CHEMBIO DIAGNOSTICS, INC.
Form 10-K
March 08, 2012

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, 2011

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 $22,598,000.

As of March 6, 2012, the registrant had 63,668,096 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, 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.”

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, as well as our syphilis and canine leishmaniasis tests have been developed on our patented Dual Path Platform (DPP®), does not require in-licensing. The DPP® HIV test, detects antibodies to HIV in oral fluid samples as well as in all blood matrices. We anticipate completing United States FDA regulatory submissions for this product, which we anticipate launching under Chembio’s brand, in 2013.

Our new product pipeline 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 point-of-care market segment of the nearly $40 billion global in-vitro diagnostic market that is estimated to be $6-8 billion with an overall growth rate of 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, such as these products 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 as 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: 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. A Clinical Laboratory Improvement Act (hereinafter "CLIA"; see Governmental Regulations) waiver was 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, though 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"). The STAT PAK (both the cassette and dipstick versions) 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 approximately 15 minutes, is simple to use, has a shelf life of

24 months, and does not require refrigeration. Additionally 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 tested for multiple conditions. Clinical and laboratory studies have shown this product to have improved performance compared with all of the current FDA-approved CLIA-waived rapid tests including our own.

Regulatory Status: In 2010 we began a 3,000 patient clinical study with our DPP® HIV test in the United States which is one of the elements required to support a Pre-Marketing Approval ("PMA") application to the FDA. The trial is 98% complete and we anticipate completing the trial as soon as possible. We have already submitted two of the three modules required for a modular PMA application, and we anticipate submitting the final module containing the clinical and other required information within 30 days of completing the clinical trials. We believe that approval of our PMA application will be within approximately six months after we submit the final module. At that time, we plan to apply for CLIA waiver of this product.

The 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 (see Glossary) 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 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 will continue to employ the strategy of seeking OEM development and manufacturing agreements as a way to participate in markets that we cannot and/or choose not to serve (e.g., veterinary) , we believe that we can also develop our own branded line of products, and we plan to do this in the public health area. This brand will be launched 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 (See RECENT DEVELOPMENTS AND CHEMBIO'S PLAN OF OPERATIONS FOR THE NEXT TWELVE MONTHS).

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.

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, principally including our lateral flow HIV tests that we have continued to market outside the United States. 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 for our lateral flow HIV rapid tests outside the United States are certain countries in Africa and Asia 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 in periods of relatively lower demand, based on the variations associated with this kind of demand.

Our DPP® HIV test was approved by ANVISA 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).

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 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. 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. The actual demand for these products may be more or less than this amount. The actual amount will depend on the actual demand for the products by the specific programs for each product funded by the Brazilian Ministry of Health as well as the 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 schedule to be completed in mid-2013; thereafter Chembio may 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.

Bio-Rad Laboratories OEM DPP® Agreement- On April 6, 2008, we entered a milestone-based development agreement with Bio-Rad Laboratories N.A., a division of Bio-Rad Laboratories Inc. (NYSE:BIO), a leading in-vitro diagnostic and life science company. The agreement with Bio-Rad was for the development of a six-band multiplex product on our DPP®. Based on achieving the proof of concept for this product during 2008, in January 2009 we entered a limited exclusive license agreement with Bio-Rad related to the field of use for this application, and we continued the development work during all of 2009 and until Bio-Rad confirmed that the product specifications were met in the second quarter of 2010. In June 2010, Bio-Rad exercised its option to have Chembio transfer the manufacturing of this product to Bio-Rad subject to a royalty payment payable to Chembio pursuant to a license agreement with Bio-Rad based on Bio-Rad's net sales of the licensed product, which process was completed in October 2010. Chembio believes that Bio-Rad is proceeding with the regulatory approvals of this product, with CE Mark likely by the end of 2012, although there can be no assurance of this. We further believe that Bio-Rad has begun discussions with the FDA to discuss this product, its proposed performance claims and the intended clinical protocol to support its regulatory submission.

During 2008 to 2010, Chembio earned approximately $460,000 for product development work rendered to Bio-Rad under this agreement, plus an additional $490,000 in license and other fees related to the manufacturing transfer.

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 hand held 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. Also, because of the usage in DPP® of a separately connected sample strip, the control and delivery of sample material is substantially improved. This 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.

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 if samples have to be sent out to a laboratory which can take at least 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 1.1 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 at least several days to process. Making more people aware of their HIV status at the point-of-care will reduce the number of HIV transmissions.

Rapid HIV testing in the United States has now developed into an estimated 7 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 guidelines 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. Adoption of the 2006 CDC recommendations by a number of states continues to have an increasing impact.

In the international market, PEPFAR, the large United States funded international AIDS relief program focused on fifteen countries, was reauthorized in 2008 for up to $48 billion for FY2009-2012 (up from $15 billion in 2004-2008). PEPFAR and the Global Fund are the largest of the global initiatives that have helped to make prevention, care and life-saving treatments available to those that need them. For example, PEPFAR has the goal that by 2013 three million infected individuals will be provided treatment and 12 million new cases will be averted. To achieve these goals, more and more people are likely to get tested. As more effective treatments become available at lower costs, there is a clearer reason to be tested.

The U.S. and international economics crisis of the last few years has impacted the growth in funding of these large programs, though private donations have supplemented the governmental and non-governmental programs. Still, accountability, alleged corruption, and the eligibility of lower quality and lower cost products make these markets challenging. Throughout we believe that Chembio has remained, and is increasingly recognized as, a reputable and dependable supplier of high quality products that are available at reasonably competitive prices.

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 a potential over-the-counter market for HIV tests and we are well positioned to participate in this market, should we believe the investment is justified. After years of debate, this potential market has received increasing support by the FDA Blood Products Advisory Committee, the United States Centers for Disease Control, as well as key opinion leaders in the public health and HIV advocacy community. In 2011 Orasure Technologies Inc. announced that it had submitted its final application to the FDA for its oral fluid HIV test, which may result in FDA approval of the first over-the-counter HIV test during 2012.

