Commission initial reports of ownership and reports of changes in ownership of common stock and other equity securities of the Company. The Company believes that during the year ended December 31, 2012, each person who was an officer, director and beneficial owner of more than 10% of the Company's common stock complied with all Section 16(a) filing requirements .

Code of Ethics

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

Identification of Audit Committee; Audit Committee Financial Expert

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

ITEM 11. EXECUTIVE COMPENSATION

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

Name / Principal Position	Year	Salary [1] ($)	Bonus [2] ($)	Stock Awards ($)	Option Awards [3] ($)	All Other Compensation [5] ($)	Total ($)
Lawrence A. Siebert [4]	2013	$ 290,000	$ 50,750	$ -	$ 21,610	$ 10,240	$ 372,600
CEO	2012	$ 290,000	$ 101,500	$ -	$ 28,217	$ 10,400	$ 430,117
Javan Esfandiari	2013	$ 292,462	$ 44,625	$ -	$ 141,078	$ 8,697	$ 486,862
VP-R&D	2012	$ 263,077	$ 89,250	$ -	$ 24,811	$ 7,608	$ 384,746
Sharon Klugewicz	2013	$ 233,642	$ 5,950	$ -	$ 18,551	$ 3,542	$ 261,685
COO	2012	$ 59,769	$ 5,950	$ -	$ 109,451	$ -	$ 175,170

1 Salary is total base salary.
2 Bonuses earned in 2013 were partially based on reaching certain objectives, which included revenue dollar levels and operating profit levels, additional amounts earned were discretionary.
3 The estimated fair value of any option or common stock granted was determined in accordance with ASC 718, "Stock-Based Payment".
4 Mr. Siebert also serves as a director on the Company's board of directors. Mr. Siebert does not receive any compensation for this director role.
5 Other compensation includes an employer match to 401(K) contributions and car allowances where applicable.

Employment Agreements

Mr. Siebert. Effective, April 19, 2013, the Compensation Committee of the Board of Directors extended the Company's employment agreement (the "Employment Agreement") with Lawrence A. Siebert, the Company's President and Chief Executive Officer, for an additional one-year term through May 11, 2014, with all other terms and conditions of the Employment Agreement remaining the same. In September 2013, Mr. Siebert informed the Company that he intends to retire from his positions as President and CEO upon expiration of his contract in May 2014. Previously, effective, May 11, 2011, the Compensation Committee of the Board of Directors extended the Company's employment agreement (the "Employment Agreement") with Lawrence A. Siebert, the Company's President and Chief Executive Officer, for an additional one-year term through May 11, 2013, with an increase in salary to $290,000 per year. Previously, effective May 11, 2009, the Company's Board of Directors had approved the Company's extension of the June 15, 2006 Employment Agreement for an additional three-year term through May 11, 2012. On June 15, 2006, Mr. Siebert and the Company entered into an Employment Agreement, effective May 10, 2006, which was to terminate on May 10, 2008, extended in 2008 to May 10, 2009. Pursuant to the Employment Agreement, Mr. Siebert serves as the President and Chief Executive Officer of the Company and received an initial salary of $240,000 per year, which had been increased to $265,000 per year until Mr. Siebert agreed to a 15 percent reduction, to $225,000, effective January 19, 2009. Mr. Siebert's salary was restored to $265,000 per annum effective in July 2009. Mr. Siebert also is eligible for a bonus of up to 50% of his salary, consisting of (i) a bonus of up to 25% of his salary that is at the complete discretion and determination of the board of directors, and (ii) a bonus of up to an additional 25% of his salary that will be determined based upon revenue and earnings performance criteria established each year by the board of directors. Mr. Siebert is eligible to participate in any profit sharing, stock option, retirement plan, medical and/or hospitalization plan, and/or other benefit plans except for disability and life insurance that the Company may from time to time place in effect for the Company's executives during the term of Mr. Siebert's employment agreement. If Mr. Siebert's Employment Agreement is terminated by the Company without cause, or if Mr. Siebert terminates his Employment Agreement for a reasonable basis, as defined in the Employment Agreement, including within 12 months of a change in control, the Company is required to pay as severance Mr. Siebert's salary for six months. Mr. Siebert has agreed for a period of two years after the termination of his employment with the Company not to induce customers, agents, or other sources of distribution of the Company's business under contract or doing business with the Company to terminate, reduce, alter, or divert business with or from the Company. The terms of the extended May 11, 2011, May 11, 2009 and May 11, 2008 Employment Agreements are identical to the June 15, 2006 Employment Agreement, except that under the May 11, 2008 extended Employment Agreement, Mr. Siebert received additional consideration in the form of incentive stock options to purchase 31,250 shares of the Company's common stock exercisable at $1.04 per share, which was the closing price of the Company's common stock on June 3, 2008. The incentive stock options are immediately exercisable and they expire on the June 3, 2013.

Mr. Esfandiari. The Company entered into an employment agreement effective March 5, 2013 (the "Employment Agreement"), with Mr. Esfandiari to continue as the Company's Senior Vice President of Research and Development for an additional term of three years through March 5, 2016. Mr. Esfandiari's salary under the Employment Agreement is $300,000 for the first year, with possible increases for the second year and /or for the third year. Mr. Esfandiari is eligible for a performance-based bonus of up to 50% of his base salary for each respective year, which is in the same proportions as described below under "Executive Bonus Plan". The Company also granted Mr. Esfandiari, pursuant to the Company's 2008 Stock Incentive Plan, incentive stock options to purchase 30,000 shares of the Company's common stock. The price per share of these options is equal to the fair market value of the Company's common stock as of the close of the market on March 5, 2013, which is the date on which the Agreement was effective. Of these stock options, options to purchase 10,000 shares vest on each of the first three anniversaries of the effective date of the Employment Agreement. Mr. Esfandiari is eligible to participate in any profit sharing, stock option, retirement plan, medical and/or hospitalization plan, and/or other benefit plans except for disability and life insurance that the Company may from time to time place in effect for the Company's executives during the term of Mr. Esfandiari's employment agreement. If Mr. Esfandiari's employment agreement is terminated by the Company without cause, or if Mr. Esfandiari terminates his employment agreement for a reasonable basis, as defined in the Employment Agreement, including within 12 months of a change in control, the Company is required to pay as severance Mr. Esfandiari's salary for twelve months.

