CHEMBIO DIAGNOSTICS, INC.
Form 10-K
March 07, 2013

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, 2012

or

[ ] TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to .

Commission File No. 0-30379
CHEMBIO DIAGNOSTICS, INC.
(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

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

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

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

As of the last business day of the Company's most recently completed second fiscal quarter, the aggregate market value of voting and non-voting common equity held by non-affiliates* was $28,500,000.

As of March 6, 2013, the registrant had 8,086,114 common shares outstanding.

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

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PART I

ITEM 1. BUSINESS

FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, and Section 27A of the Securities Act of 1933. Any statements contained in this report that are not statements of historical fact may be forward-looking statements. When we use the words “intends,” “estimates,” “predicts,” “potential,” “continues,” “anticipates,” “plans,” “expects,” “believes,” “should,” “could,” “may,” “will” or the negative of these ter 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 antibodies, two rapid tests for the detection of syphilis, and a rapid test for the detection of canine leishmaniasis. Three of the HIV 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. Our fourth rapid HIV test incorporates our patented Dual Path Platform® (DPP®), and does not require in-licensing. The DPP® HIV test, detects antibodies to HIV 1 & 2 in oral fluid samples as well as in all blood matrices. We received United States FDA regulatory approval for this product on December 19, 2012 and we anticipate launching it under Chembio’s brand in 2013.

Our new product pipeline, which currently includes rapid tests for Syphilis and Hepatitis-C, as well as a multiplex test that detects HIV and Syphilis specific antibodies, 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 worldwide. With the DPP® proprietary platform, we can 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 of approximately 7% per annum. POCTs, by providing prompt and early diagnosis, can reduce patient stays, lower overall costs, improve therapeutic interventions and improve patient outcomes as a result of prompt and early diagnosis. They 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 for example), 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.

PRODUCTS

Lateral Flow Rapid HIV Tests

All three of our lateral flow rapid HIV 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 (for example directly 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. We believe that this format may be an ideal candidate as an over-the-counter HIV test and we are participating in certain studies that should help to better ascertain this. 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 as Clearview® Complete HIV 1/2 (the barrel format) and Clearview® HIV 1/2 STAT PAK® (the cassette format), and by Chembio in all other markets 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.

Our third lateral flow HIV test, 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; an adhesive backing is provided as a more cost-effective and compact "housing" 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 the two FDA -approved products in 2006 and 2007, respectively. The 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. Our HIV 1/2 STAT-PAK Dipstick, although not FDA-approved, qualifies under FDA export regulations to sell to customers outside the United States subject to any required approval by the importing country.

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 Test

As in the case of our lateral flow HIV tests, our DPP® HIV test 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 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. Clinical and laboratory studies, which uniquely included test subjects down to two years of age, have shown this product to have improved performance compared with all of the current FDA-approved CLIA-waived 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% amongst 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, more of whom are on more effective medications, and for longer periods than when competitors performed their trials. We believe that this fact, combined with our product's superior performance in a direct comparative evaluation, and earlier detection than our main competitors on well characterized serum samples, combine to provide us with a significant market opportunity with this product.

Regulatory Status: In April 2012 we completed a 3,000 patient clinical study with our DPP® HIV test 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 the first quarter of 2013, we plan to commence the additional testing necessary in order to complete a CLIA waiver application for this product. We anticipate that we will be able to complete this testing and complete this application in order to launch the product in the third or fourth quarter of 2013.

The DPP® HIV test product is qualified for procurement under the President's Emergency Plan for AIDS Relief ("PEPFAR") for use with all sample matrices, and we are pursuing WHO qualification in order to enable procurement of this product by the Global Fund and United Nations agencies, including programs underwritten by them.

In June 2010, ANVISA approved the DPP® HIV test that is being marketed in Brazil through our collaboration with the Oswaldo Cruz Foundation, Brazil's leading public health institute. Given the oral fluid feature, we believe this product can be marketed as a premium-priced product that will address those market segments in the U.S. and globally that express a preference for a less invasive testing experience.

OTHER DPP® PRODUCTS

Our product pipeline currently includes a multiplex Syphilis Screen & Confirm test, a multiplex test for the separate detection of antibodies to HIV and Syphilis, and a rapid test for the detection of Hepatitis-C antibodies and antigens. We anticipate completing clinical and other requirements in order to make submissions to the FDA for the Syphilis Screen & Confirm test and the multiplex HIV-Syphilis test in 2013 for U.S. market clearance in 2014. This timetable is subject to the FDA's confirming the regulatory requirements that we believe will be applicable to these products, of which there can be no assurance. As mentioned below ("Our Rapid Test Technologies"), we also are considering development of so-called "Fourth Generation" tests that are able to detect disease prior to seroconversion to antibodies. This would allow earlier detection of diseases at an acute stage. We have completed initial feasibility studies with technologies (owned by other parties) that complement our DPP® technology and that will further enable even lower limits of analyte detection, which is a capability we believe is essential to have in order to develop new products and markets over the long term.

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. While we may continue 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, 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 Screening Assay in the United States market in 2013, to be followed by our Syphilis test and potentially other related products.

Following is a discussion of the DPP® products for which we have completed our development activity pursuant to OEM agreements with FIOCRUZ and Bio-Rad Laboratories, Inc. The statuses of products that are still under development are described in Part II Item 7 of this report.

PARTNERS INVOLVED IN MARKETING OUR PRODUCTS

On September 29, 2006, we executed marketing and license agreements with Alere. The marketing agreements (one for each of the two FDA-approved products) provide Alere with a 10-year exclusive right (until September 2016) to market our rapid HIV tests in the United States under Alere's brand. The agreements provide Chembio a non-exclusive license to certain Alere lateral flow patents that may be applicable to our lateral flow products, including for the HIV tests in the United States should Alere enter the U.S. market with a competitive rapid HIV test product and we choose to market our products directly as provided in the agreements. 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). As a result, 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.

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.

Our DPP® HIV test was approved by ANVISA, Brazil's regulatory authority, in June 2010. This approval was granted to our Brazilian partner, the Oswaldo Cruz Foundation ("FIOCRUZ"), pursuant to one of five technology transfer, supply and license agreements that we entered into with this public health organization in 2008 and 2010. See "OEM DPP® Products," below.

OEM DPP® Products

Oswaldo Cruz Foundation OEM DPP® Agreements

During 2008-2010 we signed five agreements with the Oswaldo Cruz Foundation (FIOCRUZ) in Brazil relating to 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.

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. As a result, during 2011, we shipped approximately $4.25 million of products to FIOCRUZ pursuant to the agreements, and approximately $10.86 million for fiscal year 2012. 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 under agreement with FIOCRUZ are for DPP® products for HIV screening, HIV confirmatory, Leishmaniasis, Leptospirosis and Syphilis. All of the agreements with FIOCRUZ contemplate a technology transfer and license to FIOCRUZ for the manufacture of the subject products over stipulated periods of time. These technology transfers, and the provision by Chembio of the information and training that is required for this to occur, are subject to Chembio receiving orders from FIOCRUZ for a minimum amount of products for manufacture by Chembio, which is approximately $23 million in the aggregate under the five agreements. The actual demand for these products may be more or less than this amount. The actual amount will depend on the demand for the products by the specific programs for each product funded by the Brazilian Ministry of Health for its programs as well as whether and when FIOCRUZ is able to implement the technology transfer steps including, for example, the readiness of new production facilities currently under construction that are scheduled to be completed in mid-2013; thereafter Chembio may continue to supply certain product components or receive royalty payments under some of the agreements for a defined period based on product sold by FIOCRUZ to the public health programs in Brazil.

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 and are 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.

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. The HIV confirmatory test we developed for Bio-Rad employs six different markers. We have a contract development program that involves the use of eight bands, and we have another funded multiplex product program that is pending. Our intellectual property also extends to the use of multiple test membranes that through a common sample strip utilize a single sample. Employing this feature we can develop so-called “Fourth Generation” tests that are able to detect antigens prior to seroconversion to antibodies, as well as antibodies. If developed successfully, this would allow earlier detection of diseases at an acute stage, which improves health outcomes. We have completed initial feasibility studies with technologies (owned by others) that uniquely complement our DPP® technology and that will assist in these efforts by enabling even lower limits of analyte detection. This is a capability which we believe is essential to have in order to develop new products and market opportunities over the long term.

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. However, 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.

There are approximately 53,000 new diagnoses of HIV infection in the United States each year, according to the CDC. In time, most of these infections progress to AIDS. The CDC estimates that approximately 1.2 million individuals in the U.S. are living with HIV, with an estimated 250,000 Americans, or more than 20%, unaware that they are infected. It is 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 that do get tested in public health settings will often not return or call back for their test results from samples that have to be sent out to a laboratory and that can take up to several days to process. 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. This is from zero in 2003 when Orasure Technologies, Inc. received the first FDA approval for a rapid HIV test. We believe that the US professional HIV rapid test market (not including the OTC 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-$150 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 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. Importantly, in November 2012 the United States Preventive Services Task Force ("USPSTF") finally fully embraced these CDC routine HIV testing recommendations. This USPSTF draft 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") . If finalized as anticipated, 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. Currently most public health testing in the United States is funded by grants allocated to high prevalence areas by the CDC, but we believe this will shift to an insurance-funded model under the ACA in the years to come.

