CHEMBIO DIAGNOSTICS, INC.
Form 10-K
March 05, 2010

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, 2009

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 __ 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. [ ]

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 [ ] (Do not check if a smaller reporting company)	Smaller reporting company [X]

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

As of the last business day of the Company's most recently completed second fiscal quarter, the aggregate market value of voting and non-voting common equity held by non-affiliates* was $3,550,000.

As of March 3, 2010, the registrant had 61,989,901 common shares outstanding.

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

TABLE OF CONTENTS

PART I

ITEM 1. BUSINESS

FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, and Section 27A of the Securities Act of 1933. Any statements contained in this report that are not statements of historical fact may be forward-looking statements. When we use the words "intends," "estimates," "predicts," "potential," "continues," "anticipates," "plans," "expects," "believes," "should," "could," "may," "will" or the negative of these 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

Chembio Diagnostics, Inc. (referred to collectively with its subsidiary as the "Company") and its subsidiary develop, manufacture and market 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. Three of these products employ lateral flow technology, 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 distributed by Inverness Medical Innovations, Inc. ("Inverness") in the United States. Our fourth rapid HIV test, which we more recently developed on our patented Dual Path Platform (DPP®) technology, detects antibodies to HIV in oral fluid samples, as well as all blood matrices.

On March 13, 2007, we were issued United States patent #7,189,522 for our Dual Path Platform (DPP®) rapid test system. Additional patent protection for DPP® has issued or is pending worldwide. We participate in the point-of-care segment of the nearly $40 billion global in-vitro diagnostic market. The global point-of-care segment of the IVD industry 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. This is not to say that every test should be done at the point-of-care. A careful analysis needs to be performed when evaluating whether there is a need for a rapid point-of-care test versus a laboratory test.

In the areas of infectious and sexually transmitted diseases (such as Influenza and HIV for example), the utility of a rapid point–of-care test has been well established, and large markets have been established for these kinds of tests globally. It is within these areas of infectious diseases and sexually transmitted diseases, which tend to have the higher growth rates in the point-of-care segment where we have focused and will continue to focus our business, with an emphasis on the U.S. market.

PRODUCTS

Lateral Flow Rapid HIV Tests

The major component of our revenue growth in 2009 was increased sales of our lateral flow rapid HIV tests and related components. 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. The increased availability, greater efficacy and reduced costs for anti-retroviral treatments (ARVs) for HIV is also having a tremendous impact on 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. All four of our rapid HIV tests are qualitative "yes/no" tests for the detection of antibodies to HIV 1 & 2 with results available within approximately 15 minutes. The tests differ principally only in the method of sample collection and test procedure, flexibility with different sample types, and cost of manufacture. Prior to our agreement with Inverness and, more recently, the development of our DPP® HIV 1/2 Screening Assay for use with oral fluid or blood samples, our rapid HIV tests had been marketed under either our SURE CHECK® or STAT-PAK® trademarks. Pursuant to our agreement with Inverness, the SURE CHECK® product (which incorporates a proprietary barrel format) is now being marketed by Inverness as Clearview® Complete HIV 1/2 and the cassette format of our HIV 1/2 STAT-PAK (we also have a third product known as HIV 1/2 STAT-PAK dipstick) is now being marketed by Inverness in the United States as Clearview® HIV 1/2 STAT-PAK®. We continue to market our STAT-PAK® cassette and dipstick outside the United States through other marketing channels. In addition, in 2009 we amended the agreement with Inverness, which previously had global exclusivity for the barrel format product, to a non-exclusive outside of North America.

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 Inverness' Clearview® Complete HIV 1/2) and for our HIV 1/2 STAT-PAK (now Inverness' Clearview® HIV 1/2 STAT-PAK in the United States only) products. A Clinical Laboratory Improvement Act ("CLIA") waiver was granted by the FDA for the HIV 1/2 STAT-PAK in November 2006 and for the two Inverness Clearview® brands in October 2007. CLIA waiver is required in order to market the products for use in hospital emergency rooms, public health clinics and physicians' offices, where the level of training is traditionally less than the training at clinical laboratories and laboratories in hospitals. These settings constitute the largest portion of the available market for our products. Our third lateral flow rapid HIV test, HIV 1/2 STAT-PAK Dipstick and our DPP® oral fluid HIV test, though not FDA approved, qualify under FDA export regulations to sell, subject to any required approval by the importing country, to customers outside the United States. The dipstick product is our most competitively priced version of our three rapid HIV tests, and was designed primarily for resource-constrained, donor-funded markets that have large test volume needs. In addition, we have received approval from a number of potential importing countries for our three lateral flow HIV tests. .. All three of our lateral flow HIV tests have qualified for procurement under the President's Emergency Plan for AIDS Relief ("PEPFAR"). In October 2009 we submitted supplemental documentation that had been requested to our Notified Body in connection with our efforts to obtain CE marking for the two FDA-approved rapid HIV test products. In late January 2010 we were informed that additional data was being requested, and we are determining the time and cost.

DPP® HIV 1&2 Assay for Use with Oral Fluid (or Blood) Samples

We have also completed development of and are now commercializing our DPP® HIV 1&2 Assay for use with oral fluid samples. Oral fluid testing is an established alternative to blood testing for diagnostic tests, including HIV tests. It provides a fast and easy method for sample collection, enabling non-medical professionals to collect samples for testing. It is also often patient preferred, providing a more comfortable test. In certain public health clinics, staffs choose not to handle blood specimens; thus, oral sample collection provides a viable alternative. The DPP® HIV test, which is based on our patented DPP® technology, also includes a patent-pending system comprised of an oral fluid swab and sample buffer vial. This feature enables samples to be fully extracted in buffer solution before application to the test device, and also allows the extracted sample to be stored and retested. Internal and field studies have shown

sensitivity and specificity well in excess of FDA requirements on oral fluid as well as all blood matrices.

Regulatory Status: During 2008 Chembio conducted extensive internal panel studies of this product and a limited field study that suggested outstanding performance; two much larger field evaluations were completed in 2009 that will supplement our pending U.S. clinical studies. During the second half of 2009 we prepared a proposed clinical trial protocol and submitted it to the FDA in support of our application for an Investigational Device Exemption (IDE) which we submitted and was granted during the fourth quarter of 2009. This approved protocol permits us to move forward with the clinical trials performance data, along with other required product and manufacturing data, in support of a Pre-Marketing Approval (PMA) application to the FDA. We anticipate commencing and completing the clinical trials and submitting the PMA application during 2010 and receiving approval of the PMA during 2011.

PARTNERS INVOLVED IN MARKETING OUR HIV PRODUCTS

On September 29, 2006 we executed marketing and license agreements with Inverness. The marketing agreements (one for each of the two FDA approved products) each provide Inverness with a 10-year exclusive right for the marketing of our rapid HIV tests in the United States. The agreements also grant us a license to Inverness' lateral flow patents that may be applicable to certain of our other products, including those that we had under development at the time of the grant of the license. As part of these agreements, we also settled litigation that had been ongoing with another company, StatSure Diagnostics, Inc.(SDS), relating to the proprietary barrel device that is incorporated into our Sure Check® HIV 1/2 product, which is also marketed exclusively as Inverness Clearview® Complete HIV 1/2 in the United States, Europe and Asia. SDS is a party to the marketing agreement with Inverness and Chembio that pertains to that product.

We are beginning to register our DPP® oral fluid HIV test in selected markets receiving funding from the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). PEPFAR recently approved our product as qualified for procurement pursuant to the USAID waiver procedure (for use with oral fluid or blood samples). Also, as described above, our DPP® oral fluid HIV test is one of three products pending regulatory approval in Brazil pursuant to OEM technology transfer, supply and license agreements we have in place with FIOCRUZ as described below. We are considering various options for marketing this product in the United States including a direct sales model for certain or all market segments.

We have appointed distributors and OEM partners internationally for our lateral flow HIV tests. Our largest markets for our lateral flow HIV rapid tests outside the United States are several countries in Africa, Brazil (OEM) and Mexico. During 2009 we appointed Bio-Rad Laboratories, Inc. as our distributor of our HIV 1/2 STAT-PAK® product in Mexico. We have distributors interested in distributing our products in Europe once we receive the CE Marking, for which there can be no assurance.

OTHER LATERAL FLOW RAPID TESTS

We also have commercially available lateral flow tests for Chagas Disease and a line of tests for the detection of tuberculosis in humans and certain animal species. These products represented approximately 1.5% of our product revenues during 2009. . The Company entered the rapid test market segment with lateral flow technology and for many years, even before the development of our lateral flow HIV tests, our revenues were almost entirely based on this technology, primarily pregnancy tests. Because of the limited license we entered with Inverness to manufacture and market only certain applications of lateral flow technology, and also because we have now developed our own patent-protected rapid point-of-care technology platform (DPP®) which we believe provides certain advantages over lateral flow technologies, all of our other products and products that we are developing utilize this patented platform.

OTHER DPP® PRODUCTS

Chembio-Branded DPP® Products

DPP® Syphilis Screen & Confirm- DPP® Syphilis Screen & Confirm is a simple multiplex point-of-care test that can detect both non-treponemal and treponemal antibodies to syphilis from a whole blood sample within 20 minutes. Studies have been performed at the CDC on a total of 459 banked specimens of which 219 were characterized as positive and 240 as negative by RPR (standard lab test for non-treponemal). Out of the 459 samples, 289 were characterized as positive and 170 characterized as negative by the TPPA test (standard lab treponemal test). DPP® Syphilis Screen & Confirm non-treponemal had a sensitivity of 90.5% and a specificity of 100% compared to RPR and a sensitivity of 93% and a specificity of 92% compared to TPPA. This assay offers several market advantages over the current two-tier system of screening and confirmatory testing. This is the first assay in the United States that would afford the opportunity for a single-visit diagnosis and treatment. Retrospective studies have been performed at Chembio and CDC during 2008 and 2009. A multi-phase field study sponsored by the WHO and with participation by CDC is ongoing. Interference and cross-reactivity studies have been completed at an external

laboratory. FDA regulatory clearance for this test is available through a 510(K) submission. The FDA has approved our proposed protocol (IDE) for the prospective clinical trials that will be part of this. We plan to commence the regulatory activities for FDA clearance during the second quarter of 2010 and anticipate that clearance will be granted in the first quarter of 2011.

OEM DPP® Products

Oswaldo Cruz Foundation OEM DPP® Agreements

During 2008 we signed four agreements with the Oswaldo Cruz Foundation (FIOCRUZ) in Brazil relating to products based on our DPP® technology for Leptospirosis, Canine Leishmaniasis, screening for HIV 1/2 with oral fluid samples, and a 5-band multiplex point-of-care confirmation test for HIV 1&2. These products will initially be manufactured by Chembio but will be distributed by FIOCRUZ under its Bio-Manguinhos Division's label. These entities are affiliated with the Brazilian Ministry of Health. We have completed development of three of these products (Leishmaniasis and the HIV screening and confirmation tests), and we have substantially completed development of the Leptospirosis test. The leishmaniasis and confirmatory tests have been submitted for and are still pending regulatory approval in Brazil; the HIV screening test regulatory submission has not been made yet. We now expect that these products will be approved by Brazilian regulatory authorities during the second quarter of 2010. These agreements contemplate an eventual transfer of the manufacture of the subject products to FIOCRUZ over stipulated periods of time subject to Chembio first receiving orders for a minimum amount of products for manufacture by Chembio; thereafter Chembio will receive royalty payments for a number of years based on product sold by FIOCRUZ to the public health programs in Brazil. In December 2009 Chembio received purchase orders from FIOCRUZ for the three products for which development has been completed and that are pending regulatory approval in the aggregate amount of approximately $2.4 million. The orders are of course in each case subject to the attainment of regulatory approval for the relevant product, of which there can be no assurance. In addition, upon attainment of regulatory approval of these three products, Chembio will be due fees from FIOCRUZ stipulated in these agreements in the aggregate amount of approximately $900,000.

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. Certain of our new DPP® products will incorporate reader technologies that can help record and report test results and reduce subjectivity of results sometimes found with visually read tests. 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. This format provides 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 can also use hand held and desktop readers to objectively measure, quantify, record and report 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.

Target Market

Rapid HIV Tests

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 25%, unaware that they are infected. It is these 250,000 infected people that 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 if samples have to be sent out to a laboratory which can take at least several days to process. Healthcare officials believe that by making more people aware of their HIV status, it will reduce the number of HIV transmissions.

Rapid HIV testing in the United States has now developed into a 5-6 million test market. This is from zero in 2003 when Orasure received FDA approval for the first 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 about 50% of all HIV tests done in the United States for clinical purposes. Assuming an average price to the manufacturers of $10.00 per test, a total potential market of $180 million U.S. market is inferred.

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 now in place provide 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 has begun to have an impact.

In addition, in December 2009 Medicare issued new rules that now require it to pay for HIV tests for individuals covered by Medicare.

In the United States, the need for rapid HIV tests has been developing first in the public health and hospital emergency room and labor and delivery room segments, and to some extent also in the physicians' office laboratories. Of the estimated 25-30 million HIV tests performed in clinical settings in the United States, rapid HIV tests now account for approximately 20-25% of this market, or approximately 6 million tests of this total. We believe that the United States market share available to rapid HIV tests will grow by approximately 15-20% per annum.

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, The Global Fund and other global initiatives have succeeded in making life-saving treatments available now to well in excess of one million individuals. PEPFAR has a goal by 2013 of treating three million infected individuals and averting 12 million new cases. 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. Other programs such as UNAIDS are significant participants in the global effort to prevent further transmission and save the lives of those already infected, as well as care for their families that are impacted.

For oral fluid testing we believe that in several markets there is a meaningful segment of individuals who will be more inclined to be tested for HIV when offered a non-invasive test. The most well-established market for oral fluid HIV testing is the United States. There is also now an opportunity to participate in the over-the-counter market for HIV tests. This opportunity received important support by the FDA and CDC in November 2009. While initial support from public health and regulatory officials was indicated in 2006, a follow-up November 2009 meeting of the FDA Blood Products Advisory Committee on this subject confirmed the support by public health and HIV positive community advocates, and provided further clarity as to the regulatory pathway for such market.

Syphilis Rapid Test

Recent data indicate that approximately 70,000-100,000 new cases of syphilis are occurring annually in the U.S. The CDC's latest Sexually Transmitted Disease study, released in November 2009, reported that: 1) although only 13,500 of new syphilis cases were reported in 2008 (<20% of total amount of estimated new cases), that is still an 18 percent increase from 2007, suggesting increased numbers of new cases, 2) 63 percent of syphilis cases were among men who have sex with men, and 3) syphilis rates among women increased 36 percent from 2007 to 2008.

Syphilis can be treated with antibiotics, but untreated can cause pelvic inflammatory disease, infertility, ectopic pregnancy and can infect newborns. Treatment cannot be provided without a confirmed diagnosis of an active, previously untreated case of syphilis.

Current testing algorithms 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. This product is able to accurately detect the presence or absence of each of these markers in one rapid point-of-care test device, thereby enabling prescription of antibiotics at the point-of-care where there is the presence of both markers.

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 opportunity is a minimum of 3 million tests, which is approximately 20% of the total number syphilis tests performed in the United States 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.

Marketing Strategy

Our marketing strategy is to:

- Support, review and assess the marketing and distribution efforts of our rapid HIV tests by Inverness Medical Innovations, Inc. Inverness, which is a leading marketer of point-of-care diagnostic products, has significantly expanded its distribution footprint since we signed our agreement with Inverness, and we believe that this will enhance opportunities for Inverness to market our rapid HIV tests. In particular, Inverness has been very active in acquiring point-of-care product lines serving hospital emergency rooms and physicians' offices.

- 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.

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.

Research and Development

During 2009 and 2008, $2.9 million and $2.6 million, respectively, were spent on research and development (including regulatory activities). These expenses were in part underwritten by funding from R&D contracts and grants of $1.3 million in 2009 and $.7 million in 2008. 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, 2009, we employed 104 people, including 103 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 for an additional three-year term through May 11, 2012. 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") application 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 Inverness 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 will be 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 Inverness 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 India, as well as 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 owned 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.