Ms. Klugewicz. The Company entered into an employment agreement dated May 22, 2013 with Ms. Klugewicz's (the "Employment Agreement"), effective May 22, 2013 (the "Effective Date"). The Agreement provides that she will serve as the Company's COO for a term of two years. Ms. Klugewicz will receive an annual salary of $250,000, with the option of a discretionary, performance-based annual cash bonus of up to 37.5% of her base salary. The Employment Agreement also provides for a grant of 5,000 options to purchase shares of the Company's common stock, vesting at a rate of 2,500 shares on each of the first and second anniversaries of the Effective Date. In the event Ms. Klugewicz's employment is terminated by reason of disability or for "cause", as defined in the Employment Agreement, all compensation including her base salary, her right to receive a performance bonus, and the vesting of any unvested options, will cease as of her termination date, and Ms. Klugewicz will receive no severance benefits. If the Company terminates Ms. Klugewicz's employment without cause or Ms. Klugewicz terminates her employment for a reasonable basis, as defined in the Employment Agreement (which definition includes involuntary termination within a six-month period upon a "Change of Control"), then the Company will pay Ms. Klugewicz her base salary for a period of six months as severance, and all her unvested stock options shall immediately become vested. The Employment Agreement also contains provisions prohibiting Ms. Klugewicz from (i) soliciting the Company's employees for a period of twenty-four months following her termination, (ii) soliciting the Company's customers, agents, or other sources of distribution of the Company's business for a period of twelve months following her termination, and (iii) for a period of twelve months following termination of this Agreement, except where termination is involuntary upon a "Change in Control," engaging or participating in any business that directly competes with the business activities of the Company in any market in which the Company is in business or plans to do business. The foregoing description of the Employment Agreement is qualified in its entirety by reference to the full text of the Employment Agreement.

Neither Mr. Larkin, Mr. Ippolito nor Mr. Steele has an employment contract with the Company.

Executive Bonus Plan

The Company has established a bonus plan for its executives who do not have a contract. For the fiscal year ended December 31, 2013, there were three executives eligible for this bonus plan. Each executive can earn up to 25% of that executive's salary in the form of a cash bonus. The Compensation Committee determined that 80% of the executive's bonus will be quantitative factors, based on the budget. 20% will be based on other factors and will be discretionary. The plan, during 2013 for the 80%, called for a sliding percentage of the executive's salary, from zero to 10% for attaining certain revenue goals, and from zero to 10% of the executive's salary for attaining certain operating profit goals. The Company achieved approximately 98.75% of its revenue goals for 2013, which would result in a bonus of 7% of each executive's salary, and achieved 110% of its operating profit goal, which would result in a bonus of 1% of salary, for a total of 8% of salary. The Compensation Committee granted approximately 15% of salary in bonuses for the three subject executives.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END 2013

	Option Awards					Stock Awards		
Name	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price ($)	Option Expiration Date	Option Vesting Date	Number of Shares of Stock That Have Not Vested (#)	Market Value of Shares of Stock That Have Not Vested ($)	Foot-note
Lawrence A. Siebert	5,215		5.56	2/26/2018	2/16/2013			**4**
	9,063		4.00	2/16/2017	2/16/2012			**3**
	16,667		1.04	5/6/2014	5/6/2012			**2**
	16,667		1.04	5/6/2014	5/7/2011			**2**
	16,667		1.04	5/6/2014	5/6/2010			**2**
Javan Esfandiari	10,000		5.44	3/5/2018	3/5/2014			**1**
		10,000	5.44	3/5/2018	3/5/2015			**1**
		10,000	5.44	3/5/2018	3/5/2016			**1**
	4,765		5.56	2/26/2018	2/16/13			**4**
	7,969		4.00	2/16/2017	2/16/2012			**3**
	12,500		2.16	3/4/2015	3/5/2013			**1**
	12,500		2.16	3/4/2015	3/5/2012			**1**
	12,500		2.16	3/4/2015	3/5/2010			**1**
	12,500		1.04	5/6/2014	5/6/2012			**2**
Sharon Klugewicz		2,500	4.50	5/22/2018	5/22/2014			**1**
		2,500	4.50	5/22/2018	5/22/2015			**1**
	630		5.56	2/6/2018	2/6/2013			**4**
	12,000		4.45	9/4/2017	9/4/2013			**5**
		12,000	4.45	9/4/2017	9/4/2014			**5**
		12,000	4.45	9/4/2017	9/4/2015			**5**

1 Options issued in connection with an employment contract and under the 2008 Stock Incentive Plan.

2 On May 7, 2009 in accordance with the terms of the Company's 2008 Stock Incentive Plan, the Company granted certain employees of the Company, options to purchase an aggregate of 365,625 shares of the Company's common stock. The exercise price for these options is equal to $1.04 per share. The options become exercisable in thirds on the first, second and third anniversaries of the date of the grant. Each option granted will expire and terminate, if not exercised sooner, upon the earlier to occur of (a) 30 days after termination of the employee's employment with the Company or (b) the fifth anniversary of the date of grant. The fair value of these options is being amortized over the vesting life of the options.

3 On February 16, 2012, the Company determined to grant on February 16, 2012, to certain employees of the Company, options to purchase an aggregate of 203,125 shares of the Company's common stock. The exercise price for these options was the last traded market price for the Company's common stock on February 16, 2012, which was $4.00 per option. The options become exercisable on the effective date of the grant. Each option granted will expire and terminate, if not exercised sooner, upon the earlier to occur of (a) 30 days after termination of the employee's employment with the Company or (b) the fifth anniversary of the effective date of grant.

4 On February 26, 2013, the Company determined to grant on February 26, 20123 to certain employees of the Company, options to purchase an aggregate of 16,360 shares of the Company's common stock. The exercise price for these options was the last traded market price for the Company's common stock on February 26, 2013, which was $5.56 per option. The options become exercisable on the effective date of the grant. Each option granted will expire and terminate, if not exercised sooner, upon the earlier to occur of (a) 30 days after termination of the employee's employment with the Company or (b) the fifth anniversary of the effective date of grant.

5 Options issued in connection with the start of employment with the Company and under the 2008 Stock Incentive Plan.

Director Compensation

All non-employee directors are paid an $18,000 annual retainer in semi-annual payments, and once every five years, on the date of the annual meeting of stockholders that directors are elected or re-elected (every 5 years), receive stock options to acquire, subject to vesting as described below, 46,875 shares of the Company's common stock, with an exercise price equal to the market price on the date of the grant. Stock options to acquire 9,375 shares become exercisable on the date of grant, and options to acquire an additional 9,375 shares become exercisable on the date of each of the four succeeding annual meetings of stockholders if and to the extent that the non-employee director is reelected as a director at each such annual meeting. The audit committee chairman is paid an annual retainer of $2,500, paid semi-annually. In addition, the non-employee directors are paid $1,000 in cash for each board of directors' meeting attended, and paid $500 in cash for each telephonic board of directors meeting. The non-employee directors who are members of a committee of the board of directors are paid $500 in cash for each committee meeting attended, or $750 in cash for each committee meeting attended if that non-employee director is the committee chairman. Directors also may be paid for serving ad hoc committees of the Board. In fact, when the Board established its Special Committee in 2013 to handle the search for a new CEO, the Chairman of the Committee was paid $12,000 per month, and the other two director-members of the Committee was paid $8,000 per month.