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). PEPFAR directly supported HIV testing and counseling for more than 11 million pregnant women in fiscal year 2012 and testing and counseling for more than 49 million people. The U.S. is 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.

For FY 2012, President Obama requested $7.2 billion, including $5.6 billion for bilateral HIV/AIDS programs, $1.3 billion for the Global Fund, and $254 million for bilateral TB programs. For FY 2013, President Obama is requesting $6.4 billion, including more than $4.5 billion for bilateral HIV/AIDS programs, $1.6 billion for the Global Fund, and $232 million for bilateral TB programs. The U.S. deficit crisis is likely to impact funding of these large programs, and the eligibility of lower quality, non-U.S. sourced products make these markets challenging.

Chembio, is unique with four U.S.-manufactured rapid HIV tests, three FDA-approved, and 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.

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.

There is also now an over-the-counter market for HIV self-testing and we are uniquely positioned to participate in this market, should we believe the investment is justified. So far one company, Orasure Technologies Inc., received FDA approval for an over-the-counter (self-testing) version of its previously professional-market-approved HIV test. The FDA approval was granted in July 2012, the product was launched in October, and Orasure is investing heavily in developing this market, with the initial results modest though with some promise even if not nearly for the levels speculated by some .

Based on the fact that FDA requires that any over-the-counter HIV test to have first been approved for the professional market, we believe that Chembio is the only other company that can participate in this market opportunity if it chooses to. Although there is a third company, Trinity Biotech, that meets that condition, they have stated that they do not intend to pursue this market. Therefore Chembio is carefully monitoring developments in this market, which may be significant during 2013. Currently we could initiate the over-the-counter approval process with either of our two blood tests. We have completed a preliminary self-study for our Sure Check "barrel" device as the final component to our preparing and submitting an Investigational Device Exemption ("IDE") application to the FDA during the first quarter of 2013. Provided we submit this application and it is granted, that would enable us to begin clinical trials by the time we gather better information as to how the Orasure product is doing in the market. And now that we have received approval of our pre-marketing application for our DPP® oral fluid HIV test, we could additionally, or alternatively, pursue over-the-counter approval for that product once we receive the CLIA waiver grant for that product. We believe that we will wait at least some additional months before commencing these clinical trials because (1) 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; (2) Orasure's initial results are not convincing of a large market, though this possibility remains and Orasure is likely to spend heavily on this for some time and (3) we are 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 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 tests (called non-treponemal and treponemal markers), each requiring trained personnel in laboratory settings and several days to receive back results, in order to confirm an active, previously untreated case. The screening test still employed in the United States is known as RPR; it utilizes an old technology that has a high degree of false positive results.

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. Unlike HIV testing, where a positive result first requires a confirmatory test, and then further tests to measure viral load before expensive treatment decisions are made, an individual with a confirmed active case of syphilis can be prescribed antibiotics immediately.

We believe the opportunity for our recently developed combination HIV-Syphilis test is significant in the U.S. and globally, and we anticipate making significant progress in 2013 in order to capitalize on these opportunities.

Marketing Strategy

Our marketing strategy is to:

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 since we signed our agreement with them, and although we believe that this will enhance opportunities for Alere to market our rapid HIV tests, the product line is a very small one for them, notwithstanding the strong growth they have enjoyed with respect to our products.

Leverage our DPP® intellectual property and regulated 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

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.

Research and Development

During 2012 and 2011, $4.5 million and $4.9 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 $1.3 million in 2012 and $1.8 million in 2011. 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, 2012, we employed 174 people. We have entered into employment contracts with our President, Lawrence Siebert, 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 Mr. Siebert provides that Mr. Siebert will serve as the Chief Executive Officer and President of the Company through May 11, 2013. 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.

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 clinical utility by showing that the device is capable of identifying new infections. Given the low prevalence of HIV, the FDA will require 30 new HIV cases to be identified, supplemented by additional data and this is the study the Company will perform during 2013.

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

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

One or more of the Company's rapid HIV tests are also approved or pending approval for marketing in several foreign jurisdictions, including but not limited to Brazil, Mexico, and a number of other nations in the developing world.

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

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®. 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 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 our agreements in 2006 with Alere for the marketing of our HIV tests, we were granted non-exclusive licenses to certain lateral flow technology for certain products manufactured and marketed by Chembio including but not limited to our HIV tests. 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 patents that we believe will strengthen the DPP® intellectual property and have also filed for patent protection for certain other point-of-care technologies or applications thereof.

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

Corporate History

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

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

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

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 statements.

Glossary

AIDS	Acquired Immunodeficiency Syndrome. AIDS is caused by the Human Immunodeficiency Virus, HIV.
ALGORITHM (parallel or serial)	For rapid HIV testing this refers both to method or protocol (in developing countries to date) for using rapid tests from different manufacturers in combination to screen and confirm patients at the point-of-care, and may also refer to the specific tests that have been selected by an agency or ministry of health to be used in this way. A parallel algorithm uses two screening tests from different manufacturers and a tie-breaker test only if there is a discrepancy between the screening tests results. A serial algorithm only uses a second confirmatory test if there is a positive result from the screening test, meaning that the number of confirmatory tests used is equal to the positivity rate in the testing venue. A tie-breaker test resolves discrepancies between the screen and the confirmatory test.
ANTIBODY	A protein which is a natural part of the human immune system produced by specialized cells to neutralize antigens, including viruses and bacteria that invade the body. Each antibody producing cell manufactures a unique antibody that is directed against, binds to and eliminates one, and only one, specific type of antigen.
ANTIGEN	Any substance which, upon entering the body, stimulates the immune system leading to the formation of antibodies. Among the more common antigens are bacteria, pollens, toxins, and viruses.
	Anti-Retroviral Treatments for AIDS
ANVISA	The National Health Surveillance Agency of Brazil
ARVs	Anti-retroviral medications developed to fight AIDS
CDC	United States Centers for Disease Control and Prevention
CLIA waiver	Clinical Laboratory Improvement Act designation that allows simple tests to be performed in point-of-care settings such as doctor's offices, walk-in clinics and emergency rooms.
DIAGNOSTIC	Pertaining to the determination of the nature or cause of a disease or condition. Also refers to reagents or procedures used in diagnosis to measure proteins in a clinical sample.
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. The risks described below are those we currently believe may materially affect us. An investment in our Common Stock involves a high degree of risk, and should be considered only by persons who can afford the loss of their entire investment.

Risks related to our industry, business and strategy

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

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

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. Alere has no rapid HIV tests that are approved for marketing in the U.S. and Alere is obligated to inform us of any such products within certain time frames. We believe that Alere is committed to successfully marketing our products in the U.S.. Alere may however choose to develop or acquire competing products for marketing in the U.S. and such an action could have at least a temporary material adverse effect on the marketing of these products until such time as alternative marketing arrangements could be implemented. In particular Alere manufactures and markets outside the United States a rapid HIV test product called Determine® that, with its widely available so-called "3rd generation" test, is the leading screening product 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. The newest Determine HIV version is the so called "4th Generation" version Determine test which, according to its claims, detects HIV antibodies and the P24 HIV antigen which is present in HIV positive individuals' blood samples before antibodies are, and therefore is able to detect HIV infection earlier than tests that solely rely on antibody detection, such as Chembio's and all of the other currently FDA approved rapid HIV tests, which all require an immune response before detection can occur. The actual performance of the 4th generation Alere product has been inconsistent with regard to meeting these and other performance claims, although recently it has been reformulated, though limited data has been published since such reformulation. Regardless Alere continues to make statements that it is seeking FDA approval of this product which, if approval is granted, would make it a competitive product to the Chembio products that Alere markets as Clearview® Complete (barrel) and Clearview HIV ½ STAT PAK® (cassette). Under our agreements, Alere is in fact expressly permitted to "exploit" such a product (a "permitted competing product") in the United States without breaching the agreement, though there are defined alternative consequences that would follow in such case: for the cassette product, Chembio may at any time after Alere begins to "exploit" the Determine product in the United States either terminate the agreement with Alere or make the agreement with Alere non-exclusive; for the barrel product, Chembio and StatSure Diagnostics (the other party to the Alere 3-way agreement pertaining to the barrel product) will need to jointly agree to either continue the agreement with Alere or to make the barrel agreement with Alere non-exclusive in the United States. As part of any decision by Chembio to market either product, Alere would expand the lateral flow license granted to allow Chembio to market the product under Chembio brands, if necessary.

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 is older than lateral flow, which requires handling of multiple components (3 vials of solution) to perform the test in multiple steps. However, these steps can be accomplished in less than ten minutes, and the actual test results occur in only one minute after those steps are completed. Therefore sample-to-result time is shorter than any of the competitive products. There are settings where that reduce total test time may be a distinct advantage. However, thus far Biolytical's market penetration has been negligible.

Although we have no specific knowledge of any other competitor's product that are a 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.

We have developed an oral fluid rapid HIV test as well as other applications utilizing our Dual Path Platform technology, which we believe will enhance our competitive position in HIV rapid testing and other fields. During 2012 we made significant progress toward the commercialization of this product. However we still have technical, manufacturing, regulatory and marketing challenges to meet before we will know whether we can successfully commercialize products incorporating this technology. There can be no assurance that we will overcome these challenges.