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 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 Inverness for the marketing of our HIV tests, we were granted non-exclusive licenses to their 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 lateral flow patents, 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 Inverness' lateral flow patents will not be challenged or that other patents containing claims relevant to the Company's lateral flow or DPP® products will be not be granted and that licenses to such patents, if any, will be available on reasonable terms, if any. Inverness has aggressively enforced its lateral flow intellectual property. Most recently in 2008 Inverness brought a patent infringement lawsuit against Orasure. The suit was settled in late 2009 with a $3 million payment by Orasure to Inverness and other considerations.

The DPP® technology provides us with our own intellectual property and we believe 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 several other patents issued or pending related to other point-of-care technologies or applications thereof. The DPP® patent has been issued in certain other jurisdictions and is being prosecuted in many others.

The peptides used in our rapid HIV tests are patented by Adaltis Inc. and are licensed to us under a 10-year non-exclusive license agreement dated August 30, 2002. In connection with their 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 Chagas, Tuberculosis and Leishmaniasis tests. 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 Chembio Diagnostic Systems Inc. through which Chembio Diagnostics 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. Approximately 12,208,505 of the shares distributed are free of restrictions and may be sold or otherwise transferred immediately. An additional 2,560,822 of the distributed shares are expected to become eligible for resale on March 24. The other approximately 4,138,104 shares are expected to become eligible for resale on May 25, 2010.

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.
ARVs	Anti-Retroviral Treatments for AIDS
CD-4	The CD4+ T-lymphocyte is the primary target for HIV infection because of the affinity of the virus for the CD4 surface marker. Measures of CD4+ T-lymphocytes are used to guide clinical and therapeutic management of HIV-infected persons.
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 doctors 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
FDA	United States Food and Drug Administration
FDIC	Federal Deposit Insurance Corporation
FAS	Financial Accounting Standard
HIV	Human Immunodeficiency Virus. HIV (also called HIV-1), a retrovirus, causes AIDS. A similar retrovirus, HIV-2, causes a variant disease, sometimes referred to as West African AIDS. HIV infection leads to the destruction of the immune system.
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.
MOH	Ministry of Health
MOU	Memoranda of Understanding
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.
SPUTUM	Expectorated matter; saliva mixed with discharges from the respiratory passages
TB	Tuberculosis (TB) is a disease caused by bacteria called Mycobacterium tuberculosis. The bacteria usually attack the lungs. But, TB bacteria can attack any part of the body such as the kidney, spine, and brain. If not treated properly, TB disease can be fatal. TB is spread through the air from one person to another. The bacteria are put into the air when a person with active TB disease of the lungs or throat coughs or sneezes. People nearby may breathe in these bacteria and become infected.
UNAIDS	Joint United Nations Program on HIV/AIDS
USAID	United States Agency for International Development
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 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.

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.

For example, the European Union and other jurisdictions have a requirement that diagnostic medical devices used to test human biological specimens must receive regulatory approval known as a CE mark, or be registered under the ISO 13.485 medical device directive. The letters “CE” are the abbreviation of the French phrase “Conforme Européene,” which means “European conformity.” ISO (“International Organization for Standardization”) is the world’s largest developer of standards with 148 member countries. As such, export to the European and other jurisdictions without the CE or ISO 13.485 mark is not possible. In 2007, we received ISO 13.485 certification, in 2008, we received a CE registration for our Chagas test, and during 2009 we expected to receive CE registration for our two FDA approved HIV tests. However, additional data and documentation has been requested and there are no assurances that we will be able to secure this certification although we are not aware of any material reason why such approval will not be granted. However, if for any reason a CE registration is not granted, our ability to export our products could be adversely impacted.

We can manufacture and sell our products only if we comply with regulations of government agencies such as the FDA and the USDA. 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, Inverness 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. Although we have no specific knowledge of any 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 could enhance our competitive position in HIV rapid testing and other fields. 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 have granted Inverness 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. Inverness has no rapid HIV tests that are approved for marketing in the U.S., we are not aware of any rapid HIV products that Inverness is even contemplating for the U.S., and Inverness is obligated to inform us of any such products as soon as it is able to do so. Inverness does have rapid HIV tests manufactured by several subsidiaries outside the U.S. that are being actively marketed outside the U.S., primarily in developing countries. Our HIV 1/2 STAT PAK cassette and dipstick products compete against these Inverness products, and we specifically acknowledge in our agreements with Inverness the existence of such other products. Moreover, except for a product in the HIV barrel field as defined in our agreement with Inverness, Inverness is permitted under our agreements to market certain types of permitted competing rapid HIV tests in the U.S. Under these conditions, we could choose to terminate the applicable agreement with Inverness or change the agreement to a non-exclusive agreement, and Inverness would expand the lateral flow license granted to the Company to allow the Company to market the product independently or through other marketing partners. While we believe that Inverness is committed to successfully marketing our products particularly in the U.S. and other developed countries where our products are or become approved for marketing, Inverness may choose to develop or acquire competing products for marketing in the U.S. as well as other markets where they are marketing our SURE CHECK® HIV 1/2 product, 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. While we also believe that the expansion of our license to the Inverness lateral flow patents substantially facilitates our ability to make alternative marketing arrangements, there can be no assurance that the modification of marketing arrangements and the possible corresponding delays or suspension of sales would not have a material adverse effect on our business.

In addition, 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.

Although we have been granted non-exclusive licenses to the lateral flow patents owned by Inverness Medical Innovations, Inc. , there is no assurance that their lateral flow patents will not be challenged or that licenses from other parties may not be required, if available at all. 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, 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 worldwide. 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, 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, in addition to the market success of our products, on 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 in amounts necessary to continue our business, or at all.

Our revenues and gross margins have increased significantly in recent periods, and our operating and net losses have decreased significantly in recent periods. Nevertheless, prior to 2009 we sustained significant operating losses since 2004. At December 31, 2009, we had a stockholders' equity of $3.08 million and a working capital surplus of $1.49 million. The Company estimates that its resources are sufficient to fund its needs through the end of 2010 and beyond or that, in the alternative, it could raise additional capital although the terms under which that capital could be raised would likely be very dilutive to current shareholders. The Company's liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenues (the Company received $340,000 in 2009 for license fees for which we need to meet certain milestones to earn); (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 (including production equipment of $323,500 that the Company has contracted for) 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 2010 or, in the alternative, be successful in raising sufficient capital to fund its needs through 2010.

Approval and launch of our DPP® products in Brazil during 2010 and increased sales to other developing world markets in 2010 is critical to our business plan and if we fail to meet this objective, we may not generate revenues in the amounts we expect, or in amounts necessary to fund our planned research, development and regulatory expenses in 2010.

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; and
- competition
- pricing
- 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.

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 We also have a license to manufacture, use and sell products used to screen for antibodies to HIV-2. In addition, our SURE CHECK®, DPP® and STAT-PAK® trademarks have been registered in the U.S. 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.

During 2008 and in the first quarter of 2009 we terminated a number of employees who have had access to proprietary and confidential information. In connection with the termination of several of these employees whose positions were terminated, individuals executed severance agreements that include strong covenants by these former employees to keep our proprietary information confidential. Despite these and other 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 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 for an additional three-year term through May 11, 2012. 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 on our ability to participate in large government 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 the PEPFAR Program, UN Global Fund initiatives and other programs funded by large donors. We have initiated several strategies to participate in these programs, such as introduction of our DPP® HIV test for use with oral fluid samples. 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, we have a history of incurring net losses and we cannot be certain that we will be able to sustain profitability.

Since the inception of Chembio Diagnostic Systems, Inc. in 1985 and through the period ended December 31, 2008, we have incurred net losses. As of December 31, 2009, we have an accumulated deficit of $37 million. We incurred net losses of $1.9 million and $2.6 million in 2008 and 2007, respectively, while showing a net profit of $309,000 in 2009.

We expect to make substantial expenditures for sales and marketing, and continue to make expenditures for regulatory submissions, product development and other purpose that may make it more difficult to maintain profitability for any given period or periods. 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 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 market. 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 2007, 2008 and 2009 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 101,000 shares per day over the three months ended March 1, 2010. 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 and may approve or take actions that may be adverse to your interests.

As of March 1, 2010, our named executive officers, directors and 5% stockholders beneficially owned approximately 13.9% of our voting power. For the foreseeable future, to the extent that our current stockholders vote similarly, they will be able to exercise control over many matters requiring approval by the board of directors or our stockholders. As a result, they will 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 23,400 square feet of industrial space for $14,683 per month. The space is utilized for research and development activities (approximately 2,600 square feet), offices (approximately 2,640 square feet) and production (approximately 18,160 square feet). The lease term expires on April 30, 2014. Additional space may be required as we expand our research and development activities. We do not foresee any significant difficulties in obtaining any required additional facilities. We entered into a second lease effective February 1st of 2010, the principle terms of this lease are the same as the one entered into in 2009 and are as follows: (a) a lease term ending April 30, 2014; (b) an initial rent of $11,350 per month plus $3,333 for the second lease (March and April of 2010 are free and the month of April in 2011, 2012 and 2013 is also free) ; (c) the monthly rent for year two of the lease (does not apply to second 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 (years two through four of the second lease) will increase each year by the lower of (i) the change in the consumer price index, or (ii) two and one half percent.

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.

PART II

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

Market Information

Our common stock is quoted on the OTC Bulletin Board under the symbol "CEMI." The table below sets forth the high and low bid prices per share of our common stock for each quarter of our two most recently completed fiscal years. These prices represent inter-dealer quotations without retail markup, markdown, or commission and may not necessarily represent actual transactions.

Fiscal Year 2009	High Bid	Low Bid
First Quarter	$.135	$.075
Second Quarter	$.18	$.085
Third Quarter	$.23	$.12
Fourth Quarter	$.39	$.20

Fiscal Year 2008	High Bid	Low Bid
First Quarter	$0.30	$0.11
Second Quarter	$0.26	$0.08
Third Quarter	$0.28	$0.15
Fourth Quarter	$0.21	$0.10

Rule 15g-9 of the Securities and Exchange Commission, known as the Penny Stock Rule, imposes requirements on broker/dealers who sell securities subject to the rule to persons other than established customers and accredited investors. 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 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 2007, 2008 and 2009 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 February 2, 2010, there were approximately 1,100 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 ending December 31, 2009. Prior year's financial statements have been reclassified to conform to current year presentation As of the year ended December 31, 2008 the Company reclassified its royalty and license expenses to cost of goods sold, instead of selling, general and administrative expenses.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
SELECTED HISTORICAL FINANCIAL DATA

Statement of Operations Data:	December 31, 2009		December 31, 2008		December 31, 2007		December 31, 2006		December 31, 2005	
TOTAL REVENUES	$13,834,248		$11,049,571		$9,230,948		$6,502,480		$3,940,730	
GROSS PROFIT	5,860,405	42%	3,851,721	35 %	2,795,710	30 %	1,608,272	25 %	944,648	24 %
OVERHEAD COSTS:										
Research and development expenses	2,883,696	21%	2,605,343	24 %	1,906,653	21 %	1,401,472	22 %	1,364,898	35 %
Selling, general and administrative expenses	2,659,382	19%	3,317,046	30 %	3,765,221	41 %	4,786,993	74 %	2,877,737	73 %
	5,543,078		5,922,389		5,671,874		6,188,465		4,242,635	
INCOME (LOSS) FROM OPERATIONS	317,327		(2,070,668)		(2,876,164)		(4,580,193)		(3,297,987)	
OTHER INCOME (EXPENSES):	(8,267)		121,898		249,272		(414,827)		45,987	
NET INCOME (LOSS)	309,060	2 %	(1,948,770)	-18%	(2,626,892)	-28%	(4,995,020)	-77 %	(3,252,000)	-83 %
Dividends accreted/payable in stock to preferred stockholders and a beneficial conversion feature	-		-		5,645,310		3,210,046		3,517,022	
NET INCOME (LOSS) ATTRIBUTABLE TO COMMON STOCKHOLDERS	$309,060		$(1,948,770)	-18%	$(8,272,202)	-90%	$(8,205,066)	-126%	$(6,769,022)	-172%

Basic income (loss) per share	$0.00	$(0.03)	$(0.57)	$(0.80)	$(0.88)
Diluted income (loss) per share	$0.00	$(0.03)	$(0.57)	$(0.80)	$(0.88)
Weighted average number of shares outstanding, basic	61,946,435	61,266,954	14,608,478	10,293,168	7,705,782
Weighted average number of shares outstanding, diluted	75,041,932	61,266,954	14,608,478	10,293,168	7,705,782

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 were 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. Specifically, 1) our ability to obtain necessary regulatory approvals for our products; and 2) our ability to increase revenues and operating income, 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," "expects," "intends," "plans," "anti "believes," "estimates," "predicts," "potential," "continues" or the negative of these terms or other comparable terminolo 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 four 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 two 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. The DPP® HIV Screening Assay, will be manufactured as an OEM product for the Brazilian market pursuant to one of our agreements with FIOCRUZ.

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

Oswaldo Cruz Foundation OEM DPP® Agreements - During 2008 we signed four agreements with the Oswaldo Cruz Foundation (FIOCRUZ) in Brazil relating to products based on our DPP® technology for Leptospirosis, Canine Leishmaniasis, screening for HIV 1/2 with oral fluid samples, and a 5-band multiplex point-of-care confirmation test for HIV 1&2. We have completed development of three of these products (Leishmaniasis and the HIV screening and confirmation tests), and we have substantially completed development of the Leptospirosis test. Two of the three products developed have been submitted for regulatory approval evaluations in Brazil and we expect the third will be filed very shortly; we expect that these products will be approved by Brazilian regulatory authorities (ANVISA for HIV tests and MAPA for canine test), although there can be no assurance, during the first part of 2010, triggering initial orders as well as approximately $1 million in technology transfer fee payments to the Company.

During 2009, we received purchase orders from FIOCRUZ for the three products for which development has been completed and that are pending regulatory approval in the aggregate of approximately $2.4 million. These orders are subject to regulatory approval, of which there can be no assurance. If regulatory approval is obtained, we anticipate additional orders in 2011. We are currently considering entering additional agreements based on a similar model with them in 2010.

Bio-Rad Laboratories OEM DPP® Agreement- On April 6, 2008, we entered a 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 is for the development of a six band multiplex product on our DPP®. We will complete development of this product by the middle of 2010, by which time Bio Rad will have paid us approximately $600,000 in development costs plus $340,000 for a DPP® license limited to this product. Thereupon, CE marking and FDA approval will be sought by Bio-Rad with Chembio in a supporting role as manufacturer. We 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.

Battelle/CDC DPP® Influenza Immunity Test – In December 2009 Chembio entered into a milestone-based development agreement for up to approximately $900,000 in connection with the development and initial supply of a multiplex, rapid point-of-care ("POC") influenza immunity test. The agreement contemplates a period of approximately nine months in which the development activity is to be completed. Chembio entered this agreement with Battelle Memorial Institute which has a master contract with the United States Centers for Disease Control and Prevention ("CDC") to enter into, implement and provide technical oversight of agreements relating to pandemic preparedness on behalf of CDC. Our work plan has been delivered and been approved, which are the first two milestones triggering approximately $178,000 in payments to Chembio. No agreement is in place for the manufacture, commercialization or license for this product assuming it is successfully developed in accordance with the specifications.

The objective of the project is to develop a product that can determine an individual's immunity to seasonal and novel influenza viruses, including novel swine H1N1, either in the field or in an outpatient setting. The test will have six different parameters (representing different influenza strains) plus a control line on a single POC DPP® device. The test will allow visual interpretation of results and/or will be used with a portable digital reader that will be customized for this application. Public health experts believe that rapid responses in the field require a POC test for influenza immunity, as well as infection. Current test platform technologies for infection and immunity are not suitable for reliable POC testing.

DPP® Hepatitis C and DPP® Hepatitis C/HIV Oral Fluid Antibody Tests - Prototypes of these products have been developed and are being evaluated in a study that has been organized by the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) at the Centers for Disease Control and Prevention (CDC) of the Department Of Health and Human Services. The evaluation will be completed during 2010 and the results should be useful in helping to ascertain the performance characteristics of these products in comparison to other products that will also be in this evaluation. Chembio’s DPP® HIV 1/2 test is also being evaluated in this study.