DIRECTOR COMPENSATION

Name	Fees Earned or Paid in Cash ($) [1]	Option Awards ($) [2]	Total ($)
Katherine L. Davis	$ 62,500	$ -	$ 62,500
Barbara DeBuono	67,000	-	67,000
Pete Kissinger	56,500	-	56,500
Gary Meller	29,500	-	29,500

1 Fees earned or paid in cash represents a yearly fee and fees for meeting expenses: (a) Ms.Davis received an $18,000 annual fee as a member of the board of directors, a $2,500 annual fee as Audit Committee chairman, $30,000 in fees as a member of the CEO Search Committee and $12,000 in meeting fees earned during 2013; (b) Dr. DeBuono received an $18,000 annual fee as a member of the board of directors, $40,000 in fees as chairperson of the CEO Search Committee and 9,000 in meeting fees; (c) Dr. Kissinger received an $18,000 annual fee as a member of the board of directors, $30,000 in fees as a member of the CEO Search Committee and $8,500 in meeting fees; (d) Dr. Meller received an $18,000 annual fee as a member of the board of directors, and $11,500 in meeting fees.

2 Each outside member of the board of directors is granted, once every five years, the right to purchase 375,000 shares of the company's common stock with an exercise price equal to the market price on the date of the grant as part of their annual compensation. One-fifth of these options are exercisable on the date of grant, one-fifth become exercisable on the first anniversary of the date of grant, and additional one-fifths become exercisable on the second through fourth anniversary of the date of grant. The fair value of options at the date of grant was estimated using the Black-Scholes option pricing model.

Compensation Committee Interlocks and Insider Participation

No executive officer of the Company served as a member of the Board of any other public company during the year ended December 31, 2013. No member of the Compensation Committee served as an executive officer of any other public company during the year ended December 31, 2013. No interlocking relationship exists between the members of our Compensation Committee and the Board or compensation committee of any other company. As of March 1, 2014, the members of the Compensation Committee were Gary Meller (Chairman), Katherine Davis, and Barbara DeBuono, all of whom are deemed by the Board of Directors to be independent.

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

The following table sets forth certain information regarding the beneficial ownership of our common stock by each person or entity known by us to be the beneficial owner of more than 5% of the outstanding shares of common stock, each of our directors, each of our "named executive officers", and all of our directors and executive officers as a group as of March 1, 2014.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percent of Class
Siebert, Lawrence [1] 3661 Horseblock Road Medford, NY 11763	853,789	9.09%
Esfandiari, Javan [2] 3661 Horseblock Road Medford, NY 11763	156,235	1.66%
Larkin, Richard [3] 3661 Horseblock Road Medford, NY 11763	68,620	.73%
Ippolito, Tom [4] 3661 Horseblock Road Medford, NY 11763	46,799	.50%
Steele, Michael [5] 3661 Horseblock Road Medford, NY 11763	12,785	.14%
Klugewicz, Sharon [6] 3661 Horseblock Road Medford, NY 11763	22,630	.24%
Meller, Gary [7] 3661 Horseblock Road Medford, NY 11763	95,625	1.02%
Davis, Katherine L. [8] 3661 Horseblock Road Medford, NY 11763	48,922	.52%
DeBuono, Barbara [9] 3661 Horseblock Road Medford, NY 11763	30,079	.32%
Kissinger, Peter [10] 3661 Horseblock Road Medford, NY 11763	30,079	.32%
GROUP [11]	**1,365,562**	**14.06%**
Wellington Management Company, LLP 280 Congress Street Boston, MA 02210	670,980	7.20%
Norman H. Pessin 366 Madison Ave, 14 th Floor New York, NY 10017	449,770	4.82%

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

The beneficial ownership percent in the table is calculated with respect to the number of outstanding shares (8,086,114) of the Company's common stock outstanding as of March 6, 2013; and with respect to each stockholder, the denominator is the sum of the number of common shares outstanding and the number, if any, of outstanding options included in that stockholder's beneficial ownership. Each stockholder's ownership is calculated as the number of shares of common stock owned plus the number of shares of common stock into which any preferred stock, warrants, options or other convertible securities owned by that stockholder can be converted within 60 days.

The term "named executive officer" refers to our principal executive officer, our two most highly compensated executive officers other than the principal executive officer who were serving as executive officers at the end of 2012, and two additional individuals for whom disclosure would have been provided but for the fact that the individuals were not serving as executive officers of the Company at the end of 2012.

(1) Includes 64,279 shares issuable upon exercise of options exercisable within 60 days.
(2) Includes 72,734 shares issuable upon exercise of options exercisable within 60 days. Does not include 20,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(3) Includes 48,217 shares issuable upon exercise of options exercisable within 60 days. Does not include 9,375 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(4) Includes 40,712 shares issuable upon exercise of options exercisable within 60 days. Does not include 7,812 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(5) Includes 12,785 shares issuable upon exercise of options exercisable within 60 days. Does not include 24,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(6) Includes 12,630 shares issuable upon exercise of options exercisable within 60 days. Does not include 29,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(7) Includes 37,500 shares issuable upon exercise of options exercisable within 60 days. Does not include 9,375 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(8) Includes 37,500 shares issuable upon exercise of options exercisable within 60 days. Does not include 9,375 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(9) Includes 30,079 shares issuable upon exercise of options exercisable within 60 days. Does not include 18,750 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(10) Includes 30,079 shares issuable upon exercise of options exercisable within 60 days. Does not include 18,750 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(11) Includes footnotes (1)-(10).

Equity Compensation Plan Information

	Combined Equity Compensation Plans - Information as of December 31, 2013		
Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column (a)
	(a)	(b)	(c)
Equity compensation plans approved by security holders [1]	656,398	$ 2.57	43,132
Equity compensation plans not approved by security holders	-	-	-
Total	656,398	$ 2.57	43,132

1 The "Number of Securities to be Issued Upon Exercise of Outstanding Warrants and Rights" represents 93,750 from the 1999 Stock Option Plan and 562,648 under the 2008 Stock Incentive Plan. The 2008 Stock Incentive Plan was increased by 125,000 units at the Annual Stockholder meeting held September 23, 2011. The "Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans" represents shares issuable under the 2008 Stock Incentive Plan.

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

The executive officers of the Company are as follows: Lawrence A. Siebert, president, chief executive officer and chairman of the board of directors of the Company, Sharon Klugewicz, chief operating officer, Richard J. Larkin, chief financial officer of the Company, and Javan Esfandiari, executive vice president of Research and Development of the Company.

On February 16, 2012, the Company granted options to purchase the following numbers of shares of the Company's common stock set forth below to the executive officers of the Company named below. The exercise price for these options was the last traded market price for the Company's common stock on February 16, 2012, which was $4.00 per option. The options become exercisable on the effective date of the grant. Each option granted will expire and terminate, if not exercised sooner, upon the earlier to occur of (a) 30 days after termination of the employee's employment with the Company or (b) the fifth anniversary of the effective date of grant.