We plan to introduce our recently 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 once it is CLIA-waiver, currently anticipated by the end of 2013,

but for which there can be no assurance. Under our 2006 Agreement with Alere, Alere has a right of first negotiation for the right to market any new rapid HIV antibody detection test that we develop. In accordance with this provision in our agreement, we presented this product to Alere in 2007, and in 2007 Alere waived its right of first negotiation under the agreement. While such waiver does not prevent Alere from reconsidering the marketing of this product, we have no reason to believe that they will. Also, although we believe that the primary market opportunity for the DPP® HIV product is for those customers that have a clear preference for an oral fluid HIV test, the product is also likely to compete to some extent with our FDA-approved rapid HIV tests being marketed by Alere. Therefore this could have a material and adverse effect on our business with Alere.

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, we own no issued patents covering lateral flow technology, and the field of lateral flow technology is complex and characterized by a substantial amount of litigation, so the risk of potential patent challenges is ongoing for us in spite of our DPP® patent. Moreover, we believe that certain lateral flow patents are going to expire in the next couple of years which may materially impact the competitive landscape.

Although we have been granted non-exclusive licenses to the lateral flow patents owned by Alere, there is no assurance that its lateral flow patents will not be challenged or that licenses from other parties may not be required, if available at all. In addition, certain of the Alere patents will expire in the next couple of years which expiration could open the market to certain competitors. In the event that it is determined that a license is required and it is not possible to negotiate a license agreement under a necessary patent, we may be able to modify our HIV rapid test products and other products such that a license would not be necessary. However, there is no assurance that we would be able to do so, and even if accomplished, this alternative could delay or limit our ability to sell these products in the U.S. and other markets, which would adversely affect our results of operations, cash flows and business.

On March 13, 2007, our Dual Path Platform Immunoassay Device patent application was issued as United States patent no. 7,189,522. Additional protection for this intellectual property is pending in a number of other countries. This platform has shown improved sensitivity as compared with conventional platforms in a number of studies. However several factors go into the development and performance attributes of products, and the ability of our products to successfully compete will depend on several other factors including but not limited to our having a patent rapid test platform technology.

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.

Our revenues and gross margins have increased significantly in recent periods, and we have been profitable for four consecutive years. Nevertheless, prior to 2009 we sustained significant operating losses since 2004, and we incurred an operating and net loss as recently as the third quarter of 2012. At December 31, 2012, we had a stockholders' equity of $13.9 million and a working capital surplus of$7.6 million. The Company estimates that its resources are sufficient to fund its needs through the end of 2013 and beyond. 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 2013 or, in the alternative, be successful in raising sufficient capital to fund its needs through 2013 and thereafter.

The increase in revenues we experienced in 2012 was almost entirely attributable to the distribution of our DPP® products in Brazil by the Ministry of Health as supplied by our contract partner, the Oswaldo Cruz Foundation (FIOCRUZ). However the agreements we have with FIOCRUZ have limited purchase requirements remaining for most of the five products that, in the aggregate, are less than our revenues realized from FIOCRUZ in 2012, and even these requirements pertain only in order to trigger a technology transfer right for the applicable product. Moreover, we have recently been advised by FIOCRUZ that the scale-up of the Brazilian Ministry of Health's programs that are utilizing our HIV and Syphilis tests is going more slowly than anticipated., Taken together, this is likely to result in significantly reduced revenues to FIOCRUZ in 2013 versus 2012.

Therefore, in order for our 2013 revenues to be of the same level as in 2012 we would need to increase revenues from other customers in excess of the decreased 2013 sales to FIOCRUZ, which is possible.

We anticipate increased revenues from Alere in 2013 and we are attempting to increase international sales of our products. However, a number of factors can slow or prevent these increases, or substantially increase the cost of achieving these increases 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; and
pricing.

If we are unable to increase our revenues from domestic and/or international sales to make up for the decreases in sales to FIOCRUZ, 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, it is not its exclusive supplier. 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, 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 Mr. Siebert provides that Mr. Siebert will serve as the Chief Executive Officer and President of the Company through May 11, 2013. 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.

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 and funding may be reduced, or 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.

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

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 four years. Moreover in 2013 we expect to make substantial expenditures for regulatory submissions, product development and other purposes which may impact profitability. Our ability to continue profitability in the future will primarily depend on our ability to increase sales of our products, 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 44,000 share per day over the three months ended March 1, 2013 as compared to less than 4,375 shares per day (after accounting for the 1 for 8 reverse split that was effectuated on May 30, 2012) over the three months ended March 6, 2012. Therefore, there has been a significant increase in the liquidity of our stock based on this comparison, and our stock began trading on NASDAQ in early June, 2012. However, continued 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 6, 2013, our named executive officers, directors and 5% stockholders beneficially owned approximately 16.4% of our voting power. In addition, we have one large institutional investor that beneficially owned 8.3% 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 administrative offices and research facilities are located in Medford, New York. We lease approximately 30,600 square feet of industrial space for $20,530 per month. The space is utilized for research and development activities (approximately 4,160 square feet), offices (approximately 4,640 square feet) and production (approximately 21,800 square feet). The lease term expires on April 30, 2014. The monthly rent for the year ending April 30, 2014 will increase by the lower of (i) the change in the consumer price index, or (ii) five percent; and (d) the monthly rent for years three through five of the lease will increase each year by the lower of (i) the change in the consumer price index, or (ii) two and one half percent. Additional space may be required as we expand our production and research and development activities. We do not foresee any significant difficulties in obtaining any required additional facilities.

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 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

Fiscal Year 2011	High Bid	Low Bid
First Quarter	$ 4.00	$ 3.12
Second Quarter	$ 4.64	$ 3.28
Third Quarter	$ 3.84	$ 3.28
Fourth Quarter	$ 3.84	$ 2.88

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, 2013, there were approximately 1,800 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

During 2012, we issued unregistered securities, including 3,752 unregistered shares of our common stock and options to purchase 3,750 unregistered shares of our common stock to The Benchmark Company, LLC ("Benchmark"). The shares were issued to Benchmark in four installments under the below terms. The options granted to Benchmark the right to purchase up to 3,750 unregistered shares of our common stock at the purchase price of $4.00 per share on or before March 19, 2015. One-quarter of the options granted vested on each of the dates set forth in the chart below. These securities were issued to Benchmark in consideration for services provided to the Company and were not subject to any underwriting discounts or commissions.

Unregistered Shares Issued to Benchmark

Date	Number of Shares	Market Price Per Share	Consideration
March 19, 2012	938	$ 3.84	$ 3,601.92
June 19, 2012	938	$ 4.80	$ 4,502.40
September 19, 2012	938	$ 4.31	$ 4,042.78
December 19, 2012	938	$ 4.58	$ 4,296.04

The issuance of these securities was not registered under the Securities Act of 1933, as amended (the "Act"). These securities were issued in reliance on an exemption from registration under Section 3(b) or Section 4(2) of the Act, and Rule 506 promulgated under the Act, based on the fact that Benchmark is an "accredited investor" as such term is defined in Rule 501 of Regulation D.

ITEM 6. SELECTED FINANCIAL DATA

Presented in this table are selected financial data for the past five years ended December 31, 2012.

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

Statement of Operations Data:

	December 31, 2012		December 31, 2011		December 31, 2010		December 31, 2009		December 31, 2008	
TOTAL REVENUES	$25,610,595		$19,388,036		$16,704,703		$13,834,248		$11,049,571	
GROSS MARGIN	10,789,991	42%	9,390,303	48%	8,100,699	48%	5,860,405	42%	3,851,721	35 %
OPERATING COSTS:										
Research and development expenses	4,486,302	18%	4,878,119	25%	2,586,308	15%	2,883,696	21%	2,605,343	24 %
Selling, general and administrative expenses	4,851,587	19%	3,424,297	18%	2,940,721	18%	2,659,382	19%	3,317,046	30 %
	9,337,889		8,302,416		5,527,029		5,543,078		5,922,389	
INCOME (LOSS) FROM OPERATIONS	1,452,102		1,087,887		2,573,670		317,327		(2,070,668)	
OTHER INCOME (EXPENSES):	(1,584)		(12,325)		(14,503)		(8,267)		121,898	
INCOME (LOSS) BEFORE INCOME TAXES	1,450,518	6 %	1,075,562	6 %	2,559,167	15%	309,060	2 %	(1,948,770)	-18%
Income tax (benefit) provision	509,237		(5,133,229)		45,823		-		-	
NET INCOME (LOSS)	$941,281		$6,208,791		$2,559,167		$309,060		$(1,948,770)	-18%
Basic income (loss) per share	$0.12		$0.79		$0.33		$0.04		$(0.25)	
Diluted income (loss) per share	$0.11		$0.73		$0.29		$0.03		$(0.25)	

Weighted average number of shares outstanding, basic	7,986,030	7,874,807	7,762,858	7,743,304	7,658,369
Weighted average number of shares outstanding, diluted	8,614,944	8,556,284	8,865,114	9,380,242	7,658,369

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 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, two of which will be marketed under Chembio's label (DPP® HIV 1/2 Screening Assay and DPP® Syphilis Screen & Confirm) and several others that have been developed specifically related to private label agreements with The Oswaldo Cruz Foundation ("FIOCRUZ") for the Brazilian public health market, as explained below.