DPP® Influenza –We have developed a prototype multiplex test for FLU A/B Antigen Detection. [This is not to be confused with the immune status antibody detection test we are developing for the U.S. CDC]. This prototype, if successfully developed into a commercial product, would be competitive to the current point-of-care FLU A/B products marketed by Quidel, Meridian, Binax (Inverness) and others. We believe that we can develop a test that performs better than the current market leaders, and so that there is therefore a significant opportunity to participate in this market. We are also considering additional parameters for this product that would further differentiate it in the market. This product will be our first commercial antigen detection test on DPP® and we believe that this has independent value to demonstrate the capabilities of our technology to access large markets beyond serological antibody detection markets. Our current plan is for development to be completed and initiation of our FDA 510(k) submission activities during 2010.

DPP® Leptospirosis – In June, as we previously reported, we were awarded a three-year $3 million Small Business Innovative Research (SBIR) Phase II grant from the United States National Institutes of Health (NIH) to fully develop, validate, and commercialize a rapid diagnostic test for Leptospirosis for general use worldwide, and our work is progressing on schedule. The test will be developed with DPP® and will utilize proprietary reagents developed by Cornell University and the Oswaldo Cruz Foundation at the Brazilian Ministry of Health. Development of the test will

be in collaboration with the Division of Infectious Diseases, Weill Medical College, Cornell University in New York and the Oswaldo Cruz Foundation, the largest biomedical research institution in Latin America. In the Phase I work completed in 2008, which occurred with this same collaborative group, novel diagnostic targets were identified and evaluated in a prototype test in Chembio's patented DPP® format. The studies demonstrated that the test prototype had an overall sensitivity of 85% and a specificity of 90% using serum samples of Leptospirosis patients from Brazil and Thailand. Furthermore, the DPP® prototype had a sensitivity of 78% in identifying Leptospirosis in the first 7 days of illness, the "window-of-opportunity" during which initiation of antimicrobial therapy provides the greatest benefit.

Other Research & Development Activities - Chembio continues to work with commercial, governmental and private organizations in order to obtain R&D contracts & 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® and creating important collaborative relationships. We have other grant applications pending. In April 2009 we entered into a Services Agreement with the Infectious Disease Research Institute to develop DPP® products for Leishmaniasis and Leprosy for which we have received $125,000 and which, subject to attainment of development milestones, will additionally provide us with approximately $125,000 within the next six months. The second year provides for another $150,000, subject to the attainment of development milestones. During the first quarter of 2009 we entered into a funded feasibility study agreement with the Foundation for Innovative and Novel Diagnostics (FIND), a non-profit organization funded by the Gates Foundation, related to development of serological tests for Tuberculosis and Malaria using our DPP®. The Company received $165,000 from FIND and as a result of our achievement of all milestones, we recognized revenue of $99,000 in the first and second quarters as well as $66,000 during the third quarter with further development activity pending a full evaluation and comparison of results.

There can be no assurance that any of these projects will continue, meet regulatory or other technical requirements and specifications, and/or that if continued, will result in completed products, or that such products, if successfully completed, will be successfully commercialized.

Platform Enhancements - In addition to the specific products we plan to commercialize we also are pursuing enhancements to our DPP® technology platform during 2010 and 2011. These enhancements include enabling a simplified test procedure, lowering the overall manufacturing costs, enabling development of combination antibody and antigen assays, and integrating molecular sample amplification systems with our detection system. We are active in each of these areas and also are pursuing patent protection where applicable.

Regulatory Activities
CE Mark for FDA approved HIV tests – we provided all testing and related documentation that was requested by our Notified Body during the second quarter, however additional data was requested in correspondence we received in January and we are evaluating the cost/benefit of producing this information at this time. Under our agreement with Inverness, as now amended, we no longer have the obligation to obtain a CE Marking for the Clearview® Complete HIV 1/2.

Regulatory Approvals in Brazil through the Oswaldo Cruz Foundation (FIOCRUZ) – We anticipate that FIOCRUZ will receive required approvals from its regulatory agencies during the first and/or second quarter of 2010 for the DPP® Leishmaniasis, HIV Confirmatory, and the DPP® HIV screening tests.

DPP® HIV 1/2 Screening Assay for Oral Fluid - Field evaluations in Africa have been completed of this product that will supplement our pending U.S. clinical studies: During the second half of 2009 we prepared a proposed clinical trial protocol and submitted it to the FDA in support of our application for an Investigational Device Exemption (IDE) which we submitted and was approved during the fourth quarter of 2009. This approved protocol permits us to move forward with the clinical trials performance data, along with other required product and manufacturing data, in support of a Pre-Marketing Approval (PMA) application to the FDA. We have commenced the clinical trials at two sites and we anticipate completing the clinical trials and submitting the PMA application during 2010 and receiving approval of the PMA during 2011.

DPP® Syphilis Screen & Confirm - The first phase of a multi-center evaluation sponsored by the World Health Organization commenced during the third quarter and we have received only limited first phase results. During the third quarter, we submitted a proposed clinical plan to the FDA (Pre-IDE "Investigational Device Exemption") and we are currently reviewing the FDA response. We have also begun to identify clinical testing sites, have performed additional validation, interfering substance, and cross-reactivity studies on the product at Chembio and at external laboratories. There is no point-of-care test for syphilis cleared for marketing in the United States, and we believe that

our product, with its multiplexed capacity to identify both treponemal and non-treponemal markers, provides a reliable indication of an active, untreated case of syphilis at the point-of-care.

The table below provides a preliminary summary estimated timetable for the regulatory approval and commercialization of the DPP® HIV Screening Assay and the DPP® Syphilis Screen & Confirm Assay in major markets. There can be no assurance that these dates will be accurate.

Market	DPP® HIV 1/2 Screening Assay	DPP® Syphilis Screen & Confirm
Developing World	2010	2010
CE Mark0	2nd Half 2011	First Half 2010
US FDA	2nd Half 2011	First Half 2011

Recent Events

In May 2009, certain warrants to purchase an aggregate of 2,489,120 shares of common stock expired, at an average exercise price of $.764. These warrants were related to the Series A Preferred Stock Offering and other warrants related to the 2004 merger.

In January 2010, certain warrants to purchase an aggregate of 4,960,370 shares of common stock expired, at an average exercise price of $.474. These warrants were related to the initial 2005 Series B Preferred Stock Offering (see Form 8-K filed on January 31, 2005 with the SEC for further details on this offering).

We entered into a lease effective February 1, 2010 for additional warehouse space; see Item 2 for more information.

In February 2010, the Company took possession of the automated assembly equipment (mentioned below under Equipment Purchase Commitment). This equipment is expected to provide for faster throughput and thereby increasing capacity of our manufacturing facility, in addition to reducing labor costs. The machine will need to go through a validation process and is expected to be in serviced during the second quarter of 2010.

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. Please see Item 11 of this Form 10-K for further details.

RESULTS OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2009 AS COMPARED WITH THE YEAR ENDED DECEMBER 31, 2008

Revenues:

Selected Product Categories:	For the years ended			
	December 31, 2009	December 31, 2008	$ Change	% Change
HIV	$ 10,792,947	$ 9,192,297	$ 1,600,650	17.41 %
DPP	619,530	126,000	493,530	391.69 %
Other	960,016	1,037,471	(77,455)	-7.47 %
Net Product Sales	12,372,493	10,355,768	2,016,725	19.47 %
License and royalty income	121,896	-	121,896	100.00 %
R&D contracts and grants	1,339,859	693,803	646,056	93.12 %
Total Revenues	$ 13,834,248	$ 11,049,571	$ 2,784,677	25.20 %

Revenues for our HIV tests and related components during the year ended December 31, 2009 increased by $1.60 million over the same period in 2008. This was primarily attributable to increased sales to our distributor in the United States which increased 148%, or $3.13 million, to $5.24 million in 2009 as compared with $2.11 million in 2008. This increase offset reduced sales to Africa, which decreased by 21.6%, or $1.53 million, to $5.55 million in 2009 as compared with $7.08 million in 2008. Sales of our DPP product increased because we are working with our partner in Brazil to get several products approved in Brazil. The increase in R&D contracts and grants involving our patented DPP® technology, of which $1,161,000 was received and $1,340,000 was earned in 2009, adding $21,000 to deferred revenues as of December 31, 2009.

Gross Margin:

Gross Margin related to Net Product Sales:	For the years ended			
	December 31, 2009	December 31, 2008	$ Change	% Change
Gross Margin per Statement of Operations	$ 5,860,405	$ 3,851,721	$ 2,008,684	52.15 %
Less:R&D contracts and grants, license and royalties	1,461,755	693,803	767,952	110.69 %
Gross Margin from Net Product Sales	$ 4,398,650	$ 3,157,918	$ 1,240,732	39.29 %
Gross Margin %	35.55 %	30.49 %		

The increase in our gross margin resulted primarily from increased average unit prices on product sales as a result of the increased sales to Inverness, which are at higher average unit prices, and decreased sales to Africa, which are at lower average unit prices.

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, 2009	December 31, 2008	$ Change	% Change
Clinical & Regulatory Affairs:				
Wages and related costs	$ 321,830	$ 262,191	$ 59,639	22.75 %
Consulting	35,560	27,231	8,329	30.59 %
Share-based compensation	12,916	-	12,916	100.00 %
Clinical trials	69,499	138,792	(69,293)	-49.93 %
Other	32,056	60,822	(28,766)	-47.30 %
Total Regulatory	$ 471,861	$ 489,036	$ (17,175)	-3.51 %
R&D Other than Regulatory:				
Wages and related costs	$ 1,541,295	$ 1,354,557	$ 186,738	13.79 %
Consulting	74,194	138,436	(64,242)	-46.41 %
Share-based compensation	62,180	84,935	(22,755)	-26.79 %
Materials and supplies	462,806	282,281	180,525	63.95 %
Other	271,360	256,098	15,262	5.96 %
Total other than Regulatory	$ 2,411,835	$ 2,116,307	$ 295,528	13.96 %
Total Research and Development	$ 2,883,696	$ 2,605,343	$ 278,353	10.68 %

Expenses for Clinical & Regulatory Affairs for the year ended December 31, 2009 decreased by $17,000 as compared to the same period in 2008. This was primarily due to expenses we incurred in 2008 for external clinical trials conducted in order to lower the age limitation of our FDA approved rapid HIV tests from 18 to 13 years of age in 2008, which did not recur. This decrease was partially offset by an increase in wages and related costs.

R&D expenses other than Clinical & Regulatory Affairs increased by $295,000 in the year ended December 31, 2009 as compared with the same period in 2008 and were primarily related to an increase in personnel and material costs required to perform the work related to funded research and development contracts and grants all related to our patented DPP® technology. These increases were partially offset by a decrease in consulting cost and the reduced cost of share-based compensation related to the value of employee stock options issued and amortized.

Selling, General and Administrative Expense:

Selected expense lines:	For the years ended December 31, 2009	December 31, 2008	$ Change	% Change
Wages and related costs	$ 1,075,532	$ 1,261,511	$ (185,979)	-14.74 %
Consulting	165,371	187,494	(22,123)	-11.80 %
Commissons	302,515	365,774	(63,259)	-17.29 %
Share-based compensation	98,356	187,908	(89,552)	-47.66 %
Marketing materials	22,779	38,379	(15,600)	-40.65 %
Investor relations	72,888	123,654	(50,766)	-41.05 %
Legal, accounting and Sox 404 compliance	470,843	556,118	(85,275)	-15.33 %
Travel, entertainment and trade shows	61,316	92,576	(31,260)	-33.77 %
Other	389,782	503,632	(113,850)	-22.61 %
Total S, G &A	$ 2,659,382	$ 3,317,046	$ (657,664)	-19.83 %

Selling, general and administrative expenses for the year ended December 31, 2009 decreased by 20% as compared with the same period in 2008. During the second half of 2008 and continuing in 2009 the Company implemented a series of cost reductions that have resulted in lower S,G&A expenses in almost every category in 2009 year to date with the exception of sales commissions which, decreased as a result of a decrease in commissionable sales (and not from the Company's cost reductions) as compared with the 2008 period.

Other Income and Expense:

	For the years ended December 31, 2009	December 31, 2008	$ Change	% Change
Other income	$ (6,696)	$ 95,812	$ (102,508)	-106.99 %
Interest income	9,032	34,403	(25,371)	-73.75 %
Interest expense	(10,603)	(8,317)	(2,286)	-27.49 %
Total Other Income and (Expense)	$ (8,267)	$ 121,898	$ (130,165)	-106.78 %

Other income and (expense) for the year ended December 31, 2009 decreased 107% as compared with the same period in 2008 primarily as a result of a decrease in the net amounts received from New York State related to a program for qualified emerging technology companies. Interest income for the year ended December 31, 2009 decreased due to a decrease in available funds to invest in interest bearing accounts.

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED DECEMBER 31, 2009 AS COMPARED WITH THE THREE MONTHS ENDED DECEMBER 31, 2008

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE THREE MONTHS ENDED
(UNAUDITED)

	December 31, 2009	December 31, 2008
REVENUES:		
Net product sales	$ 3,127,454	$ 2,244,753
License and royalty income	38,186	-
Research grant income	385,801	206,141
TOTAL REVENUES	3,551,441	2,450,894
Cost of product sales	1,920,636	1,835,604
GROSS PROFIT	1,630,805	615,290
OPERATING EXPENSES:		
Research and development expenses	755,836	652,906
Selling, general and administrative expenses	657,310	620,695
	1,413,146	1,273,601
INCOME (LOSS) FROM OPERATIONS	217,659	(658,311)
OTHER INCOME (EXPENSES):		
Other income	-	107,363
Interest income	1,949	4,446
Interest expense	(2,394)	(3,901)
	(445)	107,908
INCOME (LOSS) BEFORE INCOME TAXES	217,214	(550,403)
Provision for income taxes	-	-
NET INCOME (LOSS)	$ 217,214	$ (550,403)
Basic earnings (loss) per share	$ 0.00	$ (0.01)
Diluted earnings (loss) per share	$ 0.00	$ (0.01)
Weighted average number of shares outstanding, basic	61,950,988	61,944,901
Weighted average number of shares outstanding, diluted	75,365,550	61,944,901

See accompanying notes to consolidated financial statements

Revenues:

Product Categories:	For the three months ended December 31, 2009	December 31, 2008	$ Change	% Change
HIV	$ 2,963,671	$ 1,963,383	$ 1,000,288	50.95 %
DPP	-	126,000	(126,000)	-100.00 %
Other	163,783	155,370	8,413	5.41 %
Net Product Sales	3,127,454	2,244,753	882,701	39.32 %
License and royalty income	38,186	-	38,186	100.00 %
R&D contracts and grants	385,801	206,141	179,660	87.15 %
Total Revenues	$ 3,551,441	$ 2,450,894	$ 1,100,547	44.90 %

Revenues for our HIV tests during the three months ended December 31, 2009 increased by approximately 51% or $1,000,000 over the same period in 2008. This was primarily attributable to increased sales in North America, primarily from sales to Inverness of our HIV products which increased by $1,292,000 to $1,833,000, and partially offset by a decrease in sales to Brazil of $374,000. The increase in R&D contracts and grants was primarily due to revenue our recent NIH grant for Leptospirosis, which was effective as of June 1, 2009. License and royalty income represents our royalties from Brazil under our 2004 technology transfer and license agreement.

Gross Margin:

Gross Margin related to Net Product Sales:	For the three months ended December 31, 2009	December 31, 2008	$ Change	% Change
Gross Margin per Statement of Operations	$ 1,630,805	$ 615,290	$ 1,015,515	160.05 %
Less:R&D contracts and grants, license and royalties	423,987	206,141	217,846	105.68 %
Gross Margin from Net Product Sales	$ 1,206,818	$ 409,149	$ 797,669	194.96 %
Gross Margin %	38.59 %	18.23 %		

The increase in our gross margin resulted primarily from increased sales volume and average unit prices as a result of the increased sales to Inverness, which are at higher average unit prices and decreased sales to Africa, which are at lower average unit prices. The increase in our gross margin in the three months ended December 31, 2009 also includes a decrease of $225,000 in the royalty expense paid to Inverness as partial reimbursement for Inverness' royalty payments to Bio-Rad Laboratories, Inc. pursuant to Inverness' HIV-2 sublicense agreement with Bio-Rad.