Name of Executive Officer	Number of Shares of Common Stock Options
Richard Bruce - Vice President of Operations	2,563
Javan Esfandiari – Executive Vice President of R&D	7,969
Tom Ippolito - Vice President of Regulatory Affairs, QA & QC	3,000
Richard J. Larkin – Chief Financial Officer	2,797
Lawrence A. Siebert – Chief Executive Officer	9,063

On February 25, 2013, the Company granted options to purchase the following numbers of shares of the Company's common stock set forth below to the executive officers of the Company named below. The exercise price for these options was the last traded market price for the Company's common stock on February 26, 2013, which was $5.56 per option. The options become exercisable on the effective date of the grant. Each option granted will expire and terminate, if not exercised sooner, upon the earlier to occur of (a) 30 days after termination of the employee's employment with the Company or (b) the fifth anniversary of the effective date of grant.

Name of Executive Officer	Number of Shares of Common Stock Options
Richard Bruce - Vice President of Operations	1,520
Javan Esfandiari – Executive Vice President of R&D	4,765
Tom Ippolito - Vice President of Regulatory Affairs, QA & QC	1,775
Sharon Klugewicz – Vice President of QA/QC	630
Richard J. Larkin – Chief Financial Officer	1,670
Lawrence A. Siebert – Chief Executive Officer	5,215
Michael Steele – Vice President of Sales and Marketing	785

The Company entered into an employment agreement effective March 5, 2013 (the "Employment Agreement"), with Mr. Esfandiari to continue as the Company's Senior Vice President of Research and Development for an additional term of three years through March 5, 2016. The Company entered into an employment agreement, effective May 22, 2013 (the "Employment Agreement"), with Ms. Klugewicz to become the Company's Chief Operating Officer for a term of two years through May 22, 2015. See Item 11 for more details.

Director Independence

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

ITEM 14. **PRINCIPAL ACCOUNTANT FEES AND SERVICES**

Audit Fees

For the years ended December 31, 2013 and 2012 the Company engaged BDO USA, LLP as its independent accounting firm to audit of the Company's annual financial statements included on Form 10-K, including reviews of the quarterly financial statements and assistance with and review of documents filed with the SEC, for $159,950 and $119,000 respectively in fees.

Audit-Related Fees

For the years ended December 31, 2013 and 2012, the Company's independent accounting firm, BDO USA, LLP, did not provide the Company with any assurance and related services reasonably related to the performance of the audit or review of the Company's financial statements that are not reported above under "Audit Fees."

Tax Fees

For the years ended December 31, 2013 and 2012, the Company's independent accounting firm, BDO USA, LLP, billed the Company $17,500 and $20,000, respectively for professional services for tax compliance, tax advice and tax planning.

All Other Fees

For the years ended December 31, 2013 and 2012, the Company's independent accounting firm, BDO USA, LLP, did not provide the Company with any services for other matters.

Audit Committee Pre-Approval Policies

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

ITEM 15.

EXHIBITS INDEX

Number	Description
3.1	Articles of Incorporation, as amended. (1)
3.2	Amended and Restated Bylaws. (2)
4.1*	Form of Employee Option Agreement. (3)
4.2	1999 Equity Incentive Plan, as amended. (5)
4.3	2008 Stock Incentive Plan, as amended. (5)
4.4	Rights Agreement, dated March 8, 2010 (6)
4.5	Form of Warrant (to be filed by amendment)
10.1*	Employment Agreement dated June 15, 2006 with Lawrence A. Siebert, as extended. (7)(11)
10.2*	Employment Agreement dated March 5, 2013 with Javan Esfandiari (10).
10.3*	Employment Agreement dated May 22, 2013 with Sharon Klugewicz (12)
10.3	HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Alere and StatSure. (8)
10.4	HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (8)
10.5	Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (8)
10.6	Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (8)
10.8	Secured Revolving Demand Note, dated as of April 30, 2013, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (12)
10.9	Loan and Security Agreement, dated as of April 30, 2013, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (12)
14.1	Ethics Policy (9)
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 annual report on Form 10-KSB filed with the Commission on March 31, 2005.
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 annual report on Form 10-KSB filed with the Commission on March 12, 2008.
4	Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on May 11, 2005.
5	Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on Auguust 3, 2012.
6	Incorporated by reference to the Registrant's registration statement on Form 8-A filed with the Commission on March 11, 2010.
7	Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on June 21, 2006.
8	Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on October 5, 2006.
9	Incorporated by reference to the Registrant's Annual Report on Form 10-KSB filed with the Commission on March 30, 2006.
10	Incorporated by reference to the Registrant's Annual Report on Form 10-K filed with the Commission on March 7, 2013.
11	Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on April 25, 2013.
12	Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on August 8, 2013.
(*)	An asterisk (*) beside an exhibit number indicates the exhibit contains a management contract, compensatory plan or arrangement which is required to be identified in this report.

SIGNATURES

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

CHEMBIO DIAGNOSTICS, INC.

Date: March 6, 2013

By /s/ Lawrence A. Siebert
Lawrence A. Siebert
President, Chief Executive Officer and
Chairman 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/ Lawrence A. Siebert Lawrence A. Siebert	Chief Executive Officer, President and Chairman Of The Board (Principal Executive Officer)	March 6, 2014
/s/ Richard J. Larkin Richard J. Larkin	Chief Financial Officer (Principal Financial & Accounting Officer)	March 6, 2014
/s/ Gary Meller Dr. Gary Meller	Director	March 6, 2014
/s/ Katherine L. Davis Katherine L. Davis	Director	March 6, 2014
/s/ Pete Kissinger Pete Kissinger	Director	March 6, 2014
/s/ Barbara DeBuono Barbara DeBuono	Director	March 6, 2014

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, 2013 and 2012 and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the 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, 2013 and 2012, and the consolidated results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

BDO USA, LLP

/s/ BDO USA, LLP

Melville, New York
March __ , 2014

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

- ASSETS -

	December 31, 2013	December 31, 2012
CURRENT ASSETS:		
Cash and cash equivalents	**$ 9,650,275**	$ 2,951,859
Accounts receivable, net of allowance for doubtful accounts of $24,000 and $58,000 at December 31, 2013 and 2012, respectively	**4,592,121**	4,821,357
Inventories	**3,188,726**	2,488,071
Prepaid expenses and other current assets	**1,099,379**	747,463
TOTAL CURRENT ASSETS	**18,530,501**	11,008,750
FIXED ASSETS , net of accumulated depreciation	**1,978,232**	1,427,646
OTHER ASSETS:		
Deferred tax asset, net of valuation allowance	**3,590,207**	4,233,194
License agreements, net of current portion	**326,875**	400,000
Deposits on manufacturing equipment	**16,410**	223,584
Deposits and other assets	**44,367**	41,976
TOTAL ASSETS	**$ 24,486,592**	$ 17,335,150
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	**$ 4,309,490**	$ 3,303,923
Current portion of loans payable	**-**	51,236
Customer deposits	**-**	23,224
Current portion of obligations under capital leases	**-**	-
TOTAL CURRENT LIABILITIES	**4,309,490**	3,378,383
OTHER LIABILITIES:		
Loans payable - net of current portion	**-**	82,247
TOTAL LIABILITIES	**4,309,490**	3,460,630
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Preferred stock – 10,000,000 shares authorized, none outstanding	**-**	-
Common stock - $.01 par value; 100,000,000 shares authorized, 9,324,783 and 8,036,232 shares issued and outstanding for 2013 and 2012, respectively	**93,248**	80,362
Additional paid-in capital	**46,875,027**	41,116,149
Accumulated deficit	**(26,791,173)**	(27,321,991)
TOTAL STOCKHOLDERS' EQUITY	**20,177,102**	13,874,520
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 24,486,592**	$ $ 17,335,150