All of the Company's products other than its lateral flow tests (see PRODUCTS and Our Rapid Test Technologies) are based on the Company's patented Dual Path Platform (DPP®) technology. 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. Externally funded R&D programs were particularly instrumental in helping the Company to avoid raising capital during 2008-2010, which was a very difficult period for fundraising. 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 additional products under development that employ the DPP® technology. These product development activities are further described below.

Multiplex Influenza Immunity Test – In July 2012 we entered into a follow-on, milestone-based development agreement of up to $480,000 based on Chembio's previous successful initial development of a multiplex rapid point-of-care ("POC") influenza immunity test utilizing our patented Dual Path Platform (DPP®) technology. The agreement contemplates a period of approximately six months in which the follow-on development activity is to be completed.

Chembio entered this agreement with a private contracting organization that is engaged to enter into, implement and provide technical oversight of agreements relating to pandemic preparedness on behalf of its client, the United States Centers for Disease Control and Prevention ("CDC").

As a result of pandemic planning activities, the United States Department of Health and Human Services ("HHS") and CDC 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 these tests is especially critical for military forces, as evidenced by previous influenza outbreaks that spread rapidly through densely populated barracks and have killed thousands of soldiers.

The previous development work for this product was completed by Chembio in 2011 pursuant to an initial $900,000 contract with this same organization. The objective of this follow-on project is to further develop a rapid influenza immunity test which can be administered in the field to determine a person's influenza immunity status or in an outpatient setting incorporating certain additional subunits of influenza virus proteins. Work commenced on this follow-on development project during the third quarter, accelerated during the fourth quarter, and will be completed during the first quarter of 2013.

DPP® Hepatitis-C (HCV) Test – Development work on our DPP® HCV point-of-care rapid test continues. In June, we reported data from a study evaluating performance characteristics (sensitivity and specificity) of our first generation test, which data was published in the Journal of Clinical Virology. The study authors concluded that the Chembio blood rapid assay demonstrated acceptable sensitivity and specificity, and was comparable to conventional assays currently in use. The study results showed that the Chembio DPP® HCV finger-stick blood test had a sensitivity of 92.8% against a laboratory-based enzyme immunoassay (EIA) screening assay reference while it demonstrated 97.1% sensitivity against The Centers for Disease Control and Prevention (CDC) reference method algorithm which utilizes a third generation recombinant immunoblot assay (RIBA). The DPP® finger-stick blood test achieved 99.0% specificity on both reference methods.

During the third quarter of 2012 we completed a feasibility study on proprietary materials which we believe will enable us to develop an HCV rapid test that is equivalent to the only directly competitive product; however we were waiting to receive additional proprietary materials that we believe could enable us to improve performance and features of the test as compared to the competitive product. We have recently received these materials which are enabling us to continue our development activities with respect to the improved performance features. If these objectives are achieved, we will proceed with a full development program, and we could complete development and commence clinical trials before the end of 2013.

In July 2012, the U.S. Centers for Disease Control finalized the recommendations for testing all individuals in the United States between the ages of 45 and 65 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. With a number of new anti-retroviral therapies approved, and even more pending approval in the years ahead by the FDA, we believe that over time these new recommendations will be implemented. However, it is unclear how much of these recommendations will be funded by public health programs or under the Affordable Care Act. Regardless if these recommendations are implemented, we believe that they will take time to be funded.

DPP® Syphilis/HIV Combination Test – We have developed a combination Syphilis and HIV test and we are considering various opportunities with respect to this product for the international market at least. This is an example of the multiplexing capabilities that we expect to drive the Company's revenues and growth. We will manufacture this product as a Chembio-branded product and as a component for final assembly in other markets where we are considering collaborations. We believe there are opportunities for this product in donor-funded pre-natal testing programs aimed at the prevention of mother-to-child transmission, and the United States as well.

DPP® Tuberculosis – In February 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, we continued this development work with our DPP® technology. Several additional antigens have been identified recently to enhance antibody detection by the DPP® test prototype designed in our Phase I studies. In addition, new detection technologies are being evaluated to further increase sensitivity.

Other Potential Products and Collaborations - We are currently completing development of certain other products for single parameter and multiplex tests, utilizing our patented DPP®. We also are discussing exclusive collaborations for these products or proprietary components thereof, with certain potential international partners that, if consummated, would provide us with local assembly and distribution, a co-branded DPP® product in the designated market, and a more meaningful stake in the success of the distribution program.

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 could provide us with additional products and capabilities, 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 – We were audited by our notified body in September and our technical file is being reviewed. We expect a decision on CE Marking of these products soon.

FDA Approval for DPP® HIV 1/2 Screening 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 announced. We are now working towards a CLIA waiver with the expectation that it will be granted before the end of 2013. Our current plan is to initiate the CLIA study in March 2013, have the submission into FDA by July, and have a CLIA waiver during the fourth quarter.

DPP® Syphilis Screen & Confirm - During the fourth quarter of 2012 we received data that we had been pursuing that we believe support a De Novo FDA 510(K) clearance regulatory pathway for the product. As a result we submitted this data and other information to the FDA so that we could re-initiate clinical trials and submit our 510(k) application by the middle of 2013. In addition to a scientific journal publication in December 2012 of the results of a large study that was conducted with this product in 2010-2011 in China, we have received additional data from other studies of this product that we believe will also be useful in supporting our regulatory file. There is no point-of-care test for Syphilis that differentiates between active and past, previously treated cases, and there continues to be a substantial interest in this product by public health groups in the United States and abroad. We are confident that our DPP® Syphilis Screen & Confirm test detects primary infections more accurately than the legacy laboratory test known as Rapid Plasma Reagin (“RPR”).

In late February we received a response from the FDA that will enable us to pursue the regulatory pathway that we outlined in our submission. However there were some questions that we have concerning the FDA response and we intend to have those clarified in a meeting being scheduled this month. While we confirm our intended study approach with FDA, we are completing our protocol, have identified three clinical sites and their contracts, with the expectation that we will commence the studies in May, submit the 510(k) application to FDA by the end of the third quarter, and have an FDA clearance by mid-2014.

DPP® HIV-Syphilis – We have submitted this product for evaluation by the CDC and the WHO has accepted this product for pre-qualification in their global procurement scheme. Other international registrations are pending. We have not yet submitted a guidance request to the FDA for determining the pathways for getting this multiplex combination product approved/cleared by the FDA, but plan to soon. However we still plan to initiate the syphilis studies (the HIV component of this test is already approved pursuant to the PMA approval received in December 2012), in May, submit the 510(k) application to FDA by the end of the third quarter, and have an FDA clearance by mid-2014.

SURE CHECK® HIV OTC Study - We completed the self-testing study to meet the requirements for submitting an IDE (“Investigational Device Exemption”) application in order to commence clinical trials for this product in 2013. The IDE application can be filed now and we plan to do this soon. Thereafter, assuming the IDE is granted, the Phase II observed user clinical trials could be commenced during 2013 and the pivotal trial could be completed during 2014. This would enable a PMA approval by late-2015.

There have been very significant recent developments related to this market opportunity, as the first rapid HIV test for home use was recommended for approval by the FDA's Blood Products Advisory Committee ("BPAC") in a unanimous vote, and the test was in fact approved by the FDA in early July with widespread media attention. The manufacturer of this product, OraSure Technologies, Inc. ("OraSure"), launched this product in retail drug stores during October.

OraSure's final clinical trial for the home-use version enrolled 5,798 subjects from 17 high prevalence sites and three low prevalence sites across the country. OraSure gave subjects the test to take home and perform themselves, but also collected blood samples to compare to the results of the home-based testing. The specificity of the test remained relatively high, 99.98% (95% CI: 99.90–100%), and above BPAC's recommended threshold. However, sensitivity dropped in comparison to professional use of the kit to 92.98% from 99.3%.

Given this low performance threshold, we believe we are very well positioned with our SURE CHECK® HIV 1/2 blood test as well as our other FDA-approved products. However we believe that the development of this market will take time, and that its development will likely require OraSure to invest significantly in its development, as it is now. Orasure's first-three month period results for this product, which was in the fourth quarter of 2012, reported in February 2013 did nothing to change this expectation. Although we still believe that Chembio is the only other company that for all practical purposes has a product, let alone multiple products, that can participate in this new market, we have serious reservations about the size of the opportunity, particularly in relation to the significant investment of funds required in order to achieve regulatory approval and then commercialize the product. Nevertheless, because OraSure's product was approved with lower sensitivity than was previously expected by the FDA, this provides an opportunity for Chembio's product(s) to achieve improved performance – either with its blood and/or oral fluid HIV tests. We believe it is critical to go to this market with a substantially improved sensitivity and comparable specificity to OraSure's product, and a lower price (which would include lower packaging and distribution costs as compared with Orasure), and our current efforts are focused in this direction.

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

Recent Events

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. See Item 11 for more details.