Based on the fact that FDA has required 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, due to certain features of Trinity's product Unigold®, we do not believe they intend to pursue this potential market, particularly since Trinity has stated this themselves. Therefore Chembio is carefully monitoring developments in this market, which may be significant during 2012. Currently we could initiate the over the counter approval process with either of our two blood tests. Provided we 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 upon receiving such approval. However, the requirements for such approval are estimated to be approximately $4-6 million, and may take two to three years to complete.

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 even 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.

In February 2011 a study was released by the CDC that suggested that the "newest" laboratory screening tests, which are using technologies developed in the 1980s (i.e. Enzyme-linked Immunoassays), are resulting in a large number of suspected false positive test results, which are test results that are not in fact representing active cases of Syphilis. This study involved tests done in high throughput blood screening laboratory settings, and not necessarily clinical settings. Nevertheless we believe that the study suggests that if public health clinicians could have what is effectively the CDC-recommended laboratory testing algorithm in a point-of-care test, this could be an invaluable public health tool in higher risk testing (higher STD prevalence) settings. We believe this is the opportunity we have with this product.

Marketing Strategy

Our marketing strategy is to:

- Support, review and assess the marketing and distribution efforts of our rapid HIV tests by Alere. 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 long term creation of shareholder value.

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 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 2011 and 2010, $4.9 million and $4.1 million ($2.6 million, net of Qualified Therapeutic Discovery Project ("QTDP") grants), 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 $1.8 million in 2011 and $2.8 million in 2010. 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. Research and development and regulatory activities are explained in detail in Part II Item 7.

Employees

At December 31, 2011, we employed 140 people, including 137 full-time employees. 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 2013. 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 to 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 is being pursued 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 in fact 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 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.

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 Medical and Trinity Biotech. As new products 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 a rapid HIV test product called Determine® that, with its 3rd generation test, is the leading product used in the developing world. The Determine HIV test product line, which was until 2006 a division of Abbott Diagnostics in Japan that was then sold to Alere, has had at least a few versions, the newest of which is the so called "4th Generation" Determine test which, according to its claims, detects HIV antibodies and HIV antigen. The claim of such a 4th generation product is that it detects infection earlier than tests that solely rely on antibody detection, which required immune response before detection can occur. Alere has made statements that it is or will be seeking FDA approval of this product which, if approval is granted, could potentially be 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 in the United States without breaching the agreement, though there are defined consequences in such case: for the cassette product, Chembio may either terminate Alere or make the agreement with Alere non-exclusive, and for the barrel product, Chembio and StatSure Diagnostics (the other party to the Alere 3-way agreement pertaining to the barrel product) can jointly agree to either continue the agreement with Alere or to also make the barrel agreement non-exclusive. 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.

Although we have no specific knowledge of any other competitor's product 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 2011 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 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 FDA approved, currently anticipated in 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. We believe that this new 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 or our contract partners, sales agents, 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 three consecutive years. Nevertheless, prior to 2009 we sustained significant operating losses since 2004. At December 31, 2011, we had a stockholders' equity of $12.5 million and a working capital surplus of $6.1 million. The Company estimates that its resources are sufficient to fund its needs through the end of 2012 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 2012 or, in the alternative, be successful in raising sufficient capital to fund its needs through 2012 and thereafter.

The increase in revenues anticipated in 2012 from the launch of our DPP® products in Brazil, continued revenues from Alere from the U.S. rapid HIV test market, increased sales to developing world markets, and continued strength in our contract development and grant revenues are all critical for us to continue to maintain and increase our profitability while funding our new product regulatory approval and commercialization programs. If we fail to meet any of these objectives, we may not generate revenues in the amounts necessary to maintain and increase our profitability and/or to fund our planned research, development, regulatory, selling, general and administrative expenses in 2012.

We intend to attempt to increase international sales of our products. A number of factors can slow or prevent international sales, or substantially increase the cost of international sales, including:

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

If we are unable to increase our revenues from international sales, 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 2013. We have obtained a key man insurance policy for Mr. Esfandiari.

We believe our success depends in part on our ability to participate in large testing programs in the U.S. and worldwide and we may not be able to do so.

We believe it to be in our best interests to meaningfully participate in large testing programs. Participation in these programs 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 and 2011, we cannot be certain that we will be able to sustain profitability in 2012.

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 three years. While we anticipate growth in our product revenues in 2012 as compared with 2011, there can be no assurance of this. Moreover in 2012 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 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 would 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

In the past, our Common Stock has been classified as penny stock, and it continues to be extremely illiquid, so investors may not be able to sell as much stock as they want at prevailing market prices.

In the past, our Common Stock has been classified as penny stock. Penny stocks generally are equity securities with a price of less than $5.00 and trade on the over-the-counter bulletin board market (OTCBB, currently on the QTCQB). As a result, an investor may find it more difficult to dispose of or obtain accurate quotations as to the price of the securities that are classified as penny stocks. The "penny stock" rules adopted by the Commission under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), subject the sale of the shares of penny stock issuers to regulations that impose sales practice requirements on broker-dealers, causing many broker-dealers to not trade penny stocks or to only offer the stocks to sophisticated investors that meet specified net worth or net income criteria identified by the Commission. These regulations contribute to the lack of liquidity of penny stocks.

At the present time, transactions in our Common Stock are not subject to the "penny stock" rules because our average revenue for 2009, 2010 and 2011 exceeded $6 million per year. However, there can be no assurance that transactions in our Common Stock will not be subject to the "penny stock" rules in the future.