See accompanying notes to condensed consolidated financial statements

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

	For the years ended	
	December 31, 2013	December 31, 2012
REVENUES:		
Net product sales	**$ 27,515,786**	$ 24,327,355
License and royalty revenue	**4,906**	-
R&D, milestone and grant revenue	**2,028,917**	1,283,240
TOTAL REVENUES	**29,549,609**	25,610,595
Cost of product sales	**17,249,450**	14,820,604
GROSS MARGIN	**12,300,159**	10,789,991
OPERATING EXPENSES:		
Research and development expenses	**5,834,249**	4,486,302
Selling, general and administrative expenses	**5,461,083**	4,851,587
	11,295,332	9,337,889
INCOME FROM OPERATIONS	**1,004,827**	1,452,102
OTHER INCOME (EXPENSE):		
Other income	**7,500**	-
Interest income	**5,778**	7,911
Interest expense	**(335)**	(9,495)
	12,943	(1,584)
INCOME BEFORE INCOME TAXES	**1,017,770**	1,450,518
Income tax provision	**486,952**	509,237
NET INCOME	**$ 530,818**	$ 941,281
Basic earnings per share	**$ 0.06**	$ 0.12
Diluted earnings per share	**$ 0.06**	$ 0.11
Weighted average number of shares outstanding, basic	**8,994,080**	7,986,030
Weighted average number of shares outstanding, diluted	**9,519,968**	8,614,944

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, 2013 AND 2012

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount	Amount	Amount	Amount
Balance at December 31, 2011	7,921,021	$ 79,210	$ 40,678,696	$ (28,263,272)	$ 12,494,634
Common Stock:					
Consulting Services	3,752	38	16,441	-	16,479
Options:					
Exercised	111,459	1,114	119,276	-	120,390
Stock option compensation	-	-	293,726	-	293,726
Consulting Services-options	-	-	8,010	-	8,010
Net income	-	-	-	941,281	941,281
Balance at December 31, 2012	8,036,232	$ 80,362	$ 41,116,149	$ (27,321,991)	$ 13,874,520
Common Stock:					
New Stock from Offering	1,200,000	12,000	5,396,462	-	5,408,462
Options:					
Exercised	88,551	886	30,546	-	31,432
Stock option compensation	-	-	331,870	-	331,870
Net income	-	-	-	530,818	530,818
Balance at December 31, 2013	9,324,783	$ 93,248	$ 46,875,027	$ (26,791,173)	$ 20,177,102

See accompanying notes to consolidated financial statements

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

	December 31, 2013	December 31, 2012
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	**$ 29,778,845**	$ 23,810,911
Cash paid to suppliers and employees	**(27,506,674)**	(23,048,243)
Interest received	**5,778**	7,911
Interest paid	**(335)**	(9,495)
Net cash provided by operating activities	**2,277,614**	761,084
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of and deposits on fixed assets	**(885,609)**	(872,442)
Net cash used in investing activities	**(885,609)**	(872,442)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from option and warrant exercises	**31,432**	120,390
Proceeds from sale of common stock, net	**5,408,462**	
Payment of loan obligation	**(133,483)**	(53,551)
Payment of capital lease obligation	**-**	(14,576)
Net cash provided by (used in) financing activities	**5,306,411**	52,263
(DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	**6,698,416**	(59,095)
Cash and cash equivalents - beginning of the period	**2,951,859**	3,010,954
Cash and cash equivalents - end of the period	**$ 9,650,275**	$ 2,951,859
RECONCILIATION OF NET INCOME TO NET CASH PROVIDED BY OPERATING ACTIVITIES:		
Net Income	**$ 530,818**	$ 941,281
Adjustments:		
Depreciation and amortization	**607,822**	523,278
Provision for deferred taxes	**458,154**	471,085
Provision for doubtful accounts	**(34,000)**	28,000
Share based compensation	**331,870**	318,215
Changes in assets and liabilities:		
Accounts receivable	**263,236**	(1,850,908)
Inventories	**(700,655)**	(187,785)
Prepaid expenses and other current assets	**(159,583)**	(20,227)
Deposits and other assets	**(2,391)**	498
Accounts payable and accrued liabilities	**1,005,567**	514,423
Customer deposits and deferred revenue	**(23,224)**	23,224
Net cash provided by operating activities	**$ 2,277,614**	$ 761,084
Supplemental disclosures for non-cash investing and financing activities:		
Deposits on manufacturing equipment transferred to fixed assets	**$ 521,561**	$ 229,042

See accompanying notes to condensed consolidated financial statements

NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. (the "Company" or "Chembio") and its subsidiary, Chembio Diagnostic Systems, Inc., 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 74% of the Company's product revenues in 2013. The Company's products based on its patented DPP® platform represented approximately 24% of the Company's product revenues in 2013. The Company also has other rapid tests that together represented approximately 2% of sales in 2013. The Company's products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments both domestically and internationally. Chembio's products are sold under the Company's STAT-PAK®, SURE CHECK® or DPP® registered trademarks, or under the private labels of its marketing partners, for example the Clearview® label owned by Alere, Inc. ("Alere"), which is the Company's exclusive marketing partner for its rapid HIV lateral flow test products in the United States. These products employ lateral flow technologies that are proprietary and/or licensed to the Company. 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.

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. The Company's debt relates to borrowings under its credit facilities and term loan (see Note 7), which approximates fair value due to market interest rates.

(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. We currently do not require collateral for accounts receivable.

(f) ***Inventories:***

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

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

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

(h) ***License Agreement:***

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, 2013 and 2012 and is reported in prepaid expenses and other current assets. The long-term portion as of December 31, 2013 and 2012 is $300,000 and $400,000, respectively and is reflected in other assets on the consolidated balance sheet.

(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, 2013 and 2012, 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. As of December 31, 2013 and 2012, an aggregate of none and $23,224, respectively, of customer deposits were not recognized.

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. As of December 31, 2013 and 2012, all advanced revenues were earned.

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

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

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

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

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

(m) *I* ***ncome 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.

(n) ***Earnings Per Share***

On May 30, 2012, the Company effected a 1-for-8 reverse split of its common stock. This was done to allow the Company to move to the NASDAQ trading market from the OTCQB market, which occurred on June 7, 2012. As a result of the stock split, the outstanding 63,967,263 common shares were reduced to 7,995,918 outstanding common shares on May 30, 2012. The effect of the reverse stock split has been retroactively reflected for all periods in these financial statements.