In accordance with the terms of the Company's 2008 Stock Incentive Plan, on February 26, 2013, the Company granted, 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 to be equal to the last traded price for the Company's common stock on February 26, 2013, which was at $5.56 per share. The options become exercisable on the effective date of the grant. Each option granted will expire and terminate, if not exercised sooner, upon the earlier to occur of (a) 30 days after termination of the employee's employment with the Company or (b) the fifth anniversary of the effective date of the grant. The following table identifies the portions of these options issued to officers of the Company.

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
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
Sharon Klugewicz – Vice President of QA/QC	630

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 reverse stock split, the 63,967,265 outstanding common shares were reduced to 7,995,918 outstanding common shares on May 30, 2012.

RESULTS OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2012 AS COMPARED WITH THE YEAR ENDED DECEMBER 31, 2011

Income:

Income before income taxes for the year ended December 31, 2012 increased to $1,451,000 from $1,076,000 for the year ended December 31, 2011. Net Income decreased from $6.2 million for 2011 to $.94 million for 2012 despite the increase in income before taxes. The decrease in net income is primarily attributable to a $5.1 million benefit resulting from the partial elimination of the deferred tax asset valuation allowance in 2011. In 2012, as a result of a 39.6% increase in Net Product sales and a 34.7% decrease in non-product revenues, the Company had a $1,400,000, or 14.9%, increase in its gross margin, to $10,790,000. This increased gross margin funded increased operating expenses, the most significant of which was an increase in commission expenses of $606,000, due to the increased sales in Brazil.

Revenues:

Selected Product Categories:	For the years ended			
	December 31, 2012	December 31, 2011	$ Change	% Change
Lateral Flow HIV Tests and Components	$ 13,505,849	$ 12,865,541	$ 640,308	4.98 %
DPP Tests and Components	10,086,459	4,255,032	5,831,427	137.05 %
Other	735,047	301,738	433,309	143.60 %
Net Product Sales	24,327,355	17,422,311	6,905,044	39.63 %
License and royalty revenue	-	140,322	(140,322)	-100.00 %
R&D, milestone and grant revenue	1,283,240	1,825,403	(542,163)	-29.70 %
Total Revenues	$ 25,610,595	$ 19,388,036	$ 6,222,559	32.09 %

Revenues for our lateral flow HIV tests and related components during the year ended December 31, 2012 increased by $640,000 over the same period in 2011. This was primarily attributable to increased sales in the U.S., through Alere, of $515,000, and increased sales in Africa of $329,000; and was partially offset by decreased sales in other regions. Adding to these increases were increased other sales, which increased by 144%, or $433,000, primarily from increased sales of Chagas. Sales of our DPP® products in 2012 increased by $5,831,000, or 137%, compared to levels in 2011 as Brazil began ramping up their programs in 2012 for the five ANVISA-approved DPP® products. The decrease in R&D, milestone and grant revenue was primarily due to a decrease in grants and other development projects of $542,000 along with a decrease in royalty income of $140,000. R&D revenues in 2012 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. The decrease in R&D, milestone and grant revenue was due to revenue from milestones and certain development projects in 2011, which were not repeated. License and royalty revenue in 2011 is from royalties from Brazil under our 2004 technology transfer and license agreement, which ended prior to January 1, 2012.

Gross Margin:

Gross Margin related to Net Product Sales:	For the years ended

	December 31, 2012	December 31, 2011	$ Change	% Change
Gross Margin per Statement of Operations	$ 10,789,991	$ 9,390,303	$ 1,399,688	14.91 %
Less: R&D, milestone, grant, license and royalties	1,283,240	1,965,725	(682,485)	-34.72 %
Gross Margin from Net Product Sales	$ 9,506,751	$ 7,424,578	$ 2,082,173	28.04 %
Product Gross Margin %	39.08 %	42.62 %		

The gross margin dollar increase of $1.40 million included a 28% increase in gross margin from product sales, thereby more than offsetting a 35% decrease in non-product revenues. The 3.5% decrease in our product gross margin percentage was primarily due to increased overhead items, especially in the fourth quarter. In the fourth quarter we went to a third shift, increased overtime and had to hire temporary employees (all who needed training) in order to fulfill the large back orders we had going into the quarter. In addition, during 2012 we incurred more scrap than expected and we have taken steps to correct this and many other issues to reduce costs in the future. DPP® sales represented approximately 41% of sales in the year ended December 31, 2012 as compared to approximately 24% in the year ended December 31, 2011.

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, 2012	December 31, 2011	$ Change	% Change
Clinical and Regulatory Affairs:				
Wages and related costs	$ 436,668	$ 465,688	$ (29,020)	-6.23 %
Consulting	61,664	7,677	53,987	703.23 %
Stock-based compensation	28,278	18,858	9,420	49.95 %
Clinical trials	820,083	1,244,239	(424,156)	-34.09 %
Other	46,217	58,191	(11,974)	-20.58 %
Total Regulatory	1,392,910	1,794,653	(401,743)	-22.39 %
R&D Other than Regulatory:				
Wages and related costs	1,956,536	2,145,377	(188,841)	-8.80 %
Consulting	137,789	68,791	68,998	100.30 %
Stock-based compensation	41,838	36,765	5,073	13.80 %
Materials and supplies	646,271	552,456	93,815	16.98 %
Other	310,958	280,077	30,881	11.03 %
Total other than Regulatory	3,093,392	3,083,466	9,926	0.32 %
Total Research and Development	$ 4,486,302	$ 4,878,119	$ (391,817)	-8.03 %

Expenses for Clinical & Regulatory Affairs for the year ended December 31, 2012 decreased by $402,000 as compared to the same period in 2011. This was primarily due to the higher expenses we incurred in 2011 for clinical trials conducted for our DPP® HIV Screen Assay.

R&D expenses other than Clinical & Regulatory Affairs increased by $10,000 in the year ended December 31, 2012 as compared with the same period in 2011 and were primarily related to an increase in consulting, material and supply and other expenses, partially offset by decreases in personnel costs.

Selling, General and Administrative Expense:

Selected expense lines:	For the years ended

	December 31, 2012	December 31, 2011	$ Change	% Change
Wages and related costs	$ 1,534,440	$ 1,249,907	$ 284,533	22.76 %
Consulting	261,054	199,658	61,396	30.75 %
Commissions	1,208,946	603,377	605,569	100.36 %
Stock-based compensation	174,462	115,476	58,986	51.08 %
Marketing materials	65,249	50,900	14,349	28.19 %
Investor relations/investment bankers	282,058	176,297	105,761	59.99 %
Legal, accounting and compliance	559,569	448,676	110,893	24.72 %
Travel, entertainment and trade shows	163,704	67,504	96,200	142.51 %
Bad debt allowance (recovery)	28,000	(5,000)	33,000	-660.00 %
Other	574,105	517,502	56,603	10.94 %
Total S, G &A	$ 4,851,587	$ 3,424,297	$ 1,427,290	41.68 %

Selling, general and administrative expenses for the year ended December 31, 2012 increased by 41.7% as compared with the same period in 2011. This was primarily due to increases in commission expense of $606,000 primarily on sales to Brazil, wages and related expenses of $285,000, stock-based compensation of $59,000, consulting expenses of $61,000, professional fees of $111,000 and investor related expenses, including NASDAQ fees, of $106,000.

Other Income and Expense:

	For the years ended December 31, 2012	December 31, 2011	$ Change	% Change
Interest income	$ 7,911	$ 6,298	$ 1,613	25.61 %
Interest expense	(9,495)	(18,623)	9,128	-49.01 %
Total Other Income and (Expense)	$ (1,584)	$ (12,325)	$ 10,741	-87.15 %

Other expense for the year ended December 31, 2012 decreased approximately $10,700 to $1,600 as compared with $12,300 for the same period in 2011, primarily as a result of decreased interest expense of $9,100 due to the term loan with HSBC and an increase in interest income of $1,600.

Income tax (benefit) provision:

Prior to 2011 and through September 30, 2011, the Company had a full valuation allowance recorded against deferred tax assets. In the fourth quarter of 2011, based on our sustained profitable operating performance over the past three years and our positive outlook for taxable income in the future, the Company reevaluated its deferred tax asset. Based upon the guidance under ASC 740, we concluded that it was more likely than not that the Company would realize the benefit of such deferred tax assets, the Company reversed $5,156,000 of the valuation allowance previously recorded against its deferred tax assets, which resulted in a tax benefit increase to net income of that amount. It also increased the Company's book value by that amount. The deferred tax asset will be amortized against future income tax expense that would be payable in the absence of the net operating loss carryfoward. For the year ended December 31, 2012 the Company charged $509,000 to income tax expense and reduced the deferred tax assets by $471,085. 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, 2012	December 31, 2011	$ Change	% Change
Cash and cash equivalents	$ 2,951,859	$ 3,010,954	$ (59,095)	-1.96 %
Accounts receivable, net of allowance for doubtful accounts of $58,000 and $30,000 at December 31, 2012 and December 31, 2011, respectively	4,821,357	2,998,449	1,822,908	60.80 %
Inventories	2,488,071	2,300,286	187,785	8.16 %
Fixed assets, net of accumulated depreciation	1,427,646	1,062,276	365,370	34.40 %
	4,233,194	4,749,622	(516,428)	-10.87 %

Deferred tax asset, net of valuation allowance					
Accounts payable and accrued liabilities	3,303,923	2,789,500	514,423	18.44	%

Cash decreased by $59,000 from December 31, 2011, primarily due to the increase in accounts receivable, net of allowance change which increased by $1,823,000 along with an increase in inventories of $188,000, partially offset by an increase in accounts payable and accrued liabilities of $514,000 and utilization of the long-term deferred tax asset of $516,000 (short-term change of $45,000 nets to $471,000 overall change), (see liquidity section for more details). Net fixed assets increased primarily due to increases in manufacturing equipment and improvements.