The average daily trading volume of our Common Stock on the over-the-counter market was less than 35,000 shares per day over the three months ended March 6, 2012. If limited trading in our stock continues, it may be 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, 2012, our named executive officers, directors and 5% stockholders beneficially owned approximately 24.3% of our voting power. For the foreseeable future, 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 28,000 square feet of industrial space for $18,223 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 19,200 square feet). The lease term expires on April 30, 2014. We have entered into two additional leases: the first effective on November 1, 2011, covering 2,000 additional square feet; and the second signed on December 18, 2011, effective January 1, 2012, covering 2,600 additional square feet; principal terms of these leases are the same as the one entered into in 2009 which was as follows: (a) a lease term ending April 30, 2014; (b) an initial rent of $11,350 per month ; (c) the monthly rent for year two of the lease 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 OTCQB, which is the second of the three tiers of the OTC Market Group, under the symbol "CEMI." Prior to February 24, 2011, our stock was quoted on the OTC Bulletin Board. The table below sets forth the high and low bid prices per share of our common stock for each quarter of our two most recently completed fiscal years. These prices represent inter-dealer quotations without retail markup, markdown, or commission and may not necessarily represent actual transactions.

Fiscal Year 2011	High Bid	Low Bid
First Quarter	$ .500	$ .390
Second Quarter	$ .580	$ .410
Third Quarter	$ .480	$ .410
Fourth Quarter	$ .480	$ .360
Fiscal Year 2010	High Bid	Low Bid
First Quarter	$ .330	$ .200
Second Quarter	$ .280	$ .159
Third Quarter	$ .290	$ .210
Fourth Quarter	$ .490	$ .225

We are considering alternative markets for our stock, including but not limited to NASDAQ and NYSE-Amex. At the most recent annual meeting of Chembio shareholders in September 2011, shareholders granted authority to our board of directors to effectuate a reverse split of the Company's common stock without further shareholder approval required. This authority was granted for the two year period following the date of the authorization, for a reverse split in the range between, and including, five-to-one and fifteen-to-one. At the current level of its stock price, the Company would need to undertake a reverse stock split in order to have a stock price sufficient to qualify for listing on NASDAQ or NYSE-Amex.

Rule 15g-9 of the Securities and Exchange Commission, known as the Penny Stock Rule, imposes requirements on broker/dealers who sell securities that are subject to this rule to persons other than established customers and accredited investors (As indicated below, the Penny Stock Rule currently does not apply tp Chembio.) For transactions covered by the rule, brokers/dealers must make a special suitability determination for purchasers of the securities and receive the purchaser's written agreement to the transaction prior to sale. The Securities and Exchange Commission also has rules that regulate broker/dealer practices in connection with transactions in "penny stocks." Penny stocks generally are defined under this rule as equity securities with a price of less than $5.00 (other than securities registered on certain national securities exchanges or quoted on the NASDAQ system, provided that current price and volume information with respect to transactions in that security is provided by the exchange or system), except for securities of companies that have tangible net assets in excess of $2,000,000 or average revenue of at least $6,000,000 for the previous three years. The Penny Stock Rule requires a broker/ dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document prepared by the Commission that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker/dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker/dealer and its salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker/dealer and salesperson compensation information, must be given to the customer orally or in writing prior to effecting the transaction and must be given to the customer in writing before or with the customer's confirmation. These disclosure requirements have the effect of reducing the level of trading activity in the secondary market for penny stock issues. As a result of these rules, investors sometimes find it difficult to sell shares of penny stock issuers. At the present time, transactions in our common stock are not subject to the Penny Stock Rule because our average revenue for 2009, 2010 and 2011 exceeded $6 million per year. However, there can be no assurance that transactions in our common stock will not be subject to the Penny Stock Rule in the future.

Holders

As of March 1, 2012, there were approximately 1,550 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.

ITEM 6. SELECTED FINANCIAL DATA

Presented in this table are selected financial data for the past five years ended December 31, 2011.

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

Statement of Operations Data:

	December 31, 2011		December 31, 2010		December 31, 2009		December 31, 2008		December 31, 2007	
TOTAL REVENUES	$19,388,036		$16,704,703		$13,834,248		$11,049,571		$9,230,948	
GROSS MARGIN	9,390,303	48%	8,100,699	48%	5,860,405	42%	3,851,721	35 %	2,795,710	30 %
OPERATING COSTS:										
Research and development expenses	4,878,119	25%	2,586,308	15%	2,883,696	21%	2,605,343	24 %	1,906,653	21 %
Selling, general and administrative expenses	3,424,297	18%	2,940,721	18%	2,659,382	19%	3,317,046	30 %	3,765,221	41 %
	8,302,416		5,527,029		5,543,078		5,922,389		5,671,874	
INCOME (LOSS) FROM OPERATIONS	1,087,887		2,573,670		317,327		(2,070,668)		(2,876,164)	
OTHER INCOME (EXPENSES):	(12,325)		(14,503)		(8,267)		121,898		249,272	
INCOME (LOSS) BEFORE INCOME TAXES	1,075,562	6 %	2,559,167	15%	309,060	2 %	(1,948,770)	-18%	(2,626,892)	-28%
Income tax (benefit) provision	(5,133,229)		45,823		-		-		-	
Effect of preferred stock conversion in 2007	-		-		-		-		5,645,310	
NET INCOME (LOSS)	$6,208,791		$2,513,344		$309,060		$(1,948,770)	-18%	$(8,272,202)	-90%
	$0.10		$0.04		$0.00		$(0.03)		$(0.57)	

Basic income (loss) per share					
Diluted income (loss) per share	$0.09	$0.04	$0.00	$(0.03)	$(0.57)
Weighted average number of shares outstanding, basic	62,998,402	62,102,861	61,946,435	61,266,954	14,608,478
Weighted average number of shares outstanding, diluted	68,450,220	70,920,915	75,041,932	61,266,954	14,608,478
Balance Sheet Data:					
Working capital	$6,133,956	$4,560,277	$1,493,970	$1,663,914	$3,228,724
Total assets	15,485,744	9,086,174	6,315,250	5,914,941	6,584,997
Total liabilities	2,991,110	3,277,230	3,227,336	3,337,609	2,322,171
Shareholders' equity	12,494,634	5,808,944	3,087,914	2,577,332	4,262,826

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, and other factors. You can identify forward-looking statements by terminology such as "may," "could", "will," "should," "expect "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continues" or the negative of these term 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.