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

	For the years ended	
	December 31, 2013	December 31, 2012
Basic	**8,994,080**	7,986,030
	-	-
Diluted	**9,519,968**	8,614,944

Basic earnings per share is computed by dividing net earnings attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted earnings per share for the year ended December 31, 2013 and 2012 reflects the potential dilution from the exercise or conversion of other securities into common stock.

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, 2013	December 31, 2012
1999 and 2008 Plan Stock Options	**525,888**	628,914

There were 169,662 and 161,464 options and warrants outstanding as of December 31, 2013 and 2012, 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:***

New accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standards setting bodies that we adopt according to the various timetables the FASB specifies. The Company does not expect the adoption of recently issued accounting pronouncements to have a significant impact on the Company's results of operations, financial position or cash flow.

NOTE 3 — INVENTORIES:

Inventories consist of the following at:

	December 31, 2013	December 31, 2012
Raw materials	**$ 1,710,627**	$ 1,418,071
Work in process	**464,481**	561,530
Finished goods	**1,013,618**	508,470
	$ 3,188,726	$ 2,488,071

NOTE 4 — FIXED ASSETS:

Fixed assets consist of the following at:

	December 31, 2013	December 31, 2012
Machinery and equipment	**$ 3,158,265**	**$ 2,439,596**
Furniture and fixtures	**352,923**	**287,412**
Computer and telephone equipment	**167,045**	**151,737**
Leasehold improvements	**1,016,783**	**798,049**
Automobiles	**37,061**	**29,228**
	4,732,077	**3,706,022**
Less accumulated depreciation and amortization	**(2,753,845)**	**(2,278,376)**
	$ 1,978,232	**$ 1,427,646**

There were no capital leases at the end of December 31, 2013. Fixed assets at December 31, 2013 also include $493,000 in equipment, which has been delivered and set-up but is undergoing validation and as such is currently not being depreciated. Depreciation expense for the 2013 and 2012 years aggregated $505,000 and $423,000, respectively.

As of December 31, 2013 and 2012, the Company had paid deposits on various pieces of equipment aggregating $16,410 and $223,584, respectively. The Company is further committed to an additional obligation of $31,990 as various milestones are achieved by the various vendors.

NOTE 5 — ACCOUNTS PAYABLE AND ACCRUED LIABILITIES:

Accounts payable and accrued liabilities consist of the following at:

	December 31, 2013	December 31, 2012
Accounts payable – suppliers	**$ 1,815,369**	$ 1,686,431
Accrued commissions	**371,905**	238,150
Accrued royalties / license fees	**1,028,286**	583,923
Accrued payroll	**328,564**	262,439
Accrued vacation	**203,444**	181,636
Accrued bonuses	**317,372**	155,663
Accrued expenses – other	**244,550**	195,681
TOTAL	**$ 4,309,490**	$ 3,303,923

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, 2013 and 2012, there were no unearned advanced revenues.

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 allows 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 is payable monthly at an interest rate equal to one-quarter percent above prime per annum. The Company can repay any or all of the principal balance outstanding at any time. This is a demand note for which the bank lender can demand repayment of the entire loan, with accrued interest, at any time. The loan is subject to annual reviews, as well as an annual 30-day clean-up, during which there can be no amounts outstanding.

The Security Agreement, related to the Demand Note, contains covenants that place 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. As of December 31, 2013, nothing had been drawn down on the Demand Note and all covenants were met.

NOTE 8 — INCOME TAXES:

The provision for income taxes for the years ended December 31, 2013 and 2012, is comprised of the following:

	2013	2012
Current		
Federal	**$ 27,175**	$ 33,054
State	**1,623**	5,098
Total current provision	**28,798**	38,152
Deferred		
Federal	**454,439**	464,005
State	**3,715**	7,080
Total deferred provision	**458,154**	471,085
Total provision	**$ 486,952**	$ 509,237

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, 2013, the Company has post-change net operating loss carry-forwards of approximately $10,551,034 which expire between 2020 and 2028. In addition the Company has research and development tax credit carryforwards of approximately $1,052,000 for the year ended December 31, 2013, which expire between 2025 and 2033.

	2013	2012
Current assets		
Inventory reserves	**$ 307,080**	$ 224,694
Accrued expenses	**329,187**	226,740
Net current deferred asset	**$ 636,267**	$ 451,434
Noncurrent assets		
Net operating loss carry-forwards	**$ 3,616,089**	$ 4,236,008
Research and development credit	**1,052,166**	711,444
Other credits	**124,413**	97,234
Other	**107,808**	99,097
Gross noncurrent deferred tax assets	**4,900,476**	5,143,783
Depreciation	**(258,103)**	(199,145)
Noncurrent deferred tax assets	**4,642,373**	4,944,638
Less valuation allowances	**(1,052,166)**	(711,444)
Net noncurrent deferred tax assets	**$ 3,590,207**	$ 4,233,194

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,	
	2013	2012
Federal income tax at statutory rates	**34.00%**	34.00%
State income taxes, net of federal benefit	**.47%**	0.70%
Nondeductible expenses	**10.27%**	5.40%
Change in valuation allowance	**33.48%**	8.90%
Tax credits	**(33.48)%**	(8.90)%
Change in tax rates	**3.10%**	(5.20)%
Other	**(.01)%**	0.20%
Income tax (benefit)	**47.83%**	35.10%

Interest and penalties, if any, related to income tax liabilities are included in income tax expense. As of December 31, 2013, the Company does not have a liability for uncertain tax positions.

The Company files Federal and New York state income tax returns. Tax years for fiscal 2010 through 2012 are open and potentially subject to examination by the federal and New York state taxing authorities.

NOTE 9 — STOCKHOLDERS' EQUITY:

(a) Common Stock

The Company closed on an underwritten public offering of 1,200,000 shares of its common stock at $5.00 per share on April 3, 2013. The net proceeds of the offering, after deducting the underwriters' discounts and other offering expenses payable by the Company, was approximately $5,408,000. The Company intends to use the net proceeds for business expansion and working capital.

During 2013, options to purchase 88,551 shares of the Company's common stock were exercised at exercise prices ranging from of $1.04 to $1.76

During 2012, options to purchase 111,459 shares of the Company's common stock were exercised at exercise prices ranging from of $1.04 to $1.76.

In March 2012, June 2012, September 2012 and December 2012, the Company issued 938 shares of common stock on each date to a consultant as part of the consultant's compensation.

(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

The Company entered into an employment agreement effective May 22, 2013 ("Employment Agreement"), with Ms. Klugewicz to serve as the Company's Chief Operating Officer, which included issuing incentive stock options to purchase 5,000 shares of the Company's common stock. The options are exercisable in two equal annual installments starting on the first anniversary of the date of issue. The exercise price for these options was to be equal to the last traded price for the Company's common stock on May 22, 2013, which was $4.50 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 the employee's employment with the Company or (b) the fifth anniversary of the effective date of the grant.