28

Research and Development:

This category includes costs incurred for regulatory approvals, product evaluations and registrations.

	For the three months ended December 31, 2009	December 31, 2008	$ Change	% Change
Clinical & Regulatory Affairs:				
Wages and related costs	$ 96,284	$ 67,294	$ 28,990	43.08 %
Consulting	5,610	2,548	3,062	120.17 %
Share-based compensation	4,667	-	4,667	100.00 %
Clinical trials	23,448	-	23,448	100.00 %
Other	7,852	7,727	125	1.62 %
Total Regulatory	$ 137,861	$ 77,569	$ 60,292	77.73 %
R&D Other than Regulatory:				
Wages and related costs	$ 420,088	$ 361,630	$ 58,458	16.17 %
Consulting	10,646	33,455	(22,809)	-68.18 %
Share-based compensation	9,722	9,738	(16)	-0.16 %
Materials and supplies	102,491	91,536	10,955	11.97 %
Other	75,028	78,978	(3,950)	-5.00 %
Total other than Regulatory	$ 617,975	$ 575,337	$ 42,638	7.41 %
Total Research and Development	$ 755,836	$ 652,906	$ 102,930	15.76 %

Total expenses for Clinical & Regulatory Affairs for the three months ended December 31, 2009 increased by approximately $60,000 as compared to the same period in 2008. An increase in compensation in Clinical and Regulatory Affairs of $29,000, was the primary reason for the increase in wages and related costs. In addition, start up costs for clinical trials of our DPP® oral fluid HIV test also contributed to this increase.

Total expenses for R&D Other than Clinical & Regulatory Affairs increased by approximately $43,000 in the three months ended December 31, 2009 as compared with the same period in 2008. These increases were primarily related to an increase in compensation, materials and supplies related to R&D contracts and grants, partially offset by a reduction in the use of consultants and other expenses.

Selling, General and Administrative Expenses:

Selected expense lines:	For the three months ended December 31, 2009	December 31, 2008	$ Change	% Change
Wages and related costs	$ 324,131	$ 257,778	$ 66,353	25.74 %

Consulting		22,250		45,912		(23,662	)	-51.54 %
Commissons		15,952		50,894		(34,942	)	-68.66 %
Share-based compensation		30,414		14,082		16,332		115.98 %
Marketing materials		5,419		15,831		(10,412	)	-65.77 %
Investor relations		35,839		11,906		23,933		201.02 %
Legal, accounting and Sox 404 compliance		123,500		81,562		41,938		51.42 %
Travel, entertainment and trade shows		13,849		20,730		(6,881	)	-33.19 %
Other		85,956		122,000		(36,044	)	-29.54 %
Total S, G &A	$	657,310	$	620,695	$	36,615		5.90

Selling, general and administrative expenses (S,G&A) for the three months ended December 31, 2009 increased by 5.9% as compared with the same period in 2008. This was primarily due to increased wages and related expenses related to bonuses paid to compensate employees who had taken pay reductions during the first six months of the 2009 year.

Other Income and (Expense):

	For the three months ended December 31, 2009	December 31, 2008	$ Change	% Change
Other income (expense)	$ -	$ 107,363	$ (107,363)	-100.00 %
Interest income	1,949	4,446	(2,497)	-56.16 %
Interest expense	(2,394)	(3,901)	1,507	-38.63 %
Total Other Income and (Expense)	$ (445)	$ 107,908	$ (108,353)	-100.41 %

Other income and (expenses) for the three months ended December 31, 2009 decreased approximately $108,000 as compared with the same period in 2008, primarily as a result of a decrease in the net amounts received from New York State related to a program for qualified emerging technology companies.

LIQUIDITY AND CAPITAL RESOURCES

	For the years ended December 31, 2009	December 31, 2008	$ Change	% Change
Net cash provided by (used in) operating activities	$ 251,927	$ (1,194,227)	$ 1,446,154	-121.10 %
Net cash used in investing activities	(376,988)	(397,462)	(8,754)	2.20 %
Net cash provided by (used) in financing activities	(18,926)	(23,458)	33,760	-143.92 %
NET DECREASE IN CASH AND CASH EQUIVALENTS	$ (143,987)	$ (1,615,147)	$ 1,471,160	-91.09 %

The Company had a decrease in cash for the year ended December 31, 2009 as compared to a greater decrease in cash for the same period in 2008. The decrease during the 2009 period is primarily attributable to cash used on deposits and acquisition of fixed assets, partially offset by cash provided from operations. The decrease in the 2008 period is primarily attributable to the cash used in operations.

The Company had a working capital surplus of $1,494,000 at December 31, 2009 and a working capital surplus of $1,664,000 at December 31, 2008. The Company estimates that its resources are sufficient to fund its needs through the end of 2010 and beyond or that, in the alternative, it could raise additional capital although the terms under which that capital could be raised would likely be very dilutive to current shareholders. The Company's liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenues (the Company received $340,000 in 2009 for license fees for which we need to meet certain milestones to earn and the Company expects to receive up to $1 million in license fees from Brazil, although there can be no assurance); (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; (5) the payment of obligations and commitments (including a license fee payable of $875,000 due at the end of 2010); and (4) the investment in capital equipment (including production equipment of $323,500 that the Company has contracted for) and the extent to which it improves cash flow through operating efficiencies. There are no assurances that the Company will become profitable or generate positive cash flow by the end of 2010 or, in the alternative, be successful in raising sufficient capital to fund its needs through 2010.

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

Please see section entitled Recent Events above.

In 2009 Chembio achieved record revenues, gross margin, operating results and cash flow, including its first ever quarterly and full year profits since its reverse merger in 2004. Following net losses from 2004-2008, including our smallest loss in 2008 of nearly $2 million, we swung to net income of $309,000 in 2009. This was a notable achievement given that 2009 was the worst economy since World War II. We believe this achievement was attributable to several factors, including: (1) the $3.13 million, or 148%, increase in our rapid HIV test sales to Inverness more than offset a $1.53 million, or 21.6%, decrease in our international HIV rapid test sales. Higher average selling prices in the U.S. market for rapid HIV tests helped to produce a 36.8%, or $1.16 million, increase in our gross margin on product sales, from $3.16 million in 2008 to $4.32 million in 2009. These increased U.S. market revenues reflect the continued expansion in the U.S. rapid HIV test market, and relatively stable funding as rapid testing has taken hold, and expanded into more hospitals and public health testing venues. The increased average selling prices for our FDA PMA approved HIV rapid test products that are sold in the U.S. market as compared with those in the developing world provide us with a much more attractive return on the manufacturing, regulatory compliance and other costs (patent license fees and such as royalty expense) that are applicable to these products. This return is much lower on our international sales primarily due to the lower average selling prices of competitive products manufactured in Asia that do not have the same costs of regulatory compliance, labor and other items that we have in the United States with our products; (2) a 392%, or $494,000, increase in DPP® product sales attributable to our OEM agreements for new DPP® products with FIOCRUZ in Brazil. While such amount was significantly less than what we had anticipated, and this product was used by FIOCRUZ for regulatory submissions for the three DPP® products that have been submitted for regulatory approval in Brazil, these shipments at least allowed us to bring these products through our manufacturing process. We are optimistic that the four DPP® products we have under agreement will produce significant DPP® product and technology revenues during 2010 and beyond, although there can be no assurance of this; (3) A 93%, or $646,000, increase in R&D contracts and grants to $1.34 million in 2009 from $694,000 in 2008 more than offset the $278,000 increase in our research and development expenses from $2.61 million in 2008 to $2.88 million in 2009, as more commercial, governmental and non-governmental organizations entered into development programs with us related to our DPP® technology as we reported during 2009; and (4) 20% reduction in our SG&A expenses from $3.32 million in 2008 to $2.66 million in 2009, which decrease followed an 11.9% reduction in 2008 over 2007 and a 21.3% reduction in 2007 over 2006.

The December 31, 2009 cash balance was $144,000 less than at December 31, 2008. This was primarily due to $792,000 that was paid to Inverness pursuant to our agreement of December 2008 in which we agreed to amortize a $1.01 million liability to Inverness based on a percentage of their sales of our products beginning in 2009. Based on Inverness' anticipated sales of our products in 2010, we anticipate that the liability mentioned above will be fully amortized in the first part of 2010, thereby freeing up this cash flow used to extinguish the obligation to Inverness for other corporate purposes. Also contributing to the cash decrease was a $675,000 account receivable balance that was outstanding at the year end (which amount was paid in January 2010) and $400,000 that we invested during 2009 in new equipment and facilities (primarily our new assembly system that we took delivery of in February 2010). Partially offsetting these cash outflows were our net income, non-cash expenses, and receipt of a $340,000 license fee deposit from Bio-Rad Laboratories, Inc.

Our results in 2009 clearly guide our strategy for growth in 2010 and beyond. We believe we can best leverage our DPP® intellectual property together with our U.S.-based manufacturing and regulatory credentials by bringing proprietary products (such as our DPP® oral fluid HIV test and our Screen and Confirm Syphilis test) to the U.S. public health and other markets. Based on our current year and long range plan, we are optimistic that revenues will grow significantly in the foreseeable future, although there can be no assurance of this.

Significant revenue growth in 2010 could be realized, based on the following assumptions: (1) Increased sales of our rapid HIV tests in the U.S. market as the total market and our products' market share increases; (2) increased international sales of our HIV rapid tests primarily based on maintaining current accounts, increased sales to Nigeria where we resumed sales activity in the fourth quarter of 2009 for the first time since 2008; (3) DPP® product sales and license fees from our contracts with FIOCRUZ (including regulatory approvals required in Brazil) and completion of the product development phase in our program with Bio-Rad Laboratories, Inc. which would result in recognizing the $340,000 license fee we received in 2009; (4) a substantial increase in our R&D contracts and grants primarily based on the $900,000 development contract we entered in December 2009 with Battelle Memorial Institute and having a full year of the $2.9 million NIH grant for Leptospirosis we received in June 2009, and; (5) improved manufacturing efficiencies based on the delivery in February of our customized automated assembly system which we invested in during 2009 for both our lateral flow and DPP® products, and lower costs for certain raw materials used in our HIV tests which we will realize as a result of our having bought out a license agreement in connection with the insolvency procedures of the licensor in 2009.

We have received purchase orders from FIOCRUZ for the three products pending regulatory approval for an aggregate of over $2 million, and have an aggregate of approximately $1 million in license fees that will be payable when the products are approved. However the fees will not be paid and these orders cannot be processed and shipped unless and until regulatory approval is obtained in Brazil, which we believe will occur during the first half of 2010, but for which there can be no assurance.

The anticipated increased product and research and development revenues, if realized will be accompanied by increased product costs and research and development expenses which will be attributable to the increased R&D work primarily required by the above-mentioned R&D contracts & grants; such expenses may also increase as a result of other initiatives that we have identified that we may be undertaking to further expand and enhance our technology portfolio.

In addition, we have commenced training for the conduct of clinical trials related to our planned FDA PMA application for our DPP® oral fluid HIV test. We anticipate that the total costs for thee trials during 2010 for this and related regulatory activities could approach $2 million. Moreover, additional regulatory expenses for preparing our DPP® Syphilis Screen & Confirm test and our DPP® Flu A/B tests for 510(k) submissions will also require significant resources, though not nearly as much as the aforementioned PMA. We may attempt to enter an agreement with a marketing partner for one more of these products which could result in our being reimbursed for a portion of our regulatory expenses for one or more of these products, but there can be no assurance of this occurring or if it occurs, its timing. We can also defer some or all of these costs to ensure that we can finance them with operating

cash flow, though this would impact commercialization timetables.

Although we believe that there are still opportunities to increase our international HIV test sales and we plan to do so in 2010, we are cognizant that these markets will continue to be largely driven by price and therefore difficult for our U.S.-based cost structure (though still contributing margin), and very difficult to forecast due to their reliance on host governments' decisions which can suddenly and arbitrarily result in changes even though they are funded by foreign aid budgets, mainly PEPFAR. On the other hand, based on the outstanding data from a recent field study by the United States Centers for Disease Control of our oral fluid HIV test in Africa, where it was compared with two leading blood tests and an oral fluid test of a competitor's, we believe that there could well be significant opportunities for this product in the international market, in which we are one of only two oral fluid HIV tests approved for procurement by PEPFAR, as compared with dozens now that only work on blood matrices. Further, we believe that if studies that having been completed can show that oral fluid tests can improve prevention strategies by encouraging more people to be tested, and particularly if we can continue to lower our productions costs for this product to be more competitively priced for this market, the international opportunity for this product will be significant indeed.

If the assumptions set forth above hold true, of which there is no assurance – particularly where timing is concerned – we believe that our operating cash flow from our existing business will likely be sufficient to fund a substantial portion of the research and development and regulatory expenses required in order to begin commercializing these new products in 2011, though there can no assurance of this. We believe that we must invest in these new product approvals in order to meet our long range plan for significant growth.

We will endeavor to time the increases in our research and development expenses, with the increased R&D contracts and grants we anticipate receiving as described above. However, delays in achievement of milestones and/or their approval for the purpose of funding of payments that may be due to us can occur.

We also anticipate that our SG&A expenses, after having decreased in each of the last three years, will not continue this trend into 2010. This is attributable to: a) our having reduced this expense so significantly over the last three years; b) expenses we may incur in 2010 that are associated with the potential establishment of our own Chembio/DPP® branded product line in 2011; and c) expenses we may incur related to expansion of our board of directors and investor relations activities as compared to 2009.

Accordingly, in order to increase the likelihood that the regulatory approvals and commercialization of new DPP® products occur on a timely basis, we may choose to raise some additional capital if we believe such capital will best ensure our ability to execute our business plan on a timely basis.

Equipment Purchase Commitment:

In January 2009, the Company entered into an agreement with an equipment manufacturer to design and build equipment that will be used to automate the assembling of our tests and lower our production costs. The estimated cost of $323,500 is being paid in installments. In addition in June and November of 2009, the Company entered into an agreement with an equipment manufacturer to design and build a mold for its DPP® tests. The estimated cost of $113,800 is being paid in installments.

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 sell our products directly through our sales force and through distributors. Revenue from direct sales of our product are recognized upon shipment to the customer. Income from R&D contracts and grants are recognized in earnings in the period in which the related expenditures are incurred. Sales are recorded net of discounts, rebates and returns.

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 $15,000.

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 1.1% of accounts receivable. For example each additional 1% of accounts receivable that becomes uncollectible would reduce such balance of accounts receivable by approximately $18,000.

Income Taxes –

Income taxes are accounted for under ASC740 "Accounting for Income Taxes." ASC740 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. For example, even though we have become profitable, we may be unable to utilize our deferred tax asset, which approximates $8,418,000 at December 31, 2009.

ASC740 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.

Forming a conclusion that a valuation allowance is not needed is difficult when there is negative objective evidence such as cumulative losses in recent years. Cumulative losses weigh heavily in the overall assessment. As a result, we determined that it was appropriate to establish a valuation allowance for the full amount of our deferred tax assets.

ASC740 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 calculation of our tax liabilities involves the inherent uncertainty associated with the application of complex tax laws. We are subject to examination by various taxing authorities. We believe that as a result of our losses sustained to date, any examination would result in a reduction of our net operating losses rather than a tax liability. As such, we have not provided for additional taxes estimated under ASC740, Accounting for Uncertainty in Income Taxes.

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:

(1) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;

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

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

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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, 2009.