DPP® Leptospirosis – Our work under the three-year $3 million Small Business Innovative Research (SBIR) Phase II grant we were awarded in 2009 by the United States National Institutes of Health (NIH) to fully develop, validate, and commercialize a rapid diagnostic test for Leptospirosis for general use worldwide is progressing on schedule and we expect to complete this grant in the second quarter of 2012. The test is being developed with our DPP® technology utilizes proprietary reagents developed by Yale University and the Oswaldo Cruz Foundation at the Brazilian Ministry of Health. Development of the test has been in collaboration with the Division of Infectious Diseases, Yale University in New Haven, CT and the Oswaldo Cruz Foundation, the largest biomedical research institution in Latin America.

DPP® Tuberculosis – As reported in February 2011, we were awarded a three-year $2.9 million, subsequently reduced to $2.4 million, Small Business Innovative Research (SBIR) Phase II grant from the United States National Institutes of Health (NIH) to continue development of a simple, rapid, accurate, and cost-effective serological test for active tuberculosis that can be utilized in resource-limited settings. During 2011 we have screened and identified TB antigens useful for serological assay in co-operation with Infectious Disease Research Institute (IDRI) and during 2012 we intend to continue development of a POC test work with DPP technology.

Battelle/CDC DPP® Influenza Immunity Test – In 2010, we received approximately $804,000 from Battelle Memorial Institute pursuant to a development contract for an Influenza Immunity test. This is a multiplex antibody detection test that could be used in connection with pandemic influenza preparedness strategies to determine exposure to various strains of influenza in different geographic regions or in different population or demographic segments. Upon completing this work in early 2011 we provided prototype tests kits as required by the contract. These prototypes were evaluated by Battelle and by the CDC and, based on the satisfactory results of these prototypes, we entered into an amendment of this contract that was to begin in November 2011 to continue additional development work for this product in the fourth quarter of 2011 and the first quarter of 2012. However, due to a delay in our contract partners obtaining access to certain biomarkers necessary for the project to proceed, this development work has been postponed at least through the first quarter of 2012.

Qualifying Therapeutic Discovery Projects - On November 1, 2010, the Company was notified by the IRS that it received awards in the total amount of $1.467 million relating to six "Qualifying Therapeutic Discovery Projects" under the U.S. Patient Protection and Affordable Care Act of 2010 (P.L. 111-148), a program that was created as part of the major United States federal health care reform legislation enacted earlier that year.

Under the award guidelines, qualified therapeutic discovery projects had to show a reasonable potential to result in new therapies to treat areas of unmet medical need or to prevent, detect or treat chronic or acute diseases and conditions, reduce the long-term growth of health care costs in the United States, or significantly advance the goal of curing cancer within 30 years. Chembio's projects that received awards include products based on the Company's patented DPP(r) point-of-care diagnostic platform that are in various stages of its development pipeline such as its products for the rapid diagnosis of HIV, Hepatitis-C, and Syphilis.

Other Research & Development Activities - 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.

Chembio continues to work with commercial, governmental and private organizations in order to obtain R&D contracts and grant funding for development projects. These programs have subsidized the Company’s development expenses while expanding the applications for and know-how related to DPP®, while also creating important collaborative relationships.

There can be no assurance that any of these grant applications will result in any funding awards to the Company, nor that any of the existing research and development contracts or grants will continue 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.

Regulatory Activities

CE Mark for FDA-approved HIV tests – The final studies for the CE Marking requirements, which we have been pursuing for some time, were submitted to our notified body during October 2011. However, due to the length of time it has taken to achieve this regulatory approval, and the additional fees requested by our notified body to review our file again with the supplemental data requested, we decided to reassess the justification of this. During this reassessment we also became aware of a new submissions strategy, as well as potential new marketing opportunities for rapid HIV testing in certain markets in Europe. As a result we are in discussions with respect to this new submission strategy and we are more optimistic both on our prospects for CE Marking and for the outlook for commercial opportunities in Europe. We expect to have an updated timetable and outlook for this project during the second quarter.

Regulatory Approvals in Brazil through the Oswaldo Cruz Foundation (FIOCRUZ) – During 2011 we received notification from FIOCRUZ that our DPP® Syphilis Treponemal screening test and our DPP® Leptospirosis tests were each approved by Brazil's National Health Surveillance Agency (ANVISA). Also during 2011 our DPP® visceral canine leishmania rapid test was approved by Brazil's Ministry of Agriculture, Livestock and Food Supply ("MAPA"). This is the first diagnostic product that FIOCRUZ has successfully submitted for approval to MAPA in Brazil.

FDA Approval for DPP® HIV 1/2 Screening Assay - We began submitting the PMA (Pre-Marketing Approval) application to the FDA using the Modular PMA option, and we have thus far submitted Module I containing manufacturing information and Module II containing non-clinical data, which was submitted in the beginning of October 2011. We have enrolled 98% of the 3,000 patient clinical trial. We expect the trial to be completed as soon as possible depending on the recruitment rate of the remaining pediatric enrolees. We continue to be satisfied with the results and believe they continue to support product performance that will meet or exceed requirement for a PMA approval on oral fluid, finger-stick whole blood, venous whole blood, serum and plasma samples. Assuming early May completion, we would submit Module III to the FDA during the second quarter of 2012. Based on statutory FDA timetables, we would anticipate an FDA approval at least on an approvable PMA decision well before year end. We would then immediately apply for CLIA waiver, which is expected to take approximately three months to be granted.

Syphilis - As a result of our having received a CE Mark for the product in Q3'11 and our business development efforts during Q4'11, we have now established several European distributors for this product. Product evaluations are being completed in France and the UK. In the U.S. we have decided to incorporate a reader for the U.S. market product and as an option in Europe. We believe this will better ensure that there will be an acceptable agreement of our test results to the legacy RPR test results which is the reference for the non-treponemal marker on our dual marker test. We already are manufacturing large volumes of a visually read, treponemal-only test for Brazil with outstanding performance. This product would be an alternative pathway to bringing a syphilis POCT to the U.S. market. However such a test, like the laboratory treponemal tests, would not differentiate between active and previous infections, which are a preferred feature at least for testing in higher prevalence and risk groups. Assuming we can successfully incorporate the reader, we believe we can complete the clinical trials and make the 510(k) submission to the FDA for this product in 2012. Therefore FDA 510(k) clearance could be within the first half of 2013 followed by commercial launch in the US.