On February 26, 2013, the Company issued 16,360 options to purchase common stock to executives of the Company as part of their 2012 bonus. The options are exercisable immediately at $5.56 per share, which was the last traded price of the common stock on that day, and they expire five years from the date of issue.

The Company entered into an employment agreement effective March 5, 2013 ("Employment Agreement"), with Mr. Esfandiari to continue as the Company's Senior Vice President of Research and Development, which included issuing incentive stock options to purchase 30,000 shares of the Company's common stock. The options are exercisable in three equal annual installments starting on the first anniversary of the date of issue. The exercise price for these options was to be equal to the last traded price for the Company's common stock on March 5, 2013, which was $5.44 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 the employee's employment with the Company or (b) the fifth anniversary of the effective date of the grant.

On February 16, 2012, the Company issued 25,392 options to purchase common stock to executives of the Company as part of their 2011 bonus. The options are exercisable immediately at $4.00 per share, which was the last traded price of the common stock on that day, and they expire five years from date of issue.

In March 2012, the Company issued 3,750 options to purchase shares of the Company's common at an exercise price of $4.00 per share to a consultant as part of the consultant's compensation. On each of March 19, 2012, June 19, 2012, September 19, 2012 and December 19, 2012, 938 of these options vested. These options were valued using a Black-Scholes model at $8,010, all of which was expensed in the year ended December 31, 2012. The options are being accounted for under the variable method as per ASC 505 and $50 of the expense was reduced attributable to this method.

During the third quarter of 2012, the Company issued 72,000 options to purchase common stock to newly-hired vice-presidents of the Company. The options are exercisable in three equal annual installments starting on the first anniversary of the date of issue. An allotment of 36,000 options issued to one of the new vice presidents have an exercise price of $5.11 per share, and the 36,000 options that were issued to the other new vice president have an exercise price of $4.45 per share, which in each case was the last traded price of the common stock on the day issued. The options expire five years from date of issue.

(d) ***Warrants***

As of December 31, 2013 and 2012, 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. 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 are not exercisable until a Distribution Date. Until a Right is exercised, the holder thereof, as such, will 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 will be evidenced by the certificates for shares of Common Stock registered in the names of the holders thereof, and not by separate rights certificates until the earlier to occur of (i) the close of business on the tenth business day following a public announcement that an Acquiring Person (as defined in the Rights Agreement) acquired a Combined Ownership (as defined in the Rights Agreement) of 15% or more of the outstanding shares of the Common Stock (the "Shares Acquisition Date") or (ii) the later of (A) the close of business on the tenth business day (or such later date as may be determined by action of the Board of Directors prior to such time as any person or group of affiliated or associated persons becomes an Acquiring Person) after the date that a tender or exchange offer or intention to commence a tender or exchange offer by any person is first published, announced, sent or given within the meaning of Rule 14d-4(A) under the Securities Exchange Act of 1934, as amended, the consummation of which would result in any person having Combined Ownership of 15% or more of the outstanding shares of the Common Stock, or (B) if such a tender or exchange offer has been published, announced, sent or given before the date of the Rights Agreement, then the close of business on the tenth business day after the date the Rights Agreement was entered into (or such later date as may be determined by action of the Board of Directors prior to such time as any person becomes an Acquiring Person); (the earlier of such dates referred to in (i) and (ii), which date may include any such date that is after the date of the Rights Agreement but prior to the issuance of the Rights, being called the "Distribution Date").

NOTE 11 — EMPLOYEE STOCK OPTION PLAN:

The Company has a 1999 Stock Option Plan ("SOP") originally covering 187,500 shares of Common Stock. Under the terms of the SOP, the Compensation Committee of the Company's board is authorized to grant incentive options to key employees and to grant non-qualified options to key employees and key individuals. The options become exercisable at such times and under such conditions as determined by the Compensation Committee. The SOP was amended at the Company's 2005 stockholders' meeting. The number of options under the SOP was increased to cover 375,000 shares of common stock. It was also amended to allow independent directors to be eligible for grants under the portion of the SOP concerning non-qualified options. As of December 31, 2013, there were 93,750 outstanding options under this SOP. No additional options may be issued under the SOP more than 10 years after its adoption

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, 2013, there were 144,220 options exercised, 562,648 options outstanding and 43,132 options still available to be issued under the SIP.

The Company's results for the years ended December 31, 2013 and 2012 include stock-based compensation expense totaling $332,000 and $294,000, respectively. Such amounts have been included in the Consolidated Statements of Operations within cost of goods sold ($78,000 and $49,000, respectively), research and development ($106,000 and $71,000, respectively) and selling, general and administrative expenses ($148,000 and $174,000, respectively). In accordance with ASC 718 the Company has not recorded a deferred tax asset related to the net operating losses resulting from the exercise of disqualifying stock options in the accompanying financial statements. The cumulative amount of unrecognized tax benefits at December 31, 2013 was immaterial, and if the Company is able to utilize this benefit in the future it would result in a credit to additional paid-in capital.

Stock option compensation expense in the years ended December 31, 2013 and 2012 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 years ended December 31, 2013 and 2012 was $3.99 and $3.27 per share, respectively. 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 years ended	
	December 31, 2013	December 31, 2012
Expected term (in years)	**4-5**	4- 5
Expected volatility	**99.6-115.77%**	99.60-115.77%
Expected dividend yield	**n/a**	n/a
Risk-free interest rate	**.34-.40%**	.33-0.37%

The Company granted 51,360 new options during the year ended December 31, 2013 to employees at an average exercise price of $5.39 per share.

The following table provides stock options activity for the year ended December 31, 2013:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2012	**731,646**	**$ 2.22**	**2.19 years**	**$ 3,460,686**
Granted	51,360	$ 5.39		
Exercised	(88,551)	$ 1.33		341,729
Forfeited/expired/cancelled	(38,057)	$ 2.59		
Outstanding at December 31, 2013	**656,398**	**$ 2.57**	**1.65 years**	**$ 801,888**
Exercisable at December 31, 2013	**504,022**	**$ 2.04**	**1.16 years**	**$ 780,513**

The following table summarizes information about stock options outstanding at December 31, 2013:

	Stock Options Outstanding				**Stock Options Exercisable**		
Range of Exercise Prices	**Shares**	**Average Remaining Contract Life (Year)**	**Weighted Average Exercise Price**	**Aggregate Intrinsic Value**	**Shares**	**Weighted Average Exercise Price**	**Aggregate Intrinsic Value**
$0.000 to 1.500	328,749	0.37	$ 1.04	$ 765,985	328,749	$ 1.04	$ 765,985
1.501 to 2.000	-	-	-	-	-	-	-
2.001 to 3.500	131,250	2.28	2.62	98,818	93,750	2.54	77,438
3.501 to 4.500	128,059	2.83	4.24	-	67,183	4.13	-
4.501 to 8.000	80,840	3.92	5.32	-	26,840	5.36	-
Total	668,898	1.64	$ 2.48	$ 864,803	516,522	$ 1.94	$ 843,423

As of December 31, 2013, there was $172,000 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 0.64 years. The total fair value of shares vested during the years ended December 31, 2013 and 2012, was $118,000 and $144,000, respectively.