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 temporary 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 (53), President, Chief Executive Officer and Director. Mr. Siebert was appointed President of Chembio Diagnostics, Inc. and a member of our board of directors upon consummation of the merger. 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 (53), Chief Financial Officer. Mr. Larkin was appointed as Chief Financial Officer of Chembio Diagnostics, Inc. upon consummation of the merger. 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 (43), 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 (56), 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 (47), 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 (59), Director. Dr. Meller was elected to our Board of Directors on March 15, 2005, and currently serves on the Company's Audit, Compensation and Nominating and Corporate Governance Committees, including as Chairman of the Compensation Committee. Dr. Meller has been the president of CommSense Inc., a healthcare business development company, since 2001. CommSense Inc. works with clients in Europe, Asia, North America, and the Middle East on medical information technology, medical records, pharmaceutical product development and financing, health services operations and strategy, and new product and new market development. From 1999 until 2001 Dr. Meller was the executive vice president, North America, of NextEd Ltd., a leading internet educational services company in the Asia Pacific region. Dr. Meller also was a limited partner and a member of the Advisory Board of Crestview Capital Master LLC, which was our largest 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 (53), Director. Ms. Davis was elected to the Company's Board of Directors in May 2007, and currently serves on the Company's Audit, Compensation and Nominating And Corporate Governance Committees, including as Chairman of each of the Audit Committee and the Nominating And Corporate Governance Committee. 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.

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, 2009, 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, except for the following: (i) one Form 4 for Gary Meller filed on October 30, 2009 that covered two reports and three transactions that were not reported on a timely basis; and (ii) one Form 4 for Lawrence Siebert filed on October 30, 2009 that covered one report and seven transactions; (iii) one Form 4 for Richard Larkin filed on October 30, 2009 that covered one report and seven transactions; (iv) one Form 4 for Katherine Davis that covered one report and two transactions; and (iv) one Form 4 for Javan Esfandiari that covered one report and eleven transactions.

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 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, 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	2009	$ 265,000	$ 110,200	$ 37,950	$ -	$ 7,200	$ 420,350
CEO	2008	265,000	26,000	36,695	-	8,267	335,962
Javan Esfandiari	2009	$ 230,192	$ 29,400	$ 28,200	$ 5,000	$ 4,883	$ 297,675
VP-R&D	2008	215,692	16,000	45,297	28,702	5,872	311,563
Tom Ippolito	2009	$ 181,500	$ 35,600	$ 21,150	$ -	$ 140	$ 238,390
VP-Regulatory	2008	173,631	12,000	8,129	-	1,708	195,468

1 Salary is total base salary.
2 Bonuses earned in 2009 were partially based on reaching certain objectives, which included revenue dollar levels and operating profit levels, additional amounts earned were discretionary. Bonuses earned in 2008 were paid solely on a discretionary basis, and not pursuant to any bonus plan.
3 The estimated fair value of any option or common stock granted was determined in accordance with ASC 718, "Share-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, 2009, the Company's Board of Directors approved the Company's extension of the June 15, 2006 employment agreement (the "Employment Agreement") with Lawrence A. Siebert, the Company's President and Chief Executive Officer, for an additional three-year term. 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, 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, 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. 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, consisting of (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 to purchase 100,000 shares vest on the effective date, options to purchase an additional 100,000 shares of the stock options vested on the second anniversary of the Employment Agreement, and options to purchase an additional 100,000 shares of the stock options vested 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. Esfandiari terminates his employment agreement for a reasonable basis, as defined in the Employment Agreement including within 12 months of a change in control, the Company is required to pay as severance Mr. Esfandiari’s salary for twelve months.

Mr. Ippolito does not have an employment contract with the Company.

Executive Bonus Plan

The Company has established a bonus plan for its executives who do not have a contract. For the fiscal year ended December 31, 2010, there were three executives eligible for this bonus plan. Each executive can earn up to 25% of that executive’s salary in the form of a bonus. Half of the amount, or 12.5%, is determined by the Compensation Committee in its discretion, and the other half is subject to the Company’s attaining certain objectives based on revenue and operating profit levels for the fiscal year for which the bonus is paid. The plan, during 2009, called for a sliding percentage of the executive’s salary, from zero to 6.25% for attaining 85% to 100% of revenue goals, and from zero to 6.25% of the executive’s salary for attaining between zero percent to 150% of the designated operating profit goals. The Company achieved 98.3% of its revenue goals for 2009, resulting in a bonus of 5.5% of each executive’s salary, and achieved greater than 150% of its operating profit goal, resulting in a bonus of 6.25% of salary, for a total of 11.75% of salary. In addition, the Compensation Committee approved approximately 8% of salary in discretionary bonuses for the subject executives, bringing the total bonus to approximately 20% of salary. Goals for 2010 have not yet been established.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END 2009

Name	Option Awards					Stock Awards		
	Number of Securities Underlying Unexcercised Options Excerciseable (#)	Number of Securities Underlying Unexcercised Options Unexcersable (#)	Option Exercise Price ($)	Option Expiration Date	Option Vesting Date	Number of Shares of Stock That Have Not Vest (#)	Market Value of Shares of Stock That Have Not Vested ($)	Foot-note
Lawrence A. Siebert		133,333	0.13	5/6/2014	5/6/2012			5
		133,333	0.13	5/6/2014	5/7/2011			5
		133,333	0.13	5/6/2014	5/6/2010			5
	250,000		0.13	6/3/2013	6/3/2008			3
	75,000		0.22	2/15/2013	2/15/2008			2
	50,000		0.13	5/28/2011	1/1/2007			1, 4
	50,000		0.13	5/28/2011	4/17/2006			1, 4
	10,000		0.13	5/4/2011	4/17/2006			4
	50,000		0.13	5/4/2011	5/5/2004			4
Javan Esfandiari		100,000	0.13	5/6/2014	5/6/2012			5
		100,000	0.13	5/6/2014	5/7/2011			5
		100,000	0.13	5/6/2014	5/6/2010			5
	100,000		0.13	4/23/2012	3/5/2009			1, 4
	100,000		0.13	4/23/2012	3/5/2008			1, 4
	60,000		0.22	2/15/2013	2/15/2008			2
	25,000		0.13	5/28/2011	5/28/2007			4
	100,000		0.13	4/23/2012	4/23/2007			1, 4
	18,750		0.13	3/24/2011	1/1/2007			4
	25,000		0.13	5/17/2010	1/1/2007			4
	25,000		0.13	5/28/2011	4/17/2006			1, 4
	25,000		0.13	5/28/2011	4/17/2006			1, 4
	5,000		0.13	5/4/2011	4/17/2006			4
	25,000		0.13	5/17/2010	4/17/2006			4
	18,750		0.13	3/24/2011	3/24/2006			4
	30,000		0.13	5/4/2011	5/5/2004			4
Tom Ippolito		75,000	0.13	5/6/2014	5/6/2012			5
		75,000	0.13	5/6/2014	5/7/2011			5
		75,000	0.13	5/6/2014	5/6/2010			5
	50,000		0.22	2/15/2013	2/15/2008			2
	15,000		0.13	3/24/2011	3/24/2006			4

1 Stock issued in connection with an employment contract and under the 1999 Stock Option Plan.
2 On February 15, 2008 the Company granted options under the 1999 Stock Option Plan.
3 Options issued in connection with an employment contract and under the 2008 Stock Incentive Plan.

4 On May 7, 2009, the Compensation Committee of the Company reduced, to $0.13 per share, the exercise price of each outstanding employee option that was issued under the 1999 Equity Incentive Plan (the "1999 Plan") for which the exercise price was greater than $0.44 per share of the Company's common stock. There was no other change made to the terms of the stock options other than the reduction in the exercise price. A total of 1,036,750 options were affected and the fair value difference of the options before and after the reduction was $31,660 and was expensed in the three months ended June 30, 2009.

5 On May 7, 2009 in accordance with the terms of the Company's 2008 Stock Incentive Plan, the Company granted certain employees of the Company, options to purchase an aggregate of 2,925,000 shares of the Company's common stock. The exercise price for these options is equal to $0.13 per share. The options become exercisable in thirds on the first, second and third anniversaries of the date of the grant. Each option granted will expire and terminate, if not exercised sooner, upon the earlier to occur of (a) 30 days after termination of the employee's employment with the Company or (b) the fifth anniversary of the date of grant. The fair value of these options is being amortized over the vesting life of the options.

DIRECTOR COMPENSATION

Name	Fees Earned or Paid in Cash ($) 1	Option Awards ($) 2	Total ($)
Katherine L. Davis	$ 29,500	$ 31,950	$ 61,450
Gary Meller	26,500	$ 31,950	58,450
James D. Merselis3	1,000	-	1,000

1 Fees earned or paid in cash represents a yearly fee and fees for meeting expenses: (a) Ms. Davis received an $18,000 annual fee as a member of the board of directors, a $2,500 annual fee as audit committee chairman and $9,000 in meeting fees paid during 2009; (b) Mr. Meller received an $18,000 annual fee as a member of the board of directors, and $8,500 in meeting fees; (d) Mr. Merselis received $1,000 in meeting fees.
2 Each outside member of the board of directors is granted, once every five years, the right to purchase 375,000 shares of the company's common stock with an exercise price equal to the market price on the date of the grant as part of their annual compensation. One-fifth of these options are exercisable on the date of grant, one-fifth become exercisable on the first anniversary of the date of grant, and additional one-fifths become exercisable on the second through fourth anniversary of the date of grant. The fair value of options at the date of grant was estimated using the Black-Scholes option pricing model.
3 Mr. Merselis resigned from our Board of Directors on February 9, 2009.

Director Compensation

All non-employee directors are paid an $18,000 annual retainer, semi-annually, and once every five years, on the date of the annual meeting of stockholders that directors are elected or re-elected (every 5 years), receive stock options to acquire 375,000 shares of the Company's common stock, with an exercise price equal to the market price on the date of the grant. Stock options to acquire 75,000 shares become exercisable on the date of grant, and options to acquire an additional 75,000 shares become exercisable on the date of each of the four succeeding annual meetings of stockholders if and to the extent that the non-employee director is reelected as a director at each such annual meeting. The audit committee chairman is paid an annual retainer of $2,500, paid semi-annually. In addition, the non-employee directors are paid $1,000 in cash for each board of directors' meeting attended, and paid $500 in cash for each telephonic board of directors meeting. The non-employee directors who are members of a committee of the board of directors are paid $500 in cash for each committee meeting attended, or $750 in cash for each committee meeting attended if that non-employee director is the committee chairman.

Compensation Committee Interlocks and Insider Participation

No executive officer of the Company served as a member of the Board of any other public company during the year ended December 31, 2009. No member of the Compensation Committee serves as an executive officer of any other public company during the year ended December 31, 2009. No interlocking relationship exists between the members of our Compensation Committee and the Board or compensation committee of any other company.

40

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

The following table sets forth certain information regarding the beneficial ownership of our common stock by each person or entity known by us to be the beneficial owner of more than 5% of the outstanding shares of common stock, each of our directors and each of our "named executive officers" and all of our directors and executive officers as a group as of March 1, 2010.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Owner	Percent of Class	
Siebert, Lawrence (1) 3661 Horseblock Road Medford, NY 11763	6,933,615	11.10	%
Esfandiari, Javan (2) 3661 Horseblock Road Medford, NY 11763	777,573	1.24	%
Larkin, Richard (3) 3661 Horseblock Road Medford, NY 11763	267,672	0.43	%
Ippolito, Tom (4) 3661 Horseblock Road Medford, NY 11763	65,000	0.10	%
Bruce, Richard (5) 3661 Horseblock Road Medford, NY 11763	135,075	0.22	%
Meller, Gary (6) 3661 Horseblock Road Medford, NY 11763	534,300	0.86	%
Davis, Katherine L. (7) 3661 Horseblock Road Medford, NY 11763	150,650	0.24	%
GROUP (8)	8,863,585	13.89	%
Inverness Medical Innovations, Inc. 51 Sawyer Road, Suite 200 Waltham, MA 02453	5,367,840	8.66	%
Crestview Capital Offshore Fund, Inc. 95 Revere Drive, Suite A Northbrook, IL 60062	3,356,040	5.41	%

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

The beneficial ownership percent in the table is calculated with respect to the number of outstanding shares (61,944,901) of the Company's common stock outstanding as of March 17, 2009. Each stockholder's ownership is

calculated as the number of shares of common stock owned plus the number of shares of common stock into which any preferred stock, warrants, options or other convertible securities owned by that stockholder can be converted within 60 days.

The term “named executive officer” refers to our principal executive officer, our two most highly compensated executive officers other than the principal executive officer who were serving as executive officers at the end of 2008, and two additional individuals for whom disclosure would have been provided but for the fact that the individuals were not serving as executive officers of the Company at the end of 2008.

(1) Includes 485,000 shares issuable upon exercise of options exercisable within 60 days. Does not include 400,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(2) Includes 557,500 shares issuable upon exercise of options exercisable within 60 days. Does not include 300,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(3) Includes 212,500 shares issuable upon exercise of options exercisable within 60 days. Does not include 275,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(4) Includes 65,000 shares issuable upon exercise of options exercisable within 60 days. Does not include 225,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(5) Includes 135,000 shares issuable upon exercise of options exercisable within 60 days. Does not include 225,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(6) Includes 234,000 shares issuable upon exercise of options exercisable within 60 days. Does not include 300,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(7) Includes 150,650 shares issuable upon exercise of options exercisable within 60 days. Does not include 300,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(8) Includes footnotes (1)-(8)

.

Equity Compensation Plan Information

Combined Equity Compensation Plans - Information as of December 31, 2009			
Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column (a) (c)
Equity compensation plans approved by security holders1	5,586,900 1	$ 0.152	1,821,350
Equity compensation plans not approved by security holders	--	--	--
Total	5,586,900	$ 0.152	1,821,350

1 The “Number of Securities to be Issued Upon Exercise of Outstanding Warrants and Rights” represents 2,408,250 from the 1999 Stock Option Plan and 3,178,650 under the 2008 Stock Incentive Plan. The “Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans” represents shares issuable under the 2008 Stock Incentive Plan.

42

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

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

On May 7, 2009, the Compensation Committee of the Company reduced, to $0.13 per share, the exercise price of each outstanding employee option that was issued under the 1999 Equity Incentive Plan (the "1999 Plan") for which the exercise price was greater than $0.44 per share of the Company's common stock. There was no other change made to the terms of the stock options other than the reduction in the exercise price. A total of 1,036,750 options were affected. Mr. Siebert, Mr. Esfandiari and Mr. Larkin had options to purchase common stock that were so reduced of 160,000, 497,500 and 137,500, respectively.

In addition, on May 7, 2009 in accordance with the terms of the Company's 2008 Stock Incentive Plan, the Company granted certain employees of the Company, options to purchase an aggregate of 2,925,000 shares of the Company's common stock. The exercise price for these options is equal to $0.13 per share. The options become exercisable in thirds on the first, second and third anniversaries of the date of the grant. Each option granted will expire and terminate, if not exercised sooner, upon the earlier to occur of (a) 30 days after termination of the employee's employment with the Company or (b) the fifth anniversary of the date of grant. Mr. Siebert, Mr. Esfandiari and Mr. Larkin received options to purchase common stock of 400,000, 300,000 and 275,000, respectively.

During the quarter ended December 31, 2008, Inverness notified the Company that Inverness had entered into a contract with Bio-Rad Laboratories, Inc. ("Bio-Rad") for royalties on Bio-Rad's patent for the detection of HIV-2 antibodies. The agreement also provided for Inverness to pay past royalties. On June 25, 2009, the Company and Inverness Medical Innovations, Inc. (Inverness) entered into a letter agreement whereby certain obligations aggregating approximately $1,010,000 as of December 31, 2008 were agreed to be paid from future revenues. The obligations include the Company's share under its agreements with Inverness for the amount of HIV-2 royalties that Inverness paid when Inverness entered into an HIV-2 license agreement with Bio-Rad Laboratories, Inc. of approximately $485,000 and royalties owed by Chembio on lateral flow licenses to Inverness of approximately $525,000 as of December 31, 2008. Under the agreement Inverness will retain an additional 10% of Clearview® HIV 1/2 STAT-PAK® net sales and 5% of Clearview® Complete HIV 1/2 net sales until these obligations are extinguished. The approximate aggregate balance due is $242,000 as of December 31, 2009.

Director Independence

Our common stock trades on the OTC Bulletin Board. As such, we are not currently subject to corporate governance standards of listed companies, which require, among other things, that the majority of the board of directors be independent.