Sure Check® HIV OTC Study - We have made progress toward completing the requirements for submitting an IDE ("Investigational Device Exemption") application. This exemption must be granted in order to begin clinical studies that would be necessary to gain FDA approval of this product, which approval could take two or three years from the time that we initiate such clinical studies. We believe that this year (2012) there will be external events that will help us to better define the market opportunity. This principally includes a meeting of the FDA's Blood Products Advisory Committee (date not determined yet) that is likely to result in a final recommendation concerning the application by Orasure Technologies for OTC use of its oral fluid HIV test. Assuming it is recommended, and the product is actually launched, we will be able to assess the market approach and its reception by their targeted consumers. This information will help us before we commit additional significant sums to this program. We can do this knowing that we are the only company other than this competitor that has a device that is qualified to begin the studies necessary to gain OTC approval.

Since our meeting with the FDA in October 2011 which clarified the regulatory pathway to commercialization, we continue to make progress towards the HIV rapid test for Over-the-Counter (OTC) market. We have completed the "instructional manual" for home-testing using the Flesch-Kincaid readability tests. The initial validation on the comprehension of the manual has been initiated in the first quarter of 2012 using groups identified during our market research (completed in 2011), this group will comprise of individuals with limited education and/or English as a second language.

In addition to making progress towards the regulatory path for commercialization, we are actively working with public health agencies to begin studies in 2012. The objective of these studies is to understand the barriers and facilitators to uptake home testing and other strategies that can be employed to prevention and care of certain demographics at risk to HIV infection. These studies, while providing invaluable health care strategies, can provide feedback to Chembio

to improve upon or validate the design of the product to assure it remains safe and effective in a non-professional laboratory setting.

Recent Events

In accordance with the terms of the Company's 2008 Stock Incentive Plan, on February 16, 2012, the Company determined to grant on February 16, 2012, to certain employees of the Company, options to purchase an aggregate of 203,125 shares of the Company's common stock. The exercise price for these options was to be equal to the last traded price for the Company's common stock on February 16, 2012, which was at $.50 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	20,500
Javan Esfandiari – Executive Vice President of R&D	63,750
Tom Ippolito - Vice President of Regulatory Affairs, QA & QC	24,000
Richard J. Larkin – Chief Financial Officer	22,375
Lawrence A. Siebert – Chief Executive Officer	72,500

RESULTS OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2011 AS COMPARED WITH THE YEAR ENDED DECEMBER 31, 2010

Income:

Income before income taxes for the year ended December 31, 2011 decreased to $1,076,000 from $2,559,000 for the year ended December 31, 2010. Net Income increased from $2.5 million for 2010 to $6.2 million for 2011 despite the decrease in income before taxes. The increase in income is attributable to a $5.1 million addition resulting from the partial elimination of the tax valuation allowance. In 2011, as a result of a 28.9% increase in Net Product sales and a 38.4% decrease in non-product revenues, the Company had a $1,290,000, or 15.9%, increase in its gross margin, to $9,390,000. This increased gross margin funded increased operating expenses, the most significant of which was increase clinical trial expenses of $590,000. Also, during the fourth quarter of 2010, the Company was awarded $1,467,000 of Qualified Therapeutic Discovery Project grants which reduced R&D Expense in 2010.

Revenues:

Selected Product Categories:	For the years ended			
	December 31, 2011	December 31, 2010	$ Change	% Change
Lateral Flow HIV Tests and Components	$ 12,865,541	$ 12,111,560	$ 753,981	6.23 %
DPP Tests and Components	4,255,032	628,101	3,626,931	577.44 %
Other	301,738	776,698	(474,960)	-61.15 %
Net Product Sales	17,422,311	13,516,359	3,905,952	28.90 %
License and royalty revenue	140,322	432,238	(291,916)	-67.54 %
R&D, milestone and grant revenue	1,825,403	2,756,106	(930,703)	-33.77 %
Total Revenues	$ 19,388,036	$ 16,704,703	$ 2,683,333	16.06 %

Revenues for our lateral flow HIV tests and related components during the year ended December 31, 2011 increased by $754,000 over the same period in 2010. This was primarily attributable to increased sales in the U.S., through Alere, of $1,928,000, in Asia of $1,665,000, and increased sales to Mexico of $874,000, partially offset by decreased sales to Africa of $3,789,000. These increases were partially offset by reduced other sales, which decreased by 61%, or $475,000. Sales of our DPP® products in 2011 increased by $3,627,000, or 577%, compared to levels in 2010. Most of the DPP® product sold in 2011 related to products that were approved for sale in Brazil as compared to products sold in 2010, which sales primarily related to products used by FIOCRUZ in evaluations and submissions to Brazilian regulatory agencies for approval. The decrease in R&D, milestone and grant revenue was primarily due to $1,221,000 earned in 2010 as a result of the completion of certain milestones, versus $570,000 in 2011. In addition $804,000 in 2010 from Battelle for influenza immunity test was not repeated in 2011. R&D revenues in 2011 also 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. License and royalty revenue in 2010 includes fee payments of $340,000 from Bio-Rad pursuant to the License Agreement we signed with them in January 2009, partially offsetting this decrease was increased royalties of $48,000 from Brazil under our 2004 technology transfer and license agreement.

Gross Margin:

Gross Margin related to Net Product Sales:	For the years ended			
	December 31, 2011	December 31, 2010	$ Change	% Change
Gross Margin per Statement of Operations	$ 9,390,303	$ 8,100,699	$ 1,289,604	15.92 %
Less: R&D, milestone, grant, license and royalties	1,965,725	3,188,344	(1,222,619)	-38.35 %
Gross Margin from Net Product Sales	$ 7,424,578	$ 4,912,355	$ 2,512,223	51.14 %
Gross Margin %	42.62 %	36.34 %		

The gross margin increase included a 51.14% increase in gross margin from product sales, thereby more than offsetting a 38.35% decrease in non-product revenues. The 51.14% increase in our product gross margin was primarily due to the increase in product sales and from the mix of products sold in 2011, which included more products sold in the U.S, Brazilian, and Asian markets, at more favorable margins, as compared to 2010, when more products were sold to the African region which sales tend to be at somewhat lower margins.