The increase in accounts receivable was primarily attributable to a larger amount of credit sales in December of 2012 compared to December 2011. The increase in accounts payable and in inventories were both primarily due to a larger amount of materials ordered and manufactured for orders due to ship in the first quarter of 2013.

LIQUIDITY AND CAPITAL RESOURCES

	For the years ended December 31, 2012	December 31, 2011	$ Change	% Change
Net cash provided by operating activities	$ 761,084	$ 2,268,408	$ (1,507,324)	-66.45 %
Net cash used in investing activities	(872,442)	(726,680)	(145,762)	20.06 %
Net cash provided by (used in) financing activities	52,263	(667,125)	719,388	-107.83 %
(DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	$ (59,095)	$ 874,603	$ (933,698)	-106.76 %

The Company had a decrease in cash for the year ended December 31, 2012 as compared to a cash increase in the year ended December 31, 2011. The cash from operations in 2012 was primarily attributable to net income from operations of $941,000. In addition, other operating activities contributing to the increase in cash from operating activities in 2012 included an increase in accruals and payables of $514,000 and an increase in customer deposits of $23,000. These increases were partially offset by an increase in inventories of $188,000, an increase in prepaid expenses of $20,000 and an increase in accounts receivable of $1,851,000, as well as non-cash expenses totaling $1,340,000. The non-cash expenses consisted of $423,000 from depreciation expense, $318,000 in stock-based compensation expense, $100,000 in the amortization of licenses, utilization of $471,000 in deferred tax assets and an increase in allowance for doubtful accounts of $28,000. Investing activities represent the Company's investment in fixed assets. The cash provided in financing activities is primarily due to the exercise of options of $120,000 and partially offset by the payment of debt of $68,000.

Fixed Asset Commitments

As of December 31, 2012, the Company had paid deposits on various pieces of equipment aggregating $223,584, which is reflected in Other Assets on the balance sheet. The Company is further committed to additional equipment-purchase obligation of $61,071 as various milestones are achieved by the various vendors.

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

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, we are now focused on completing the requirements for a Clinical Laboratory Improvement Act (CLIA) waiver for this product in order to enable the product to be sold in the point-of-care market segments where these tests are primarily used. We anticipate this process to be completed in 2013. 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 blood POCT products sold through Alere.

We will address the public health market for the DPP HIV product through a small direct sales organization and the hospital and physician office market through distribution relationships. We are increasingly optimistic that this sales organization will also be able to market, by mid-2014, our DPP® Syphilis Screen & Confirm test and DPP® HIV-Syphilis multiplex test, and, in 2015, our Hepatitis- C (HCV) test. However each of these products has substantial development or regulatory steps ahead before they can be commercialized, even though significant progress is being made. Nevertheless, we are making significant progress toward commercializing these products.

We believe the quality, ease of use and reliability of our FDA approved products, together with their cost competitiveness, has enabled us to gain additional market share opportunities globally in 2012. However although we gained some significant new international accounts, other accounts had lower sales. This is primarily due to lower amounts of funding for the screening programs in such countries. Budgets can change dramatically from one period to the next and this can significantly impact our revenues. Also, given the nature of these large screening programs in developing world countries, large swings in orders from quarter to quarter can occur based on the sizes of orders, as evidenced in the third and fourth quarters of 2012. Our supply, technology transfer and license program to FIOCRUZ in Brazil for five different products produced over $10 million revenues for the Company, though it is not anticipated that 2013 sales to FIOCRUZ will recur at the 2012 level. We believe we will have strong sales growth of our FDA approved products sold by Alere in the United States, and we look forward to introducing our DPP® HIV 1/2 Assay, which has outstanding performance on all matrices including oral fluid samples, as soon as it is CLIA waived, which we anticipate by the end of 2013, although there is no assurance.

The Company has a number of new product and technology opportunities in addition to the aforementioned oral fluid HIV test, including two Syphilis multiplex tests. We are completing in the next month or two the application to the FDA for an Investigational Device Exemption for our Sure Check HIV 1/2 for home use so that we can begin clinical trials to pursue FDA approval for home use if and when we determine the investment is warranted.

We are working on a number of other projects based on, and/or that complement, our patented DPP® point-of-care technology, and in some cases we are now conducting feasibility studies in order to move these opportunities forward. These include potential products with application to the areas of women's health, veterinary diagnostics, and blood viruses, as well as technologies that improve the detection limits of our technology platform. We believe that these projects can ultimately result in potential new revenue streams in future periods, although there can be no assurance of this.

In addition to the core development programs that we have in place that we believe will drive long-term growth and shareholder value, we have also developed new distribution and OEM collaborations for existing products which, if successful, will help to produce additional revenue opportunities in markets where we already have an established record of success, including but not limited to Africa, Asia, and South America.

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 $25,000.

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 $48,000.

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, 2012.

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 (56), 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.

Richard J. Larkin (56), 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 from May 2000 to September 2003, and also led their 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 (46), 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.

Richard Bruce (59), Vice President, Operations. Mr. Bruce was hired in April 2000 as Director of Operations. He is responsible for manufacturing, maintenance, inventory, shipping, receiving, and warehouse operations. Prior to joining Chembio Diagnostic Systems Inc., he held director level positions at Wyeth Laboratories from 1984 to 1993. From 1993 to 1998, he held various management positions in the Operations Department at Biomerieux. From 1998 to 2000, he held a management position at V.I. Technologies. Mr. Bruce has over thirty years of operations management experience with Fortune 500 companies in the field of in-vitro diagnostics and blood fractionation. Mr. Bruce received his BS in Management from National Louis University in 1997.

Tom Ippolito (50), 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. (62), 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 Board of Director'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. Ms. Davis also served on the Board's Special Committee for handling certain strategic opportunities. Since January 2007, Ms. Davis has been the owner of Davis Design Group LLC, a company that provides analytical and visual tools for public policy design. Previously, from February 2005 to December 2006, she served as the Chief Executive Officer of Global Access Point, a start-up company with products for data transport, data processing, and data storage network and hub facilities. From October 2003 to January 2005, Ms. Davis was Lieutenant Governor of the State of Indiana, and from January 2000 to October 2003 was Controller of the City of Indianapolis. From 1989 to 2003, Ms. Davis held leadership positions with agencies and programs in the State of Indiana including State Budget Director, Secretary of Family & Social Services Administration, and Deputy Commissioner of Transportation. From 1982 to 1989 Ms. Davis held increasingly senior positions with Cummins Engine, where she managed purchasing, manufacturing, engineering, and assembly of certain engine product lines. Ms. Davis also led the startup of and initial investments by a $50 million Indiana state technology fund, serves on the not-for-profit boards of Noble of Indiana, University of Evansville Institute of Global Enterprise, Purdue College of Science Dean's Leadership Council and Indiana University School of Public and Environmental Affairs Dean's Advisory Council. 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 made her an excellent candidate for serving on the board.

Dr. Barbara DeBuono M.D., M.P.H., (57), Director. Dr. DeBuono, who was elected to the Company's Board of Directors in June 2011, is a renowned expert in public health innovation, health policy, education and research. Dr. DeBuono 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. (68), Director. Dr. Kissinger, who was elected to the Company's Board of Directors in June 2011, is a scientist, entrepreneur and academic, with a multi-faceted career in biotechnology and biomedical technologies. He is a Professor of Chemistry and Associate Department Head 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 230 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	Salary1 ($)	Bonus2 ($)	Stock Awards ($)	Option Awards3 ($)	All Other Compensation5 ($)	Total ($)
Lawrence A. Siebert4	2012	$ 290,000	$ 101,500	$ -	$ 28,217	$ 10,400	$ 430,1217
CEO	2011	281,346	101,500	-	-	12,600	395,446
Javan Esfandiari	2012	$ 263,077	$ 89,250	$ -	$ 24,811	$ 7,608	384,746
VP-R&D	2011	253,077	89,250	$ -	-	8,540	350,867
Tom Ippolito	2012	$ 196,187	$ 33,600	$ -	$ 9,340	$ 4,367	$ 243,494
VP-Regulatory	2011	190,702	33,600	-	41,997	3,958	270,257

1 Salary is total base salary.
2 Bonuses earned in 2012 and 2011 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, 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.