We are not currently subject to corporate governance standards defining the independence of our directors, and we have chosen to define an "independent" director in accordance with the NASDAQ Global Market's requirements for independent directors. Under this definition, we have determined that Katherine L. Davis currently qualifies as independent director. We do not list the "independent" definition we use on our internet website.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

All fees discussed below were paid to ParenteBeard LLC, except 2008 amounts, which were paid to Lazar Levine & Felix LLP. In February 2009, Lazar Levine & Felix LLP merged its practice into Parente Randolph, LLC, which subsequently changed their name to ParenteBeard LLC.

Audit Fees

For the years ended December 31, 2009 and 2008, the Company's independent accounting firm billed the Company $100,000 and $136,000, respectively, for fees for the audit of the Company's annual financial statements and review of financial statements included in the Company's Forms 10-Q and 10-K.

Audit-Related Fees

For the years ended December 31, 2009 and 2008, the independent accounting firm, did not provide the Company with any assurance and related services reasonably related to the performance of the audit or review of the Company's financial statements that are not reported above under "Audit Fees."

Tax Fees

For the years ended December 31, 2009 and 2008, the independent accounting firm billed the Company $20,000 and $13,500, respectively, for professional services for tax compliance, tax advice and tax planning.

All Other Fees

For the years ended December 31, 2009 and 2008, the independent accounting firm billed the Company none and $2,500 for fees associated with the preparation and filing of the Company's registration statements, responses to SEC comment letters and other related matters.

Audit Committee Pre-Approval Policies

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

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Number	Description
3.1	Articles of Incorporation, as amended. (2)
3.2	Amended and Restated Bylaws. (1)
4.8	Form of Common Stock Warrant issued pursuant to the January 26, 2005 Securities Purchase Agreement. (7)
4.9	Amended Form of Common Stock Warrant issued pursuant to the January 26, 2005 Securities Purchase Agreement.
4.10	Registration Rights Agreement, dated as of January 26, 2005, by and among the Registrant and the purchasers listed therein. (9)
4.11	Form of Warrant, dated June 29, 2006, issued pursuant to Company and purchasers of the Company's Secured Debentures. (7)
4.12	Registration Rights Agreement, dated June 29, 2006. (3)
4.14	Registration Rights Agreement, dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (3)
4.15	Form of Common Stock Warrant issued pursuant to the Securities Purchase Agreements dated September 29, 2006 (5).
4.16	Amended Form of Common Stock Warrant issued pursuant to the Securities Purchase Agreements dated October 5, 2006. (5)
4.17	Amended Form of Common Stock Warrant issued to Placement Agents pursuant to the October 5, 2005 Securities Purchase Agreement. (9)
4.18*	Form of Employee Option Agreement. (9)
4.20	1999 Equity Incentive Plan. (11)
4.20	2008 Stock Incentive Plan. (12)
10.1*	Employment Agreement dated June 15, 2006 with Lawrence A. Siebert. (4)
10.2*	Employment Agreement dated April 23, 2007 with Javan Esfandiari. (10)
10.4	Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of January 26, 2005, by and among the Registrant and the purchasers listed therein. (7)
10.5	Amendment No. 1 to Securities Purchase Agreement, dated as of January 28, 2005 by and among the Registrant and the purchasers listed therein. (8)
10.7	Security Purchase Agreement, dated June 29, 2006, among the Company and purchasers of the Company's Secured Debentures. (3)
10.11	Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (5)
10.11	Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (5)
10.12	Letter of Amendment to Securities Purchase Agreements dated as of September 29, 2006 by and among the Registrant and the Purchasers listed therein. (5)
10.13	HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Inverness and StatSure. (5)
10.14	HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Inverness. (5)
10.15	Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Inverness. (5)
10.16	Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (5)
14.1	Ethics Policy (13)
21	List of Subsidiaries.
23.1	Consent of ParenteBeard LLC, Independent Accountants.
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

32 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(1) Incorporated by reference to the Registrant's registration statement on Form SB-2 filed with the Commission on August 23, 1999 and the Registrant's Forms 8-K filed on May 14, 2004, December 20, 2007 and April 18, 2008.
(2) Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 31, 2005.
(3) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on July 3, 2006.
(4) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on June 21, 2006.
(5) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on October 5, 2006.
(6) Incorporated by reference to the Registrant's registration statement on Form SB-2 filed with the Commission on June 7, 2004.
(7) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on January 31, 2005.
(8) Incorporated by reference to the Registrant's registration statement on Form SB-2 filed with the Commission on March 28, 2005.
(9) Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 12, 2008.
(10) Incorporated by reference to the Registrant's Current Report on Form 8-K/A filed with the Commission on May 3, 2007.
(11) Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on May 11, 2005.
(12) Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on April 14, 2008.
(13) Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 30, 2006.
(*) An asterisk (*) beside an exhibit number indicates the exhibit contains a management contract, compensatory plan or arrangement which is required to be identified in this report.

SIGNATURES

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

CHEMBIO DIAGNOSTICS, INC.

Date: March 5, 2010 By /s/ Lawrence A. Siebert
Lawrence A. Siebert
President, Chief Executive Officer and
Chairman of the Board

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

Signatures	Title	Date
/s/ Lawrence A. Siebert Lawrence A. Siebert	Chief Executive Officer, President and Chairman Of The Board (Principal Executive Officer)	March 5, 2010
/s/ Richard J. Larkin Richard J. Larkin	Chief Financial Officer (Principal Financial & Accounting Officer)	March 5, 2010
/s/ Gary Meller Dr. Gary Meller	Director	March 5, 2010
/s/ Katherine L. Davis Katherine L. Davis	Director	March 5, 2010

46

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To The Board of Directors
Chembio Diagnostics, Inc. and Subsidiary
Medford, New York 11763

We have audited the accompanying consolidated balance sheets of Chembio Diagnostics, Inc. and Subsidiary (the "Company") as of December 31, 2009 and 2008 and the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2009. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Chembio Diagnostics, Inc. and Subsidiary as of December 31, 2009 and 2008, and their consolidated results of its operations and their cash flows for each of the two years in the period ended December 31, 2009 in conformity with accounting principles generally accepted in the United States of America.

PARENTEBEARD LLC

/s/ PARENTEBEARD LLC

New York, New York
March 4, 2010

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

- ASSETS -	December 31, 2009	December 31, 2008
CURRENT ASSETS:		
Cash and cash equivalents	$ 1,068,235	$ 1,212,222
Accounts receivable, net of allowance for doubtful accounts of $20,000 and $10,301 for 2009 and 2008, respectively	1,776,327	809,303
Inventories	1,555,903	1,819,037
Prepaid expenses and other current assets	266,637	225,153
TOTAL CURRENT ASSETS	4,667,102	4,065,715
FIXED ASSETS, net of accumulated depreciation	580,213	881,406
OTHER ASSETS:		
License agreements, net of current portion	700,000	940,000
Deposits on manufacturing equipment	338,375	-
Deposits and other assets	29,560	27,820
TOTAL ASSETS	$ 6,315,250	$ 5,914,941
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	$ 1,906,163	$ 2,383,021
Current portion of loan payable	9,600	-
Deferred research and development revenue	360,833	-
License fee payable	875,000	-
Current portion of obligations under capital leases	21,536	18,780
TOTAL CURRENT LIABILITIES	3,173,132	2,401,801
OTHER LIABILITIES:		
Loan payable - net of current portion	14,931	-
Obligations under capital leases - net of current portion	39,273	60,808
License fee payable - net of current portion	-	875,000
TOTAL LIABILITIES	3,227,336	3,337,609
COMMITMENTS AND CONTINGENCIES		

STOCKHOLDERS' EQUITY:				
Preferred stock – 10,000,000 shares authorized, none outstanding		-		-
Common stock - $.01 par value; 100,000,000 shares authorized, 61,979,901 and 61,944,901 shares issued and outstanding for 2009 and 2008, respectively		619,799		619,449
Additional paid-in capital		39,453,522		39,252,350
Accumulated deficit		(36,985,407)		(37,294,467)
TOTAL STOCKHOLDERS' EQUITY		3,087,914		2,577,332
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$	6,315,250	$	5,914,941

See accompanying notes to consolidated financial statements

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

	December 31, 2009	December 31, 2008
REVENUES:		
Net product sales	$ 12,372,493	$ 10,355,768
License and royalty income	121,896	-
Research grant income	1,339,859	693,803
TOTAL REVENUES	13,834,248	11,049,571
Cost of product sales	7,973,843	7,197,850
GROSS PROFIT	5,860,405	3,851,721
OPERATING EXPENSES:		
Research and development expenses	2,883,696	2,605,343
Selling, general and administrative expenses	2,659,382	3,317,046
	5,543,078	5,922,389
INCOME (LOSS) FROM OPERATIONS	317,327	(2,070,668)
OTHER INCOME (EXPENSES):		
Other income (expense)	(6,696)	95,812
Interest income	9,032	34,403
Interest expense	(10,603)	(8,317)
	(8,267)	121,898
INCOME (LOSS) BEFORE INCOME TAXES	309,060	(1,948,770)
Provision for income taxes	-	-
NET INCOME (LOSS)	$ 309,060	$ (1,948,770)
	-	-
Basic earnings (loss) per share	$ 0.00	$ (0.03)
Diluted earnings (loss) per share	$ 0.00	$ (0.03)
Weighted average number of shares outstanding, basic	61,946,435	61,266,594
	-	-
Weighted average number of shares outstanding, diluted	75,041,932	61,266,594

See accompanying notes to consolidated financial statements

F-4

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2009 AND 2008

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount	Amount	Amount	Amount
Balance at December 31, 2007	60,537,534	$ 605,375	$ 39,003,148	$ (35,345,697)	$ 4,262,826
Warrants and options:					
Excercised	1,407,367	14,074	(14,074)	-	-
Stock option compensation	-	-	263,276	-	263,276
Net loss for 2008	-	-	-	(1,948,770)	(1,948,770)
Balance at December 31, 2008	61,944,901	619,449	39,252,350	(37,294,467)	2,577,332
Warrants and options:					
Excercised	35,000	350	4,200	-	4,550
Stock option compensation	-	-	196,972	-	196,972
Net income for 2009	-	-	-	309,060	309,060
Balance at December 31, 2009	61,979,901	$ 619,799	$ 39,453,522	$ (36,985,407)	$ 3,087,914

See accompanying notes to consolidated financial statements

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

	December 31, 2009	December 31, 2008
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS:		
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers	$ 12,871,921	$ 11,186,608
Cash paid to suppliers and employees	(12,618,423)	(12,406,921)
Interest received	9,032	34,403
Interest paid	(10,603)	(8,317)
Net cash provided by (used in) operating activities	251,927	(1,194,227)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of fixed assets	13,750	-
Acquisition of and deposits on fixed assets	(390,738)	(397,462)
Net cash used in investing activities	(376,988)	(397,462)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from option exercises	4,550	-
Payment of loan obligation	(4,697)	-
Payment of capital lease obligation	(18,779)	(23,458)
Net cash provided by (used in) financing activities	(18,926)	(23,458)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(143,987)	(1,615,147)
Cash and cash equivalents - beginning of the period	1,212,222	2,827,369
Cash and cash equivalents - end of the period	$ 1,068,235	$ 1,212,222
RECONCILIATION OF NET LOSS TO NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES:		
Net income (loss)	$ 309,060	$ (1,948,770)

Adjustments:		
Depreciation and amortization	362,338	345,388
Provision for doubtful accounts	9,699	-
Loss on sale of fixed asset	6,696	-
Share based compensation	198,220	291,979
Changes in assets and liabilities:		
Accounts receivable	(976,723)	137,037
Inventories	263,134	(365,187)
Prepaid expenses and other assets	(42,732)	(10,108)
Deposits and other assets	238,260	(683,462)
Deferred revenue	360,833	(43,334)
Accounts payable and accrued expenses	(476,858)	207,230
Licenses fee payable	-	875,000
Net cash provided by (used in) operating activities	$ 251,927	$ (1,194,227)
Supplemental disclosures for non-cash investing and financing activities:		
Value of common stock issued upon cashless warrant exercise	$ -	$ 14,074
Purchase of fixed assets through a loan	29,228	

See accompanying notes to consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2009 AND 2008

NOTE 1—DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. (the "Company" or "Chembio") and its subsidiary, Chembio Diagnostic Systems, Inc., develop, manufacture, and market rapid diagnostic tests that detect infectious diseases. The Company's main products are three rapid tests for the detection of HIV antibodies in whole blood, serum and plasma samples, two of which were approved by the FDA in 2006; the third is sold for export only. Rapid HIV tests represented nearly 88% of the Company's product revenues in 2009. The Company also has other rapid tests that together represented approximately 12% of sales in 2009. The Company's products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments both domestically and internationally. Chembio's products are sold under the Company's STAT PAK®, SURE CHECK® or DPP® registered trademarks, or under the private labels of its marketing partners, for example the Clearview® label owned by Inverness Medical Innovations, Inc., which is the Company's exclusive marketing partner for its rapid HIV lateral flow test products in the United States. These products employ lateral flow technologies that are proprietary and/or licensed to the Company. All of the Company's products that are currently being developed are based on its patented Dual Path Platform (DPP®), which is a unique diagnostic point-of-care platform that has certain advantages over lateral flow technology. In 2008 and 2009 to date, the Company has completed development of its first four products that employ the DPP®, and the Company has a number of additional products under development that employ the DPP®.

NOTE 2—SIGNIFICANT ACCOUNTING POLICIES:

(a) Principles of Consolidation:

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

(b) Use of Estimates:

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

(c) Fair Value of Financial Instruments:

Fair values of cash and cash equivalents, accounts receivable, prepaid expenses and other current assets and accounts payable, loans and accrued expenses reflected in these financial statements approximate carrying value as these are short-term in nature.

(d) Statements of Cash Flows:

For purposes of the statements of cash flows the Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2009 AND 2008

(e) Concentrations of Credit Risk:

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of temporary cash investments and trade receivables. The Company places its temporary cash instruments with well-known financial institutions and, at times, may maintain balances in excess of the $250,000 FDIC Insurance limit. The Company monitors the credit ratings of the financial institutions to mitigate this risk. The Company maintains three accounts with a well established multi-national bank and as of December 31, 2009 had approximately an aggregate of $818,000 above the federally insured limit. Concentration of credit risk with respect to trade receivables is principally mitigated by the Company's ability to obtain letters of credit from certain foreign customers, and its diverse customer base both in number of customers and geographic locations. We currently do not require collateral.

(f) Inventories:

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

(g) Fixed Assets:

Fixed assets are stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets, which range from three to seven years. Leasehold improvements are amortized over the useful life of the asset or the lease term, whichever is shorter.

(h) License Agreement:

In February 2008, the Company entered into a sublicense agreement (see Note 6) for which it had initially recorded an asset of $1,000,000. This asset is being expensed over an estimated economic life of ten years. The current portion of this asset is $100,000 and is reported in prepaid expenses and other current assets. The long-term portion as of December 31, 2009 is $700,000 and is reflected in other assets.

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

In accordance with ASC 360, "Accounting for the Impairment or Disposal of Long-Lived Assets", long-lived assets to be held and used are analyzed for impairment whenever events or changes in circumstances indicate that the related carrying amounts may not be recoverable. The Company evaluates at each balance sheet date whether events and circumstances have occurred that indicate possible impairment. If there are indications of impairment, the Company uses future undiscounted cash flows of the related asset or asset grouping over the remaining life in measuring whether the assets are recoverable. In the event such cash flows are not expected to be sufficient to recover the recorded asset values, the assets are written down to their estimated fair value. We believe that the carrying values of our long-lived tangible and intangible assets were realizable at December 31, 2009.

(j) Revenue Recognition:

The Company recognizes revenue 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.

The Company recognizes income from R&D contracts and grants when earned. Grants are invoiced after expenses are incurred. Revenues from projects or grants funded in advance are deferred until earned.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2009 AND 2008

(k) Research and Development:

Research and development costs are expensed as incurred.