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, 2011	December 31, 2010	$ Change	% Change
Clinical and Regulatory Affairs:				
Wages and related costs	$ 465,688	$ 424,038	$ 41,650	9.82 %
Consulting	7,677	30,525	(22,848)	-74.85 %
Stock-based compensation	18,858	11,881	6,977	58.72 %
Clinical trials	1,244,239	654,253	589,986	90.18 %
Other	58,191	74,254	(16,063)	-21.63 %
Total Regulatory	1,794,653	1,194,951	599,702	50.19 %
R&D Other than Regulatory:				
Wages and related costs	2,145,377	1,889,702	255,675	13.53 %
Consulting	68,791	19,430	49,361	254.05 %
Stock-based compensation	36,765	73,656	(36,891)	-50.09 %
Materials and supplies	552,456	635,911	(83,455)	-13.12 %
Other	280,077	239,535	40,543	16.93 %
Total other than Regulatory	3,083,466	2,858,234	225,233	7.88 %
	$ 4,878,119	$ 4,053,184	$ 824,935	20.35 %
Less: QTDP grant	-	1,466,876	(1,466,876)	-100.00 %
Total Research and Development	$ 4,878,119	$ 2,586,308	$ 2,291,811	88.61 %

Expenses for Clinical & Regulatory Affairs for the year ended December 31, 2011 increased by $600,000 as compared to the same period in 2010. This was primarily due to expenses we incurred in 2011 for clinical trials conducted for our DPP® HIV Screen Assay. In addition, wages and related costs also contributed to the increase.

R&D expenses other than Clinical & Regulatory Affairs increased by $225,000 in the year ended December 31, 2011 as compared with the same period in 2010 and were primarily related to an increase in personnel and consulting expenses, partially offset by decreases in material costs and stock-based compensation.

On November 1, 2010, the Company was notified by the IRS that it received awards in the total amount of $1.467 million relating to six “Qualifying Therapeutic Discovery Projects” under the U.S. Patient Protection and Affordable Care Act of 2010 (P.L. 111-148), a program that was created as part of the major United States federal health care reform legislation enacted earlier in 2010. The $1.467 million reduced R&D expenses in the fourth quarter of 2010. This grant was not renewed for 2011.

Research and development expenses, before the QTDP grant, net of revenues from R&D, milestones and grants (see sub-heading Revenues above) was $3,053,000 for the year ended December 31, 2011 ($4,878,000 less $1,825,000,

this includes clinical trials of $1,244,000 and does not include the QTDP reduction) compared to $1,297,000 ($4,053,000 less $2,756,000, this includes clinical trials of $654,000) for the same period in 2010. This demonstrates that the Company has not just maintained, but in fact has increased its investment in Research & Development personnel and materials, after accounting for outside clinical trial expenses, even with lower revenues supporting these activities. This has enabled work to be done on developing a pipeline of Chembio branded products, and also to support the transfer and validation of such new products into our manufacturing operation.

Selling, General and Administrative Expense:

Selected expense lines:	For the years ended December 31, 2011	December 31, 2010	$ Change	% Change
Wages and related costs	$ 1,249,907	$ 1,076,446	$ 173,461	16.11 %
Consulting	199,658	215,391	(15,733)	-7.30 %
Commissons	603,377	183,762	419,615	228.35 %
Stock-based compensation	115,476	64,429	51,047	79.23 %
Marketing materials	50,900	17,627	33,273	188.76 %
Investor relations/investment bankers	176,297	197,183	(20,886)	-10.59 %
Legal, accounting and SOX 404 compliance	448,676	563,277	(114,601)	-20.35 %
Travel, entertainment and trade shows	67,504	59,003	8,501	14.41 %
Bad Debt Allowance	(5,000)	-	(5,000)	100.00 %
Other	517,502	563,603	(46,101)	-8.18 %
Total S, G &A	$ 3,424,297	$ 2,940,721	$ 483,576	16.44 %

Selling, general and administrative expenses for the year ended December 31, 2011 increased by 16.4% as compared with the same period in 2010. This was primarily due to increases in commission expense of $420,000 primarily on sales to Brazil, wages and related expenses of $173,000, stock-based compensation of $51,000 and marketing materials of $33,000, partially offset by decreases in investor relations of $21,000, consulting of $16,000 and legal, accounting and SOX 404 expenses of $115,000.

Other Income and Expense:

	For the years ended December 31, 2011	December 31, 2010	$ Change	% Change
Other income (expense)	$ -	$ (3,923)	$ 3,923	-100.00 %
Interest income	6,298	4,147	2,151	51.87 %
Interest expense	(18,623)	(14,727)	(3,896)	26.45 %
Total Other Income and (Expense)	$ (12,325)	$ (14,503)	$ 2,178	-15.02 %

Other (expense) for the year ended December 31, 2011 increased approximately $2,200 to $12,300 as compared with $14,500 for the same period in 2010, primarily as a result of the loss on the sale of an asset in 2010 of $3,900 not repeated in 2011 and an increase in interest income of $2,100, partially offset by increased interest expense of $3,900 due to the term loan with HSBC.