Mr. Ippolito does not have 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, 2012, there were five 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 60% of the executive’s bonus will be quantitative factors, based on the budget. 40% will be based on other factors and will be discretionary. In addition they are eligible for stock options based on a percentage of the total potential bonus earned. The plan, during 2012 for the 60%, called for a sliding percentage of the executive’s salary, from zero to 7.5% for attaining 85% to 100% of revenue goals, and from zero to 7.5% of the executive’s salary for attaining 70% to 100% of the designated operating profit goals. The Company achieved approximately 94% of its revenue goals for 2012, which would result in a bonus of 4.5% of each executive’s salary, and did not achieve 70% of its operating profit goal, which would result in a bonus of 0% of salary, for a total of 4.5% of salary. The Compensation Committee determined that the target goals were aggressive and considering the greater than 30% increase in revenues along with an increase in operating income it approved approximately 17% of salary in bonuses for the subject executives.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END 2012

	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	9,063		$ 4.00	2/16/2017	2/16/2012			5
	16,667		1.04	5/6/2014	5/6/2012			3
	16,667		1.04	5/6/2014	5/7/2011			3
	16,667		1.04	5/6/2014	5/6/2010			3
	31,250		1.04	6/3/2013	6/3/2008			2
	9,375		1.76	2/15/2013	2/15/2008			1
Javan Esfandiari	7,969		4.00	2/16/2017	2/16/2012			5
		12,500	2.16	3/4/2015	3/5/2013			2
	12,500		2.16	3/4/2015	3/5/2012			2
	12,500		2.16	3/4/2015	3/5/2010			2
	12,500		1.04	5/6/2014	5/6/2012			3
	7,500		1.04	2/15/2013	2/15/2008			1
Tom Ippolito	3,000		4.00	2/16/2017	2/16/2012			5
		7,812	4.32	5/9/2016	5/9/2014			4
		7,812	4.32	5/9/2016	5/9/2013			4
	9,375		1.04	5/6/2014	5/6/2012			3
	9,375		1.04	5/6/2014	5/7/2011			3
	9,375		1.04	5/6/2014	5/6/2010			3
	6,250		1.76	2/15/2013	2/15/2008			1

1 On February 15, 2008 the Company granted options under the 1999 Stock Option Plan.
2 Options issued in connection with an employment contract and under the 2008 Stock Incentive Plan.
3 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.
4 On May 3, 2011 and effective May 9, 2011 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 62,500 shares of the Company's common stock exercise price for these options was to be equal to the VWAP (Volume Weighted Average Price) market price for the Company's common stock on May 9, 2011. The options become exercisable evenly on the second and third anniversaries of 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 On February 16, 2012, the Company granted to certain employees of the Company, options to purchase an aggregate of 25,392 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 $.50 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.

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 2010 to handle the possible sale of the Company, the Chairman of the Committee was paid $12,000 per month, and the other director-member 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	$ 30,250	$ -	$ 30,250
Barbara DeBuono	24,500	-	24,500
Pete Kissinger	25,500	-	25,500
Gary Meller	27,500	-	27,500

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 and $9,750 in meeting fees paid during 2012; (b) Dr. DeBuono received an $18,000 annual fee as a member of the board of directors and $6,500 in meeting fees; (c) Dr. Kissinger received an $18,000 annual fee as a member of the board of directors for and $7,500 in meeting fees; (d) Dr. Meller received an $18,000 annual fee as a member of the board of directors and $9,500 in meeting fees.

2 Each outside member of the board of directors is granted, once every five years, options to purchase 46,875 shares of the company’s common stock with an exercise price equal to the market price on the date of the grant as part of 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, 2012. No member of the Compensation Committee serves as an executive officer of any other public company during the year ended December 31, 2012. 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, 2013, 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 6, 2013.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percent of Class
Siebert, Lawrence (1) 3661 Horseblock Road Medford, NY 11763	890,954	10.89%
Esfandiari, Javan (2) 3661 Horseblock Road Medford, NY 11763	143,735	1.77%
Larkin, Richard (3) 3661 Horseblock Road Medford, NY 11763	69,245	.85%
Ippolito, Tom (4) 3661 Horseblock Road Medford, NY 11763	38,987	.48%
Bruce, Richard (5) 3661 Horseblock Road Medford, NY 11763	49,717	.61%
Steele, Michael (6) 3661 Horseblock Road Medford, NY 11763	785	.01%
Klugewicz, Sharon (7) 3661 Horseblock Road Medford, NY 11763	630	.01%
Meller, Gary (8) 3661 Horseblock Road Medford, NY 11763	95,625	1.18%
Davis, Katherine L. (9) 3661 Horseblock Road Medford, NY 11763	48,922	.60%
DeBuono, Barbara (10) 3661 Horseblock Road Medford, NY 11763	20,704	.26%
Kissinger, Peter (11) 3661 Horseblock Road Medford, NY 11763	20,704	.26%
GROUP (12)	1,380,008	16.36%
Wellington Management Company, LLP 280 Congress Street Boston, MA 02210	670,980	8.30%

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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 95,529 shares issuable upon exercise of options exercisable within 60 days.
(2) Includes 50,234 shares issuable upon exercise of options exercisable within 60 days. Does not include 12,500 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(3) Includes 38,842 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.
(4) Includes 32,900 shares issuable upon exercise of options exercisable within 60 days. Does not include 15,624 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(5) Includes 13,458 shares issuable upon exercise of options exercisable within 60 days. Does not include 12,500 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(6) Includes 785 shares issuable upon exercise of options exercisable within 60 days. Does not include 36,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(7) Includes 630 shares issuable upon exercise of options exercisable within 60 days. Does not include 36,000 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 37,957 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.
(10) Includes 20,704 shares issuable upon exercise of options exercisable within 60 days. Does not include 28,125 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(11) Includes 20,704 shares issuable upon exercise of options exercisable within 60 days. Does not include 28,125 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(12) Includes footnotes (1)-(11)

Equity Compensation Plan Information

Combined Equity Compensation Plans - Information as of December 31, 2012

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance under Equity Compensation

	Rights				Plans (Excluding Securities Reflected in Column (a)
	(a)			(b)	(c)
Equity compensation plans approved by security holders1	731,646	1	$	0.212	68,961
Equity compensation plans not approved by security holders	-			-	-
Total	731,646		$	0.212	68,961

1 The “Number of Securities to be Issued Upon Exercise of Outstanding Warrants and Rights” represents 135,191 from the 1999 Stock Option Plan and 596,455 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, Richard J. Larkin, chief financial officer of the Company, and Javan Esfandiari, executive vice president of Research and Development of the Company.

In accordance with the terms of the Company's 2008 Plan, on May 9, 2011, the Company granted to certain employees of the Company options to purchase an aggregate of 62,500 shares of the Company's common stock. The exercise price for these options was to be equal to the VWAP (Volume Weighted Average Price) market price for the Company's common stock on May 9, 2011. The options become exercisable evenly on the second and third anniversaries of 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. Mr. Ippolito, Mr. Bruce and Mr. Larkin received options to purchase common stock of 15,625, 12,500 and 18,750 shares, respectively.

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
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
Sharon Klugewicz – Vice President of QA/QC	630

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. 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, 2012 and 2011, the Company engaged BDO USA, LLP as its independent accounting firm to audit the Company's annual financial statements and review of financial statements included in the Company's Forms 10-Q and 10-K for the years ended December 31, 2012 and 2011, for $109,000 and $110,000, respectively in fees.

Audit-Related Fees

For the years ended December 31, 2012 and 2011, 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, 2012 and 2011, the Company's independent accounting firm, BDO USA, LLP, billed the Company $30,000 and $44,000, respectively for professional services for tax compliance, tax advice and tax planning.

All Other Fees

For the years ended December 31, 2012 and 2011, the Company's independent accounting firm, BDO USA, LLP, did not provide the Company with any 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

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. (4)
4.3	2008 Stock Incentive Plan. (5)
4.4	Rights Agreement, dated March 8, 2010 (6)
4.5	Form of Warrant (to be filed by amendment) [to be revised]
10.1*	Employment Agreement dated June 15, 2006 with Lawrence A. Siebert. (7)
10.2*	Employment Agreement dated March 5, 2013 with Javan Esfandiari.
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)
10.7	Secured Term Note, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (9)
10.8	Secured Revolving Demand Note, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (9)
10.9	Loan and Security Agreement, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (9)
10.10	Revolving Term Note, dated as of July 22, 2011, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (10)
10.11	Loan and Security Agreement, dated as of July 22, 2011, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (10)
14.1	Ethics Policy (11)
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 April 14, 2008.
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 Quarterly Report on Form 10-Q filed with the Commission on July 29, 2010.
10	Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on November 3, 2011.
11	Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 30, 2006.
(*)	An asterisk (*) beside an exhibit number indicates the exhibit contains a management contract, compensatory plan or arrangement which is required to be identified in this registration statement.