(l) Stock Based Compensation:

The Company's 2008 Stock Incentive Plan and 1999 Stock Option Plan ("Plans") are accounted for in accordance with the recognition and measurement provisions of ASC 718. ASC 718 requires compensation costs related to share-based payment transactions, including employee stock options, to be recognized in the financial statements. In addition, the Company adheres to the guidance set forth within Securities and Exchange Commission ("SEC") Staff Accounting Bulletin No. 107 ("SAB 107"), which provides the Staff's views regarding the interaction between ASC 718 and certain SEC rules and regulations and provides interpretations with respect to the valuation of share-based payments for public companies. See Note 12 for further details.

(m) Income Taxes:

The Company accounts for income taxes under the provisions of ASC 740 "Accounting for Income Taxes". Under ASC 740, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and the tax bases of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse.

ASC 740 also prescribes a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken, or expected to be taken, in a tax return. ASC 740 also provides guidance related to, among other things, classification, accounting for interest and penalties associated with tax positions, and disclosure requirements. Any interest and penalties accrued related to unrecognized tax benefits will be recorded in tax expense.

(n) Earnings Per Share

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

	December 31, 2009	December 31, 2008
Basic	61,946,435	61,266,594
Diluted	75,041,932	61,266,594

Basic loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted earnings per share for the year ended December 31, 2009 reflects the potential dilution from the exercise or conversion of other securities into common stock. Diluted loss per share for the year ended December 31, 2008 is the same as basic loss per share, since the effects of the calculation were anti-dilutive due to the fact that the Company incurred losses for that period. The following securities, presented on a common share equivalent basis, have been excluded from the per share computations:

	For the years ended	
	December 31, 2009	December 31, 2008

1999 and 2008 Plan Stock Options	4,451,129	2,555,837
Other Stock Options	124,625	124,625
Warrants	8,519,743	14,657,050
	13,095,497	17,337,512

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2009 AND 2008

(o) Recent Accounting Pronouncements Affecting the Company:

Codification

In July 2009, the Financial Accounting Standards Board's (FASB) Accounting Standards Codification (ASC) became the single official source of authoritative, nongovernmental generally accepted accounting principles ("US-GAAP" or "GAAP") in the United States. This guidance is contained in ASC Topic 105 "Generally Accepted Accounting Principles." The historical GAAP hierarchy was eliminated and the ASC became the only level of authoritative GAAP, other than guidance issued by the Securities and Exchange Commission. This guidance is effective for interim and annual periods ending after September 15, 2009. The Company adopted the provisions of this guidance as of September 30, 2009. The Company's accounting policies were not affected by the conversion to the ASC. However, references to specific accounting standards have been changed to refer to the appropriate section of the ASC.

Fair Value Measurements

In September 2006, the FASB issued guidance that defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. This guidance is contained in ASC Topic 820 "Fair Value Measurements and Disclosures." This guidance does not require any new fair value measurements, but applies under other accounting pronouncements that require or permit fair value measurements. The effective date of this guidance for financial assets and liabilities that are recognized or disclosed at fair value on a recurring basis was January 1, 2008, and the Company did adopt the provisions of this guidance at that time as it related to financial assets and liabilities recognized or disclosed at fair value on a recurring basis. Effective January 1, 2009, pursuant to this guidance, the Company adopted the provisions of this guidance as it relates to non financial assets and liabilities that are not recognized or disclosed at fair value on a recurring basis. The adoption of this guidance had no impact on the Company's financial statements.

In April 2009, the FASB issued guidance that extends the disclosure requirements regarding the fair value of financial instruments to interim financial statements of publicly traded companies. This guidance is primarily contained in ASC Topic 825 "Financial Instruments" and ASC Topic 270 "Interim Reporting." This guidance is effective for interim periods ending after June 15, 2009. The adoption of this guidance had no impact on the Company's financial statements.

Collaborative Arrangements

In December 2007, the FASB issued guidance to participants in a collaborative arrangement which is contained in ASC Topic 808. A collaborative arrangement is a contractual arrangement that involves a joint operating activity. These arrangements involve two (or more) parties who are both (a) active participants in the activity and (b) exposed to significant risks and rewards dependent on the commercial success of the activity. Many collaborative arrangements involve licenses of intellectual property, and the participants may exchange consideration related to the license at the inception of the arrangement. Participants in a collaborative arrangement shall report costs incurred and revenue generated from transactions with third parties (that is, parties that do not participate in the arrangement) in each entity's respective income statement pursuant to such guidance. An entity should not apply the equity method of accounting to activities of collaborative arrangements. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. The adoption of this guidance had no material impact on the Company's financial statements.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2009 AND 2008

Business Combinations

On January 1, 2009, we adopted the accounting pronouncements relating to business combinations (primarily contained in ASC Topic 805 “Business Combinations”), including assets acquired and liabilities assumed arising from contingencies. These pronouncements established principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree as well as provides guidance for recognizing and measuring the goodwill acquired in the business combination and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. In addition, these pronouncements eliminate the distinction between contractual and non-contractual contingencies, including the initial recognition and measurement criteria and require an acquirer to develop a systematic and rational basis for subsequently measuring and accounting for acquired contingencies depending on their nature. Our adoption of these pronouncements will have an impact on the manner in which we account for any future acquisitions.

Non-Controlling Interests in Consolidated Financial Statements

On January 1, 2009, we adopted the accounting pronouncement on non-controlling interests in consolidated financial statements, which establishes accounting and reporting standards for the non-controlling interest in a subsidiary and for the deconsolidation of a subsidiary. This guidance is primarily contained in ASC Topic 810 “Consolidation”. It clarifies that a non-controlling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. The adoption of this standard has not had a material impact on our consolidated financial statements.

Subsequent Events

In May 2009, the FASB issued guidance that is intended to establish general standards of accounting for and disclosure of events that occur after the balance sheet date but before the financial statements are issued or are available to be issued. This guidance is contained in ASC Topic 855 “Subsequent Events.” It requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for that date. This guidance is effective for interim and annual periods ending after June 15, 2009. The Company adopted the provisions of this guidance as of June 30, 2009.

In June 2009, an update was made to “Consolidation – Consolidation of Variable Interest Entities.” Among other things, the update replaces the calculation for determining which entities, if any, have a controlling financial interest in a variable interest entity (VIE) from a quantitative based risks and rewards calculation, to a qualitative approach that focuses on identifying which entities have the power to direct the activities that most significantly impact the VIE’s economic performance and the obligation to absorb losses of the VIE or the right to receive benefits from the VIE. The update also requires ongoing assessments as to whether an entity is the primary beneficiary of a VIE (previously, reconsideration was only required upon the occurrence of specific events), modifies the presentation of consolidated VIE assets and liabilities, and requires additional disclosures about a Company’s involvement in VIEs. This update will be effective for the Company beginning January 1, 2010. The Company is evaluating the impact that this guidance will have on its financial statements, if any.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2009 AND 2008

NOTE 3—INVENTORIES:

Inventories consist of the following at December 31:

	December 31, 2009	December 31, 2008
Raw materials	$ 1,031,567	$ 836,446
Work in process	184,081	300,986
Finished goods	340,255	681,605
	$ 1,555,903	$ 1,819,037

NOTE 4—FIXED ASSETS:

Fixed assets consist of the following at December 31:

	2009	2008
Machinery and equipment	$ 1,222,216	$ 1,195,975
Furniture and fixtures	212,106	195,611
Computer and telephone equipment	329,491	329,865
Leasehold improvements	400,589	400,589
Automobiles	29,228	29,442
	2,203,630	2,151,482
Less accumulated depreciation and amortization	(1,623,417)	(1,270,076)
	$ 580,213	$ 881,406

Included in fixed assets is $70,500 and $70,500, net of accumulated depreciation of $62,600 and $40,000 of assets held under capital leases as of December 31, 2009 and 2008, respectively. Depreciation expense for the 2009 and 2008 years aggregated $362,338 and $345,388, respectively.

NOTE 5—ACCOUNTS PAYABLE AND ACCRUED LIABILITIES:

Accounts payable and accrued liabilities at December 31:

	December 31, 2009	December 31, 2008
Accounts payable – suppliers	$ 662,739	$ 634,083
Accrued royalties / license fees	612,709	1,400,941
Accrued payroll	114,234	95,135
Accrued vacation	99,057	91,895
Accrued bonuses	238,600	-
Accrued expenses – other	178,824	160,967
TOTAL	$ 1,906,163	$ 2,383,021

NOTE 6—DEFERRED RESEARCH AND DEVELOPMENT REVENUE:

In January 2009, the Company received a refundable license fee of $340,000 from Bio-Rad Laboratories, Inc., pursuant to an exclusive license of our DPP® technology for a specific field of use. The license fee will become fully earned and non-refundable based upon certain future conditions being met and is currently classified as deferred revenue. In addition, the Company recognizes income from R&D contracts and grants when earned. Grants are invoiced after expenses are incurred. Any projects or grants funded in advance are deferred until earned. As of December 31, 2009, an aggregate of $360,833 of advanced revenues was unearned.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2009 AND 2008

NOTE 7—VEHICLE FINANCING AND LICENSE FEE PAYABLE:

In June 2009, the Company purchased a vehicle for use by the CEO and obtained financing in the amount of $29,228. The financing is for a period of 3 years, is secured by the vehicle and is guaranteed by the CEO. The financing agreement provides for monthly principal and interest payments of $849 and carries an interest rate of 2.9% per annum. The balance due on this loan as of December 31, 2009 was $24,531.

Future minimum payments under this obligation, including interest as of December 31, 2009 were as follows:

Year ending December 31,

2010	$9,600
2011	9,882
2012	5,049
	24,531
Less: current maturities	(9,600)
	$14,931

In February 2008, the Company entered into a sublicense agreement (the “Agreement”), with Bio-Rad Laboratories, Inc. and Bio-Rad Pasteur (collectively, “Bio-Rad”). Bio-Rad is the exclusive licensee of the HIV-2 patent portfolio held by Institute Pasteur of Paris, France. Pursuant to the terms of the Agreement, Bio-Rad sublicensed to the Company patents related to the manufacture, use or sale of screening assays that detect HIV-2. In exchange for global non-exclusive rights to these patents, the Agreement initially provided that the Company will pay Bio-Rad a $1,000,000 sublicense fee, $500,000 payable during 2008, of which $125,000 was paid and $375,000 was payable by December 31, 2008, with the remaining $500,000 being payable by December 31, 2009. On January 29, 2009, the Company and Bio-Rad agreed to amend the Agreement so as to defer the remaining $875,000 of payments due under the Agreement to one payment due in December 2010. The Company will also pay Bio-Rad a royalty on net sales in the United States and Canada, if any, of rapid test immunoassay tests sold under the Company’s brands of Licensed Products as defined in the Agreement. The Agreement will continue until the expiration of the last-to-expire of the sublicensed patents, unless otherwise terminated at an earlier date by the Company or Bio-Rad.

NOTE 8—OBLIGATIONS UNDER CAPITAL LEASES:

The Company is obligated under capitalized leases for certain manufacturing and computer equipment.

Future minimum lease payments under these capitalized lease obligations, including interest as of December 31, 2009 were as follows:

Year ending December 31,

2010	$28,572
2011	28,572
2012	15,204
	72,348
Less: imputed interest	(11,539)

Present value of future minimum lease payments	60,809
Less: current maturities	(21,536)
	$39,273

These leases have annual interest rates ranging from 13% - 15%.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2009 AND 2008

NOTE 9—RELATED PARTIES:

In September of 2006, the Company entered into distribution and licensing agreements with Inverness Medical Innovations, Inc. ("Inverness"). As of December 31, 2009 Inverness owned 8.7% of the Company. See Note 14 where Inverness is listed as customer 1.

During the quarter ended December 31, 2008, Inverness Medical Innovations, Inc. ("Inverness") notified the Company that Inverness had entered into a contract with Bio-Rad Laboratories, Inc. ("Bio-Rad") for royalties on Bio-Rad's patent for the detection of HIV-2 antibodies. The agreement also provided for Inverness to pay past royalties. On June 25, 2009, the Company and Inverness entered into a letter agreement whereby certain obligations aggregating approximately $1,010,000 as of December 31, 2008 (included in accounts payable and accrued expenses – see Note 5) were agreed to be paid from future revenues. The obligations include the Company's royalties owed under its agreements with Inverness on lateral flow licenses . The approximate aggregate balance due is $242,000 as of December 31, 2009 and is included in accounts payable and accrued expenses – see Note 5.

NOTE 10—INCOME TAXES:

No provision for Federal or state income taxes was required for the years ended December 31, 2009 or 2008, due to the Company's utilization of net operating loss carryfoward in 2009 and its operating loss in 2008. State and local minimum taxes are included in selling, general and administrative expenses.

At December 31, 2009, the Company has unused net operating loss carry-forwards of approximately $21,500,000 which expire between 2012 and 2029. Most of this amount may be subject to annual limitations under certain provisions of the Internal Revenue Code related to "changes in ownership". In addition the Company has a research and development credit carryforward of approximately $628,000 for the year ended December 31, 2009 which expire between 2012 and 2029.

As of December 31, 2009 and 2008, the deferred tax assets related to the aforementioned net operating loss carry-forwards have been fully offset by a valuation allowance, since significant utilization of such amounts is not presently expected in the foreseeable future.

Deferred tax assets and valuation allowances consist of:

	2009	2008
Current assets		
Inventory	$ 124,000	$ 169,000
Less valuation allowance	(124,000)	(169,000)
Net current deferred asset	$ —	$ —
Noncurrent assets		
Net operating loss carry-forwards	$ 7,490,000	$ 7,750,000
Research and development credit	628,000	505,000
Other	176,000	174,000
Gross deferred tax assets	8,294,000	8,429,000
Less valuation allowances	(8,294,000)	(8,429,000)
Net deferred tax assets	$ —	$ —

The change in the valuation allowances between 2009 and 2008 are mainly due to the utilization of net operating loss carryfowards.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2009 AND 2008

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

	Year Ending December 31,			
	2009		2008	
Federal income tax (benefit) at statutory rates	34.0	%	(34.0	)%
State income taxes, net of federal benefit	-	%	-	%
Nondeductible expenses	17.8	%	3.3	%
Change in valuation allowance	(52.3	) %	31.2	%
Other	.5	%	(.5	) %
Income tax (benefit)	-	%	-	%

The Company adopted the provisions of ASC 740 in January 1, 2007. The cumulative effect of adopting ASC 740 did not have a material impact on the Company's financial position or results of operations.

Interest and penalties, if any, related to income tax liabilities are included in income tax expense. As of December 31, 2009, the Company does not have a liability for unrecognized tax benefits.

The Company files Federal and New York state income tax returns. Tax years for fiscal 2006 through 2008 are open and potentially subject to examination by the federal and New York state taxing authorities.

NOTE 11—STOCKHOLDERS' EQUITY:

(a) Common Stock

During the December 31, 2009 quarter, options to purchase 35,000 shares of the Company's common stock were exercised at an exercise price of $.13.

During the June 30, 2008 quarter, warrants to purchase 9,323,854 shares of the Company's common stock were exercised on a cashless basis, resulting in the issuance of 1,407,367 shares of common stock. These warrants were exercised on a cashless basis in connection with the Company's preferred stock and warrant amendments that were completed on December 19, 2007 ("Plan"), and the Company received no cash consideration for these issuances of common stock.

On December 19, 2007 (the "Closing Date"), amendments to the governing documents for the Company's Series A, Series B and Series C Convertible Preferred Stock (collectively, the "Preferred Stock") and for certain warrants and options (collectively, the "Non-Employee Warrants"), not including options or warrants issued to employees or directors in their capacity as such (these actions collectively, the "Plan"), were approved by the Company and the requisite percentages of the holders of the Preferred Stock and of the Non-Employee Warrants. Subsequent to these amendments, among other matters, all the Preferred Stock and certain of the Non-Employee Warrants were converted to shares of the Company's common stock.

(b) Preferred Stock

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

state of Nevada.

(c) Warrants

During 2009 certain warrants to purchase an aggregated 2,489,120 shares of common stock expired, at an average exercise price of $.764.