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 carryforward. 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, 2011	December 31, 2010	$ Change	% Change
Cash and cash equivalents	$ 3,010,954	$ 2,136,351	$ 874,603	40.94 %
Accounts receivable, net of allowance for doubtful accounts of $30,000 and $35,000 for 2011 and 2010, respectively	2,998,449	3,946,398	(947,949)	-24.02 %
Inventories	2,300,286	1,349,161	951,125	70.50 %
Prepaid expenses and other current assets	681,893	204,824	477,069	232.92 %
Fixed assets, net of accumulated depreciation	1,062,276	813,214	249,062	30.63 %
Deposits on manufacturing equipment	139,790	-	139,790	100.00 %
Deferred tax asset, net of valuation allowance	4,749,622	-	4,749,622	100.00 %
Accounts payable and accrued liabilities	2,789,500	2,055,943	733,557	35.68 %
License fee payable	-	875,000	(875,000)	-100.00 %

Cash increased by $875,000 from December 31, 2010, primarily due to the collection of accounts receivable which decreased by $948,000 along with an increase in accounts payable of $734,000, partially offset by an increase in inventories of $951,000 and by the payment to Bio-Rad of $875,000 (see reduction in license fee payable). Prepaid expenses increased primarily due to the current portion of the deferred tax asset. The Company invested $289,000 in fixed assets and deposits in fixed assets.

The decrease in accounts receivable was primarily attributable to a large amount of credit sales in December of 2010 which were collected in 2011 compared to a large amount of December 2011 sales, some of which were prepaid. 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 2012.

In addition, the increase in deferred tax asset in 2011, net of valuation allowance, was a direct result of the Company's reversal of $5,156,000 in valuation allowance previously recorded against its deferred tax assets as discussed earlier.

LIQUIDITY AND CAPITAL RESOURCES

	For the years ended December 31, 2011	December 31, 2010	$ Change	% Change

Net cash provided by operating activities	$	2,268,408		$	1,016,850	$	1,251,558		123.08	%
Net cash used in investing activities		(726,680	)		(182,292	)	(544,388	)	298.64	%
Net cash (used in) provided by financing activities		(667,125	)		233,558		(900,683	)	-385.64	%
INCREASE IN CASH AND CASH EQUIVALENTS	$	874,603		$	1,068,116	$	(193,513	)	-18.12	%

The Company had an increase in cash for each of the years ended December 31, 2011 and 2010 which were primarily attributable to cash provided by operations. The increased cash from operations in 2011 was primarily attributable to net income from operations of $1,088,000. In addition, operating activities contributing to the increase in cash in 2011 included an increase in accruals and payables of $734,000 and a decrease in receivables of $953,000. These increases were partially offset by an increase in inventories of $951,000, an increase in prepaid expenses of $71,000 and an increase in other assets of $6,000, as well as a decrease in deferred revenue of $65,000. The Company's non-cash expenses totaled $622,000, which consisted of $338,000 from depreciation expense, $189,000 in stock-based compensation expense and $100,000 in the amortization of licenses, partially offset by a decrease in allowance for doubtful accounts of $5,000. Investing activities represent the Company's investment in fixed assets. The cash used in financing activities is primarily due to the payment to Bio-Rad of $875,000 (see reduction in license fee payable) and partially offset by proceeds from the exercise of options and warrants of $288,000.

As of December 31, 2011, the Company had paid deposits on various pieces of equipment aggregating $140,000, which is reflected in Other Assets on the balance sheet. The Company is further committed to an additional equipment-purchase obligation of $152,000 as various milestones are achieved by the various vendors

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

2011 RESULTS

In 2011 Chembio achieved record product revenue growth of 28.9%, funded increased development expenses, and delivered strong Income before income taxes of $1,076,000. A $3,906,000, or 28.9%, increase in Net Product sales offset a $1,223,000 decrease in non-product revenues. This resulted in the Company producing a $1,290,000, or 15.9%, increase in its gross margin, to a record $9,390,000.

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 on anticipated continued profitability the Company believes it is more likely than not that it will realize these tax benefits and accordingly has reversed $5,156,000 of the valuation allowance previously recorded against the deferred tax assets. This reversal of the tax valuation allowance resulted in an addition of $5.1 million to the Company's net income for 2011. The Company still maintains a full valuation allowance on research and development tax credits.

The Company generated $2,268,000 in cash flow from operations in 2011, more than doubling its previous record of $1,107,000 in 2010. The Company utilized portions of this cash flow from operations to fund an $875,000 license obligation and to invest $727,000 in new equipment and facility improvements that are expected to improve efficiencies and increase capacity to serve current and anticipated demand.

The record product and resulting record total revenues were achieved as a result of the launch of four of our DPP® products in Brazil combined with strong sales growth for our two FDA-approved rapid HIV tests in the US market. We increased sales to FIOCRUZ to $4,255,000 in 2011 from $628,000 in 2010, a 577% increase, substantially exceeding the $3 million we anticipated in June 2011. Sales of our FDA approved rapid HIV tests in the US through our agreements with Alere increased $1,928,000 to a record $7,209,000, a 36.5% increase over 2010. This strong increase provides us with strong evidence of continued growth in the U.S. rapid HIV test market, and that growth is being captured at this time by our two outstanding lateral flow products distributed by Alere under their Clearview® label, as our competitors' sales were essentially flat during 2011. Our international lateral flow HIV test revenues decreased somewhat as donor-funded markets experienced uncertainties generally and in the markets we were participating in particular. Nevertheless during the year we significantly strengthened and expanded our distribution network and resulting marketing opportunities, giving us some optimism for a potential resurgence in these sales during 2012.

PLAN OF OPERATIONS FOR THE NEXT TWELVE MONTHS

The 3,000 patient study we commenced in 2010 in support of a Pre-Marketing Application approval for our DPP® HIV Screening Assay for use with oral fluid or blood samples is nearly complete. Once we complete these trials we will need approximately 30 days to submit the third and final module of the PMA to the FDA. Within 180 days we expect that the FDA will respond to our PMA application. The intent of the modular submission is to increase the possibility that we will receive such response sooner than the 180 day statutory period though this is not required and cannot be assured. Nevertheless, we believe that we will submit and get this response well within the 2012 calendar year.

As a result of our having received a CE Mark for our Syphilis Screen & Confirm product in Q3'11 and our business development efforts during Q4'11, we have now established several European distributors for this product. Product evaluations are being completed in France and the UK. Assuming we can successfully incorporate the reader into our U.S. clinical trials, we believe that we can complete the clinical trials and make the 510(k) submission to the FDA for this product during 2012. Therefore FDA 510(k) clearance could be within the first half of 2013 followed by commercial launch in the US. Alternatively we could decide to pursue a treponemal-only product in the U.S. We are already producing large quantities of the treponemal-only screening test for FIOCRUZ with excellent performance.