NOTE 12 — GEOGRAPHIC INFORMATION:

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, 2013	December 31, 2012
Africa	**$ 4,352,731**	$ 2,669,140
Asia	**115,889**	658,831
Europe	**99,146**	54,280
North America	**9,730,557**	8,630,956
South America	**13,217,463**	12,314,148
	$ 27,515,786	$ 24,327,355

Sales to Africa increased in 2013 primarily due to increased sales in Uganda by approximately $1,236,000 and Ethiopia by approximately $262,000. Sales in Asia decreased from decreased sales in the Middle East by $483,000. Sales in 2013 and 2012 to North America were primarily from sales in the U.S of approximately $9.10 million and $7.72 million, respectively and sales in 2013 and 2012 to South America were primarily from sales in Brazil of approximately $6.10 million and $10.30 million, respectively.

NOTE 13 — COMMITMENTS AND CONTINGENCIES:

Employment Contracts:

The Company has contracts with three key employees. The contracts call for salaries presently aggregating $840,000 per year. One contract expires in May 2014, one expires in May 2015 and one contract expires in March 2016. The following table is a schedule of future minimum salary commitments:

2014	$	683,000
2015		415,000
2016		300,000
2017		50,000

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 $83,000 and $64,600 for the years ended December 31, 2013 and 2012, respectively.

Obligations Under Operating Leases:

The Company leases industrial space used for office, R&D and manufacturing facilities, currently with a monthly rent of $21,814. The current lease expires on April 30, 2017. The lease provides for annual increases of 2 1/2 percent each year starting May 1, 2015. 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 $14,658. The space will be used primarily for warehousing and provides for additional office space. The lease expires on April 30, 2018. The lease provides for annual increases of three percent each year starting March 1, 2015.

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

Years ending December 31,

2014	$	463,258
2015		513,414
2016		527,151
2 017		306,018
2 018		64,066
	$	**1,873,907**

Rent expense was $250,700 and $231,700 for the years ended December 31, 2013 and 2012, respectively.

Economic Dependency:

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

	For the years ended				Accounts Receivable As of	
	December 31, 2013		December 31, 2012		December 31, 2013	December 31, 2012
	Sales	% of Sales	Sales	% of Sales		
Customer 1	$ 8,894,969	32%	$ 7,778,688	32%	$ 547,887	$ 879,089
Customer 2	6,449,385	23%	10,299,216	42%	2,064,940	1,668,156
Customer 3	6,745,939	25%	*	*	-	*

In the table above the asterisk (*) indicates that sales to the customer did not exceed 10% for the period indicated.

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

	For the years ended				Accounts Payable As of	
	December 31, 2013		December 31, 2012		December 31, 2013	December 31, 2012
	Purchases	% of Purc.	Purchases	% of Purc.		
Vendor 1	$ *	*%	$ 817,293	13%	$ 105,095	$ 114,892
Vendor 2	1,114,810	10%	$ 778,793	12%	84,161	76,932

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 2013 and 2012 the Company earned $2.0 million and $1.3 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 in 2013 and 2012, was approximately $3.7 million and $3.1 million, respectively.

a. National Institutes of Health (NIH) Grant:

In June 2009, the Company received a $3 million, three-year grant from the United States National Institutes of Health to complete development of a test for Leptospirosis. Grants are invoiced after expenses are incurred. The Company earned, for the years ended December 31, 2013 and 2012, $- and $270,000, respectively from this grant. The Company has earned an aggregate of $2,756,000 from this grant from inception through December 31, 2013, of which $898,000 was paid to sub-contractors.

In March 2011, the Company received a $2.4 million, three-year grant from the United States National Institutes of Health to complete development of a test for Tuberculosis. Grants are invoiced after expenses are incurred. The Company earned, for the years ended December 31, 2013 and 2012, $1,089,000 and $682,000, respectively from this grant. The Company has earned $2,466,000 from this grant from inception through December 31, 2013, of which $829,000 was paid to sub-contractors.

b. Battelle/CDC DPP® Influenza Immunity Test:

In July 2012 as amended in 2013, the Company entered into a follow-on, milestone-based development agreement bringing the total up to $946,000 based on Chembio's previous successful initial development of a multiplex rapid point-of-care ("POC") influenza immunity test utilizing its patented Dual Path Platform® (DPP®) technology. The follow on-agreement contemplates a period of approximately nine months in which the follow-on development activity is to be completed. The Company earned, for the years ended December 31, 2013 and 2012, $643,500 and $277,500, respectively from this grant. The Company has earned $921,000 from this grant from inception through December 31, 2013.

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

In May 2013, the Company was awarded a cooperative research agreement with a U.S. government agency for up to $766,000 for an eight-month development project to develop rapid POC diagnostic tests for five infectious diseases associated with febrile illness. The Company earned $766,000 for the year ended December 31, 2013 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.

Exhibit 21

List of Subsidiaries

Chembio Diagnostic Systems, Inc. (Delaware)

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Chembio Diagnostics, Inc.
Medford, New York

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-69460, No. 333-141555 and No. 333-151785) and on Form S-3 (No. 333-185932) as amended of our report dated March 6, 2014, relating to the consolidated balance sheets of Chembio Diagnostics Inc. and Subsidiary as of December 31, 2013 and 2012 and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years then ended appearing in this Form 10-K.

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

March 6, 2014

EXHIBIT 31.1

CERTIFICATION

I, Lawrence A. Siebert, certify that:

1. I have reviewed this Form 10-K of Chembio Diagnostics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: March 6, 2014 /s/ Lawrence A. Siebert

Lawrence A. Siebert, Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION

I, Richard J. Larkin, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 6, 2014 /s/ Richard J. Larkin

Richard J. Larkin, Chief Financial Officer

EXHIBIT 32

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

In connection with the Annual Report on Form 10-K (the "Report") of Chembio Diagnostics, Inc. (the "Company") for the year ended December 31, 2013, each of the undersigned Lawrence A. Siebert, the Chief Executive Officer of the Company, and Richard J. Larkin, the Chief Financial Officer of the Company, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of the undersigneds' knowledge and belief:

(1) This Form 10-K for the year ended December 31, 2013 fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in this Form 10-K for the year ended December 31, 2013 fairly presents, in all material respects, the financial condition and results of operations of Chembio Diagnostics, Inc. for the periods presented therein.

Dated: March 6, 2014 /s/ Lawrence A. Siebert
Lawrence A. Siebert
Chief Executive Officer

Dated: March 6, 2014 /s/ Richard J. Larkin
Richard J. Larkin
Chief Financial Officer