In January, 2010 certain warrants to purchase an aggregated 4,960,370 shares of common stock expired, at an average exercise price of $.474

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2009 AND 2008

NOTE 12—EMPLOYEE STOCK OPTION PLAN:

The Company has a 1999 Stock Option Plan ("SOP") originally covering 1,500,000 shares of Common Stock. Under the terms of the SOP, the Compensation Committee of the Company's board is authorized to grant incentive options to key employees and to grant non-qualified options to key employees and key individuals. The options become exercisable at such times and under such conditions as determined by the Compensation Committee. The SOP was amended at the Company's 2005 stockholders' meeting. The number of options under the SOP was increased to cover 3,000,000 shares of common stock. It was also amended to allow independent directors to be eligible for grants under the portion of the SOP concerning non-qualified options.

Effective June 3, 2008, the Company's stockholders voted to approve the 2008 Stock Incentive Plan ("SIP"). Under the terms of the SIP, the Compensation Committee of the Company's board shall have the discretion to select the persons to whom Awards are to be granted. Awards can be incentive stock options, restricted stock and/or restricted stock units. The Awards become vested at such times and under such conditions as determined by the Compensation Committee.

As a result of the adoption of ASC 718, the Company's results for the years ended December 31, 2009 and 2008 include share-based compensation expense totaling $198,000 and $292,000, respectively. Such amounts have been included in the Consolidated Statements of Operations within cost of goods sold ($25,000 and $19,000, respectively), research and development ($75,000 and $56,000, respectively) and selling, general and administrative expenses ($98,000 and $217,000, respectively). No income tax benefit has been recognized in the income statement for share-based compensation arrangements due to the history of operating losses.

Stock option compensation expense in the years ended December 31, 2009 and 2008 represent the estimated fair value of options outstanding which is being amortized on a straight-line basis over the requisite vesting period of the entire award.

The weighted average estimated fair value of stock options granted in the years ended December 31, 2009 and 2008 was $.13 and $.37 per share, respectively. The fair value of options at the date of grant was estimated using the Black-Scholes option pricing model. The expected volatility is based upon historical volatility of our stock and other contributing factors. The expected term is determined using the simplified method as permitted by SAB 107, as the Company has no history of employee exercise of options to date.

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

	For the years ended	
	December 31, 2009	December 31, 2008
Expected term (in years)	1 to 4	1 to 4
Expected volatility	123.81 %	109.33-112.33%
Expected dividend yield	n/a	n/a
Risk-free interest rate	.54% to 1.95%	1.91 to 2.98%

The Company granted 3,675,000 new options under the plans during the year ended December 31, 2009 at an exercise price of $.13 per share (750,000 were issued under the SOP and 2,925,000 were issued under the SIP).

On May 7, 2009, the Compensation Committee of the Company reduced, to $0.13 per share, the exercise price of each outstanding employee option that was issued under the 1999 Equity Incentive Plan (the "1999 Plan") for which the

exercise price was greater than $0.44 per share of the Company's common stock. There was no other change made to the terms of the stock options other than the reduction in the exercise price. A total of 1,036,750 options were affected and the fair value difference of the options before and after the reduction was $31,660 and was expensed in the three months ended June 30, 2009.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2009 AND 2008

In addition, on May 7, 2009 in accordance with the terms of the Company's 2008 Stock Incentive Plan, the Company granted certain employees of the Company, options to purchase an aggregate of 2,925,000 shares of the Company's common stock. The exercise price for these options is equal to $0.13 per share. The options become exercisable in thirds on the first, second and third anniversaries of the date of the grant. Each option granted will expire and terminate, if not exercised sooner, upon the earlier to occur of (a) 30 days after termination of the employee's employment with the Company or (b) the fifth anniversary of the date of grant. The fair value of these options is being amortized over the vesting life of the options.

On May 7, 2009, the Board of Directors of the Company revised the compensation of non-employee directors to increase the number of options to purchase the Company's common stock issued to directors once every five years from 180,000 to 375,000. To accommodate the transition, on June 3, 2009 at the annual meeting, non-employee directors that were re-elected were issued their five-year allotment of options and those options previously granted but not exercisable as of June 3, 2009 were cancelled. The number issued was 750,000 and the number cancelled was 216,000. The 216,000 options were treated as a re-price for accounting purposes. The fair value of these options granted is being amortized over the vesting life of the options.

The following table provides stock options activity for the years ended December 31, 2009 and 2008:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2008	2,201,500	$ 0.64	3.52 years	$ -
Impact of re-price (for accounting purposes treated as a cancellation and re-issue):				
effect as if cancelled	(1,846,500)	$ 0.64		
effect as if re-issiued	1,846,500	$ 0.48		
Granted	967,650	$ 0.18		
Exercised	-	-		
Forfeited/expired /cancelled	(752,500)	$ 0.58		
Outstanding at December 31, 2008	2,416,650	$ 0.36	3.23 years	$ -
Impact of re-price (for accounting purposes treated as a cancellation and re-issue):				
effect as if cancelled	(1,252,750)	$ 0.48		
effect as if re-issiued	1,252,750	$ 0.13		
Granted	3,459,000	$ 0.13		
Exercised	(35,000)	$ 0.13		
Forfeited/expired/cancelled	(253,750)	$ 0.17		
Outstanding at December 31, 2009	5,586,900	$ 0.15	3.59 years	$ 756,990
Exercisable at December 31, 2009	2,061,900	$ 0.19	2.27 years	$ 234,240

The following table summarizes information about stock options outstanding at December 31, 2009:

	Stock Options Outstanding				Stock Options Exercisable		
Range of Exercise Prices	Shares	Average Remaining Contract Life (Year)	Weighted Average Exercise Price	Aggregate Intrinsic Value	Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 0.13 - .13	4,930,400	3.72	$ 0.130	$ 739,560	1,405,400	$ 0.130	$ 210,810
$ 0.14 - .22	415,500	3.13	$ 0.220	24,930	415,500	$ 0.220	24,930
$ 0.23 - .45	15,000	0.96	$ 0.350	-	15,000	$ 0.350	-
$ 0.46 - .88	226,000	1.84	$ 0.498	-	226,000	$ 0.498	-
Total	5,586,900	3.59	$ 0.152	$ 764,490	2,061,900	$ 0.190	$ 235,740

As of December 31, 2009, there was $208,000 of net unrecognized compensation cost related to stock options that are not vested, which is expected to be recognized over a weighted average period of approximately 1.58 years. The total fair value of shares vested during the years ended December 31, 2009 and 2008, was $60,000 and $273,000, respectively.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2009 AND 2008

NOTE 13—GEOGRAPHIC INFORMATION:

ASC 280, "Disclosures about Segments of an Enterprise and Related Information" establishes standards for the way that business enterprises report information about operating segments in financial statements and requires that those enterprises report selected information. It also establishes standards for related disclosures about product and services, geographic areas, and major customers.

The Company produces only one group of similar products known collectively as "rapid medical tests". As per the provisions of ASC 280, management believes that it operates in a single business segment. Net sales by geographic area are as follows:

	For the years ended	
	December 31, 2009	December 31, 2008
Africa	$ 3,351,115	$ 4,740,858
Asia	165,293	227,049
Europe	111,755	160,824
Middle East	185,700	308,053
North America	6,129,789	2,415,344
South America	2,428,841	2,503,640
	$ 12,372,493	$ 10,355,768

Sales to Africa in 2009 were primarily to Ethiopia of approximately $1,700.000 and Nigeria of approximately $608,000. Sales in 2009 to North America were primarily from sales in the U.S of approximately $5,200,000 and sales in 2009 to South America were primarily from sales in Brazil of approximately $2,300,000.

During the first quarter of 2008, the Nigerian Ministry of Health published a report indicating that our designation in Nigeria as one of the screening tests in a parallel testing algorithm (wherein each patient is tested with two rapid tests from different manufacturers) to a confirmatory and/or tie-breaker test in a serial algorithm in which only positive results are confirmed with a confirmatory test, and only discrepant results between those are tested with a confirmatory test. Consequently, our sales to Nigeria decreased significantly in 2009 as compared to 2008.

NOTE 14—COMMITMENTS AND CONTINGENCIES:

Employment Contracts:

The Company has contracts with two key employees. The contracts call for salaries presently aggregating $510,000 per year. One contract expires in May 2012 and one contract expires in March 2013. The following table is a schedule of future minimum salary commitments:

2010	$508,300
2011	518,300
2012	373,750
2013	44,200
	$1,444,550

Pension Plan:

The Company has a 401(k) plan established for its employees. The Company elected to match 20% of the first 5% (or 1% of salary) that an employee contributes to their 401(k) plan. Expenses related to this matching contribution aggregated $1,534 and $23,850 for the years ended December 31, 2009 and 2008, respectively.

As of January 19, 2009, the Company suspended the matching contribution.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2009 AND 2008

Agreement with Adaltis

In October 2009, the Company entered into a letter agreement ("Agreement") with the Trustee of Adaltis, Inc, a Canadian company that filed for bankruptcy in Canada in August 2009. Pursuant to a License and Supply Agreement ("L&S Agreement") dated August 30, 2002 by and between Chembio Diagnostic Systems Inc. and Adaltis Inc., Adaltis licensed and supplied certain HIV 1&2 peptides that the Company used in certain HIV tests manufactured and sold by the Company. Under the terms of the Agreement, the Company purchased for a lump-sum amount a paid-up license to the patents through their expiration dates, thereby cancelling its obligation to pay any additional liabilities under the L&S Agreement. The Company also acquired the right to purchase the peptides from any supplier chosen by Chembio, including but not limited to the current supplier that previously supplied the Company through Adaltis pursuant to the L&S Agreement with Adaltis. The Agreement further provides for a full mutual release of all claims, including any and all obligations under the L&S Agreement.

Obligations Under Operating Leases:

The Company leases approximately 23,400 square feet of industrial space used for office, R&D and manufacturing facilities, currently with a monthly rent of $14,683. The current lease expires on April 30, 2014. We entered into a second lease effective February 1, 2010, the principal terms of this lease are the same as the one entered into in 2009 and are as follows: (a) a lease term ending April 30, 2014; (b) an initial rent of $11,350 per month plus $3,333 for the second lease (March and April of 2010 are free and the month of April in 2011, 2012 and 2013 is also free) ; (c) the monthly rent for year two of the lease (does not apply to second 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 (years two through four of the second lease) will increase each year by the lower of (i) the change in the consumer price index, or (ii) two and one half percent. The following is a schedule of future minimum rental commitments (assuming no increases):

Year ending December 31,

2010	$166,197
2011	172,863
2012	172,863
2013	172,863
2014	55,399
	$740,185

Rent expense was $145,300 and $130,300 for the years ended December 31, 2009 and 2008, respectively.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2009 AND 2008

Economic Dependency:

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

	For the years ended				Accounts Receivable
	December 31, 2009		December 31, 2008		As of
	Sales	% of Sales	Sales	% of Sales	December 31, 2009
Customer 1	$ 5,240,996	42	$ 2,111,151	26	$ 609,605
Customer 2	1,292,640	10	*	*	-
Customer 3	2,293,770	19	2,434,420	30	-
Customer 4	*	*	3,732,615	46	*

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

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

	For the years ended				Accounts Payable
	December 31, 2009		December 31, 2008		As of
	Purchases	% of Purc.	Purchases	% of Purc.	December 31, 2009
Vendor 1	$ 575,362	20	$ 627,637	21	$ -
Vendor 2	*	*	303,750	10	*

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

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

Governmental Regulation:

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

Voluntary Component Recall:

In April 2008, we initiated a voluntary recall of two lots of Control kits used with our HIV 1-2 Stat Pak® Assay distributed by Inverness under its Clearview® brand. Control kits are to be used in order to verify the operator's ability to properly perform the test and to interpret the results. These kits are supplied directly to Inverness by our vendor in accordance with our specifications and instructions. In the case of these two lots of Control kits, although they met our specifications, they were at the lower limit of such specifications, and this produced some issues with the interpretation of the Control kit results by certain customers. Chembio has provided the kit supplier with a more clearly defined specification and has reviewed copies of revised manufacturing and testing procedures to ensure implementation of the new specification. Based upon this new specification, packaged HIV Rapid Test Control Packs containing the new HIV Controls have been in distribution since May 2008. The FDA has classified this voluntary recall as a Class II recall, "a situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences are remote". Approximately $22,000 in costs were incurred in 2008. We completed all of our recall activity in 2008, including monitoring and final product disposition and in 2008 the FDA issued a letter to the Company confirming that this investigation is officially closed.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2009 AND 2008

Equipment Purchase Commitment:

In January of 2009, the Company entered into an agreement with an equipment manufacturer to design and build equipment that will be used to automate the assembling of our tests and lower our production costs. The estimated cost of $323,500 is being paid in installments. In addition in June and November of 2009, the Company entered into an agreement with a tooling manufacturer to design and build a tool for cassettes that house, its DPP® tests. The estimated cost of $113,800 is being paid in installments. As of December 31, 2009, an aggregate of $338,375 has been paid for these two items and is included in deposits and other assets on the Company's balance sheet.

R&D contracts & grants:

In 2009 and 2008, the Company earned $1,340,000 and $694,000, respectively from research grants, feasibility and development contracts. The Company is now involved in additional feasibility and development contracts related to its DPP® technology. The total expended on R&D in 2009 and 2008, not including regulatory, was approximately $2,400,000 and $2,100,000, respectively.

a. NIH Grant:

In June 2009, the Company received a $3 million, three-year grant from the United States National Institutes of Health to complete development of a test for Leptospirosis. Grants are invoiced after expenses are incurred. In addition the Company has several development contracts with third parties related to its DPP® technology. These development projects are funded in advance and are presented as deferred revenue until earned.

b. Brazil:

On January 29, 2008 we signed three new technology transfer, supply and license agreements with the Bio-Manguinhos unit of the Oswaldo Cruz Foundation of Brazil ("FIOCRUZ") for products we have developed or are have nearly completed development of.

On October 2, 2008 the Company signed a fourth technology transfer supply and license agreement with FIOCRUZ for it's DPP® HIV 1/2 rapid test (for use with oral fluid or whole blood samples).

c. Bio-Rad:

On April 16, 2008 we announced a new development agreement with Bio-Rad Laboratories, N.A. ("Bio-Rad"). The agreement with Bio-Rad is for the development of a new multiplex product that would be developed on DPP® and which would be marketed exclusively by Bio-Rad under an exclusive limited DPP® license from Chembio to Bio-Rad limited to the field of application of this product. Our agreement with Bio-Rad contemplated that we were to enter into a license agreement no later than December 2008 subject to the satisfaction of certain development and other conditions. On January 19, 2009 Chembio granted, effective December 31, 2008, a limited exclusive license within a defined field of application for Chembio's Dual Path Platform technology to Bio-Rad Laboratories, Inc. ("Bio-Rad"). The license was granted following development milestones as set forth in the agreement mentioned above. As part of this agreement, in 2009, Chembio received $340,000 from Bio-Rad as a license fee.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2009 AND 2008

d. Battelle/CDC DPP® Influenza Immunity Test:

In December 2009, Chembio entered into a milestone-based development agreement for up to approximately $900,000 in connection with the development and initial supply of a multiplex, rapid point-of-care ("POC") influenza immunity test. The agreement contemplates a period of approximately nine months in which the development activity is to be completed. Chembio entered this agreement with Battelle Memorial Institute which has a master contract with the United States Centers for Disease Control and Prevention ("CDC") to enter into, implement and provide technical oversight of agreements relating to pandemic preparedness on behalf of CDC.

NOTE 15—SUBSEQUENT EVENTS:

In January 2010, after the balance sheet date, certain warrants to purchase an aggregated 4,960,370 shares of common stock expired, at an average exercise price of $.474. These warrants were related to the initial 2005 Series B Preferred stock Offering (see Form 8-K filed on January 31, 2005 with the SEC for further details on this offering).

Subsequent to the balance sheet date the Company entered into a lease effective February 2010 for additional warehouse space, see Item 2 of our 2009 10-K for more information.

In February 2010, after the balance sheet date, the Company took possession of the automated assembly equipment (mentioned in MD&A under Equipment Purchase Commitment and Note 15). This equipment is expected to provide for faster throughput and thereby increasing capacity of our manufacturing facility, in addition to reducing labor costs. The machine will need to go through a validation process and is expected to be in serviced during the second quarter of 2010.

Subsequent to the balance sheet date 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. Please see Item 11 of this Form 10-K for further details.