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 7, 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 7, 2013
/s/ Richard J. Larkin Richard J. Larkin	Chief Financial Officer (Principal Financial & Accounting Officer)	March 7, 2013
/s/ Gary Meller Dr. Gary Meller	Director	March 7, 2013
/s/ Katherine L. Davis Katherine L. Davis	Director	March 7, 2013
/s/ Pete Kissinger Pete Kissinger	Director	March 7, 2013
/s/ Barbara DeBuono Barbara DeBuono	Director	March 7, 2013

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

Index to Consolidated Financial Statements

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of Chembio Diagnostics, Inc. and Subsidiary (the "Company") as of December 31, 2012 and 2011 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, 2012 and 2011, 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 7, 2013

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

- ASSETS -		
	December 31, 2012	December 31, 2011
CURRENT ASSETS:		
Cash and cash equivalents	$ 2,951,859	$ 3,010,954
Accounts receivable, net of allowance for doubtful accounts of $58,000 and $30,000 at December 31, 2012 and 2011, respectively	4,821,357	2,998,449
Inventories	2,488,071	2,300,286
Prepaid expenses and other current assets	747,463	681,893
TOTAL CURRENT ASSETS	11,008,750	8,991,582
FIXED ASSETS, net of accumulated depreciation	1,427,646	1,062,276
OTHER ASSETS:		
Deferred tax asset, net of valuation allowance	4,233,194	4,749,622
License agreements, net of current portion	400,000	500,000
Deposits on manufacturing equipment	223,584	139,790
Deposits and other assets	41,976	42,474
TOTAL ASSETS	$ 17,335,150	$ 15,485,744
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	$ 3,303,923	$ 2,789,500
Current portion of loans payable	51,236	53,550
Customer deposits	23,224	-
Current portion of obligations under capital leases	-	14,576
TOTAL CURRENT LIABILITIES	3,378,383	2,857,626
OTHER LIABILITIES:		
Loans payable - net of current portion	82,247	133,484
TOTAL LIABILITIES	3,460,630	2,991,110
COMMITMENTS AND CONTINGENCIES		

STOCKHOLDERS' EQUITY:		
Preferred stock – 10,000,000 shares authorized, none outstanding		-
Common stock - $.01 par value; 100,000,000 shares authorized, 8,036,232 and 7,921,021 shares issued and outstanding for 2012 and 2011, respectively	80,362	79,210
Additional paid-in capital	41,116,149	40,678,696
Accumulated deficit	(27,321,991)	(28,263,272)
TOTAL STOCKHOLDERS' EQUITY	13,874,520	12,494,634
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 17,335,150	$ 15,485,744

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, 2012	December 31, 2011
REVENUES:		
Net product sales	$ 24,327,355	$ 17,422,311
License and royalty revenue	-	140,322
R&D, milestone and grant revenue	1,283,240	1,825,403
TOTAL REVENUES	25,610,595	19,388,036
Cost of product sales	14,820,604	9,997,733
GROSS MARGIN	10,789,991	9,390,303
OPERATING EXPENSES:		
Research and development expenses	4,486,302	4,878,119
Selling, general and administrative expenses	4,851,587	3,424,297
	9,337,889	8,302,416
INCOME (LOSS) FROM OPERATIONS	1,452,102	1,087,887
OTHER INCOME (EXPENSE):		
Interest income	7,911	6,298
Interest expense	(9,495)	(18,623)
	(1,584)	(12,325)
INCOME BEFORE INCOME TAXES	1,450,518	1,075,562
Income tax provision (benefit)	509,237	(5,133,229)
NET INCOME	$ 941,281	$ 6,208,791
Basic earnings per share	$ 0.12	$ 0.79
Diluted earnings per share	$ 0.11	$ 0.73
Weighted average number of shares outstanding, basic	7,986,030	7,874,807
Weighted average number of shares outstanding, diluted	8,614,944	8,556,284

See accompanying notes to condensed consolidated financial statements

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2012 AND 2011

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount	Amount	Amount	Amount
Balance at December 31, 2010	7,779,882	$ 77,799	$ 40,203,208	$ (34,472,063)	$ 5,808,944
Warrants and options:					
Excercised	141,139	1,411	286,141	-	287,552
Stock option compensation	-	-	189,347	-	189,347
Net income	-	-	-	6,208,791	6,208,791
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:					
Consulting Services			8,010		8,010
Excercised	111,459	1,114	119,276	-	120,390
Stock option compensation	-	-	293,726	-	293,726
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

See accompanying notes to consolidated financial statements

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

	December 31, 2012	December 31, 2011
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	$ 23,810,911	$ 20,335,985
Cash paid to suppliers and employees	(23,048,243)	(18,055,252)
Interest received	7,911	6,298
Interest paid	(9,495)	(18,623)
Net cash provided by operating activities	761,084	2,268,408
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of and deposits on fixed assets	(872,442)	(726,680)
Net cash used in investing activities	(872,442)	(726,680)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from option and warrant exercises	120,390	287,552
Payment of license obligation	-	(875,000)
Payment of loan obligation	(53,551)	(54,980)
Payment of capital lease obligation	(14,576)	(24,697)
Net cash provided by (used in) financing activities	52,263	(667,125)
(DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(59,095)	874,603
Cash and cash equivalents - beginning of the period	3,010,954	2,136,351
Cash and cash equivalents - end of the period	$ 2,951,859	$ 3,010,954
RECONCILIATION OF NET INCOME TO NET CASH PROVIDED BY OPERATING ACTIVITIES:		
Net Income	$ 941,281	$ 6,208,791
Adjustments:		
Depreciation and amortization	523,278	437,828

Provision for deferred taxes	471,085	(5,155,713)
Provision for doubtful accounts	28,000	(5,000)
Share based compensation	318,215	189,347
Changes in assets and liabilities:		
Accounts receivable	(1,850,908)	952,949
Inventories	(187,785)	(951,125)
Prepaid expenses and other current assets	(20,227)	(70,978)
Deposits and other assets	498	(6,248)
Accounts payable and accrued liabilities	514,423	733,557
Customer deposits and deferred revenue	23,224	(65,000)
Net cash provided by operating activities	$ 761,084	$ 2,268,408
Supplemental disclosures for non-cash investing and financing activities:		
Deposits on manufacturing equipment transferred to fixed assets	$ 229,042	$ -

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2012 AND 2011

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 56% of the Company's product revenues in 2012. The Company's products based on its patented DPP® platform represented approximately 41% of the Company's product revenues in 2012. The Company also has other rapid tests that together represented approximately 3% of sales in 2012. 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.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2012 AND 2011

(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, 2012 and 2011 and is reported in prepaid expenses and other current assets. The long-term portion as of December 31, 2012 and 2011 is $400,000 and $500,000, 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, 2012 and 2011, 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, 2012 and 2011, an aggregate of $23,000 and none, 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, 2012 and 2011, 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) Income Taxes:

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

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

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2012 AND 2011
a

(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, 2012	December 31, 2011
Basic	7,986,030	7,874,807
	-	-
Diluted	8,614,944	8,556,284

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, 2012 and 2011 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, 2012	December 31, 2011
1999 and 2008 Plan Stock Options	628,914	681,477

There were 161,464 and 182,343 options and warrants outstanding as of December 31, 2012 and 2011, 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.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2012 AND 2011

NOTE 3 — INVENTORIES:

Inventories consist of the following at:

	December 31, 2012	December 31, 2011
Raw materials	$ 1,418,071	$ 1,340,177
Work in process	561,530	390,162
Finished goods	508,470	569,947
	$ 2,488,071	$ 2,300,286

NOTE 4 — FIXED ASSETS:

Fixed assets consist of the following at:

	December 31, 2012	December 31, 2011
Machinery and equipment	$ 2,439,596	$ 1,982,926
Furniture and fixtures	287,412	221,299
Computer and telephone equipment	151,737	460,842
Leasehold improvements	798,049	595,492
Automobiles	29,228	29,228
	3,706,022	3,289,787
Less accumulated depreciation and amortization	(2,278,376)	(2,227,511)
	$ 1,427,646	$ 1,062,276

There were no capital leases at the end of December 31, 2012. Included in fixed assets is $24,000, net of accumulated depreciation of assets held under capital leases as of December 31, 2011. Fixed assets at December 31, 2012 also include $323,000 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 2012 and 2011 years aggregated $423,000 and $338,000, respectively.

As of December 31, 2012 and 2011, the Company had paid deposits on various pieces of equipment aggregating $223,584 and $139,790, respectively. The Company is further committed to an additional obligation of $61,071 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, 2012	December 31, 2011
Accounts payable – suppliers	$ 1,686,431	$ 1,258,465
Accrued commissions	238,150	205,588

Accrued royalties / license fees		583,923		480,297
Accrued payroll		262,439		174,398
Accrued vacation		181,636		156,884
Accrued bonuses		155,663		284,375
Accrued expenses – other		195,681		229,493
TOTAL	$	3,303,923	$	2,789,500

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2012 AND 2011

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, 2012 and 2011, there were no unearned advanced revenues.

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

In June 2010, the Company entered into three agreements with HSBC Bank, NA ("HSBC"). The three agreements were: 1) a secured term note ("Term Note") of $250,000 to be repaid over sixty months; 2) a secured revolving demand note ("Demand Note") up to $250,000; and 3) a loan and security agreement ("Security Agreement").

The Term Note is payable at $4,775 per month in arrears. The payment was calculated by amortizing the $250,000 note over 60 months at an interest rate of 5.5% per annum. The Term Note matures June 2015 and is secured under the terms of the Security Agreement. In January 2013, the Company repaid this Term Note in full without penalty.

The Demand Note allows the Company to draw on the line from time to time an amount up to an aggregate of $250,000 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 and is subject to annual reviews, as well as a 30-day clean-up, during which there can be no amounts outstanding.