The Company has a number of new product opportunities and new product features that could result in new revenue streams in future periods. In each case these would utilize our patented DPP® platform to develop proprietary products, and could also combine additional proprietary features such as biomarkers in collaboration with others or other features we may add to our platform technology. These products will be developed either under the Chembio DPP® brand or the brands of potential OEM customers that incorporate our DPP® trademark. We are working on a number of new potential projects in this regard and in some cases conducting feasibility studies. These include potential products with application to the areas of women's health, veterinary diagnostics, and blood viruses. 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 the meantime, based on substantially increased revenues that are anticipated this year from our DPP® OEM products with FIOCRUZ in Brazil, combined with even modest growth in the US rapid HIV test market and/or our market share with our FDA-approved rapid HIV tests marketed by Alere, as well as possible gains from existing and/or new international distributors for our lateral flow and DPP® products. We are overall very optimistic in regards to Chembio's financial outlook for 2012, which we believe will include strong improvements to our revenues and net income. Our recording of the value of our net operating loss carry forward as a financial asset is a reflection of our optimism.

Fixed Asset Commitments

As of December 31, 2011, the Company had paid deposits on various pieces of equipment aggregating $139,790, which is reflected in Other Assets on the balance sheet. The Company is further committed to additional equipment-purchase obligation of $151,910 as various milestones are achieved by the various vendors.

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 Securities and Exchange Commission Staff Accounting Bulletin No. 104, “Revenue Recognition” (“SAB 104”). Under SAB 104, 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 $23,000.

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 $30,000.

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.

There have been no disagreements, or transactions or events similar to those which involved such disagreements or reportable events, with former accountants on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of the former accountant, would have caused it to make reference to the subject matter disagreements in connection with any of its reports.

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 management concluded that our internal control over financial reporting was effective as of December 31, 2011.

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 (55), 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 (55), 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 (45), 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 (58), 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 (49), 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. (61), 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 (55), 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 Boards' 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., (56), 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. In May 2011, Dr. DeBuono was appointed President and CEO of ORBIS International, which is dedicated to saving sight and eliminating avoidable blindness worldwide with headquarters in New York City. Previously, from 2009-2011, Dr. DeBuono was Chief Medical Officer, Partner and Global Director of Health and Social Marketing at Porter Novelli, and from 2000-2008 she was Executive Director, Public Health and Government at Pfizer Inc. Dr. DeBuono has served as Commissioner of Health for the state of New York and as Director of Health in Rhode Island and she was honored by the CDC Foundation in 2005 as one of five Public Health Heroes nationwide. She serves as adjunct professor at The George Washington University School of Public Health, and is a co-founder of The MAIA Foundation, a charity dedicated to women's health in sub-Saharan Africa. A Fellow of the American College of Physicians, Dr. DeBuono received her B.A. from the University of Rochester, her M.D. from the University of Rochester, School of Medicine, and a Masters in Public Health (M.P.H.) from Harvard University School of Public Health. Dr. DeBuono's experience in and knowledge of, both domestic and international, public health services, public health innovations, and the medical field make her an excellent candidate for serving on the board.

Dr. Peter Kissinger, Ph.D. (67), 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 the founder of Bioanalytical Systems, Inc. (NASDAQ: BASI), which he led from 1974-2007, and is Professor of Chemistry and Associate Department Head at Purdue University, West Lafayette, Indiana. Dr. Kissinger's academic research has involved the study of modern liquid chromatography techniques, and in vivo methodology for drug metabolism and the neurosciences. Dr. Kissinger has published more than 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, 2011, 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 ($)	Bonus2 ($)	Option Awards3 ($)	Stock Awards ($)	All Other Compensation5 ($)	Total ($)
Lawrence A. Siebert4	2011	$ 281,346	$ 101,500	$ -	$ -	$ 12,600	$ 395,446
CEO	2010	265,000	87,450	-	-	7,200	359,650
Javan Esfandiari	2011	$ 253,077	$ 89,250	$ -	$ -	$ 8,540	$ 350,867
VP-R&D	2010	242,923	80,850	66,030	-	4,800	394,603
Tom Ippolito	2011	$ 190,702	$ 33,600	$ 42,724	$ -	$ 3,958	$ 270,984
VP-Regulatory	2010	185,815	40,300	-	-	-	226,115

1 Salary is total base salary.
2 Bonuses earned in 2011 and 2010 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 Comapany'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 250,000 shares of the Company's common stock exercisable at $0.13 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 dated March 4, 2010, and to be effective March 5, 2010 (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 May 5, 2013. Mr. Esfandiari's salary under the Employment Agreement is $245,000 for the first year, $255,000 for the second year, and $265,000 for the final year. Mr. Esfandiari is eligible for a cash bonus of up to 50% of his base salary for each respective year, which, on June 29, 2011, was amended, effective March 5, 2011, to consist of the same components in the same percentages as the bonus components as those described immediately above for Mr. Siebert. Prior to that amendment, and since March 5, 2010, Mr. Esfandiari's bonus consisted of the following: (i) a cash bonus of up to 30% of his calendar year base salary based on the performance of the Company's Dual Path Platform Technology, which is directly related to certain annual revenue targets budgeted by management of the Company; (ii) a cash bonus of up to 10% of his calendar year base salary based on the attainment of certain specific research and development objectives, as determined by the Board, and (iii) a cash bonus of up to 10% of his calendar year base salary that is at the complete discretion and determination of the board of directors. The Company also granted Mr. Esfandiari, pursuant to the Company's 2008 Stock Incentive Plan, incentive stock options to purchase 300,000 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, 2010, which is the date on which the Agreement was effective. Of these stock options, options to purchase 100,000 shares vest on the effective date, options to purchase an additional 100,000 shares of the stock options vest on the second anniversary of the Employment Agreement, and options to purchase an additional 100,000 shares of the stock options vest on the third anniversary 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. Esfandiar