CHEMBIO DIAGNOSTICS, INC.
Form 10-K
March 03, 2011

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, 2010

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 X

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 1, 2011, the registrant had 62,240,483 common shares outstanding.

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

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PART I

ITEM 1. BUSINESS

FORWARD-LOOKING STATEMENTS

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

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

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

General

The Company (Chembio Diagnostics, Inc. and its wholly-owned subsidiary Chembio Diagnostic Systems, Inc. are collectively referred to herein as the "Company") develops, manufactures, markets and licenses rapid point-of-care diagnostic tests (POCTs) that detect infectious diseases. The Company's main products presently commercially available are four rapid tests for the detection of HIV antibodies. Three of these products employ in-licensed and proprietary lateral flow technologies (see "Our Rapid Test Technologies"), can be used with all blood matrices as samples, and are manufactured in a standard cassette format, a dipstick format, and a proprietary barrel format. The tests employing the cassette and proprietary barrel formats were approved by the FDA in 2006 and are distributed by Alere, Inc., formerly Inverness Medical Innovations, Inc. ("Alere"), in the United States. Our fourth rapid HIV test, which we more recently developed on our patented Dual Path Platform (DPP®) and does not require in-licensing, detects antibodies to HIV in oral fluid samples as well as in all blood matrices. We anticipate launching this product under Chembio's brand in 2012.

Our new product pipeline is based on this DPP® technology for which we were issued a United States patent in 2007 and for which additional patent protection has issued or is pending worldwide. With the DPP® proprietary platform, we can participate in the point-of-care market segment of the nearly $40 billion global in-vitro diagnostic market that is estimated to be $6-8 billion with an overall growth rate of 7% per annum. POCTs, by providing prompt and early diagnosis, can reduce patient stays, lower overall costs, improve therapeutic interventions and improve patient

outcomes as a result of prompt and early diagnosis. They can also prevent needless hospital admissions, simplify testing procedures, avoid delays from central lab batching, and eliminate the need for return visits.

In the areas of infectious and sexually transmitted diseases (such as 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. We have focused our product development activity within these areas as they tend to have the higher growth rates within the point-of-care segment.

PRODUCTS

Lateral Flow Rapid HIV Tests

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

Both of the above-described products are marketed exclusively in the United States by Alere as Clearview Complete HIV 1/2 (the barrel format) and Clearview HIV 1/2 STAT PAK® (the cassette format), and by Chembio in all other markets as Chembio Sure Check® HIV 1/2 and Chembio HIV 1/2 STAT PAK®. Alere has non-exclusive rights to the barrel product outside the United States.

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

Regulatory Status: The FDA approved our Pre-Market Applications (hereinafter "PMA"; see "Governmental Regulations" and Glossary) in April 2006 for our SURE CHECK HIV 1/2 (and also now Alere' Clearview® Complete HIV 1/2) and for our HIV 1/2 STAT-PAK (now Alere' Clearview® HIV 1/2 STAT-PAK in the United States only) products. A Clinical Laboratory Improvement Act (hereinafter "CLIA"; see Governmental Regulations) waiver was granted by the FDA for the HIV 1/2 STAT-PAK in November 2006 and for the two Alere Clearview® brands in October 2007. Our HIV 1/2 STAT-PAK Dipstick, though not FDA-approved, qualifies under FDA export regulations to sell, subject to any required approval by the importing country, to customers outside the United States.

All three of our lateral flow HIV tests have qualified for procurement under the President's Emergency Plan for AIDS Relief ("PEPFAR"). The STAT PAK (both the cassette and dipstick versions) are also qualified for the second largest global program, known as the Global Fund (see Glossary), through qualification with the WHO bulk procurement scheme.

DPP® HIV Test

We have completed development of and are now commercializing our DPP® HIV 1&2 Assay. As in the case of our lateral flow HIV tests, the DPP® HIV test is also a qualitative "yes/no" test for the detection of antibodies to HIV 1 & 2, delivers visual results within approximately 15 minutes, is simple to use, has a shelf life of 24 months, and does not require refrigeration. However this product, which is our first product incorporating our patented DPP® technology, can be used with oral fluid samples, as well as all blood matrices. This product also incorporates our patent-pending oral fluid collection and storage system that enables samples to be fully extracted in buffer solution before application to the test device, and also enables the extracted sample to be stored and retested or tested for multiple conditions. Most importantly, clinical and laboratory studies conducted over the last couple of years have shown this product to have improved performance compared with all of the current FDA-approved CLIA-waived rapid tests, even including our own.

Regulatory Status: In the first half of 2010 we commenced clinical studies with this product in the United States pursuant to an investigational device exemption and in support of an anticipated Pre-Marketing Approval application to the FDA. During the first quarter of 2011 we submitted the first module of such PMA application, and we anticipate submitting the final module later this year. We believe that approval of our PMA application will be within approximately six months after we submit the final module. Thereupon we would apply for CLIA waiver of this product.

The Company conducted laboratory and field studies with this product in 2007-2009 prior to our commencing the clinical trials in the United States. One of the international clinical studies was conducted by the United States Centers for Disease Control, Global AIDS Program in Mozambique ("CDC GAP"). CDC GAP is responsible for evaluating products seeking to participate in PEPFAR, and CDC GAP had already performed its standard laboratory study in 2009 that resulted in the approval for the use of the product in the U.S. government's international AIDS relief program known as PEPFAR (see Glossary) with blood matrices; the Mozambique study facilitated approval of this product for procurements by PEPFAR for use with oral fluid samples. The other study was sponsored by Chembio and was conducted at the National Hospital in Abuja Nigeria. In both of these studies the DPP® product's

performance equaled or exceeded the sensitivity and specificity of each of the other rapid tests in the study, including the only oral fluid HIV test that is currently FDA-approved. During the first quarter of 2011 we also received additional data from the CDC that further supports the previously reported performance. In order to capitalize on the PEPFAR and WHO approvals, this product still has to be registered and approved for export to a PEPFAR or Global Fund beneficiary country, and to also be one of the tests selected by such country for incorporation in such country's national testing protocol. This is a process we are undertaking in selected markets.

In June 2010 ANVISA (see Glossary) approved the DPP® HIV test in Brazil. We are also seeking to have this product approved by WHO pursuant to its bulk procurement scheme as such approval is necessary to pursue certain international donor-funded markets.

PARTNERS INVOLVED IN MARKETING OUR HIV PRODUCTS

On September 29, 2006 we executed marketing and license agreements with Alere. The marketing agreements (one for each of the two FDA approved products) provide Alere with a 10-year exclusive right (i.e. until September 2016) to market our rapid HIV tests in the United States under Alere's brand. The agreements provide Chembio a non-exclusive license to certain Alere lateral flow patents that may be applicable to our lateral flow products, principally including our lateral flow HIV tests we have continued to market outside the United States. Simultaneous with the execution of the agreements, we also settled litigation with StatSure Diagnostics, Inc.(SDS) that had been ongoing relating to the proprietary barrel device which is incorporated into one of our two FDA-approved rapid HIV tests (See Lateral Flow HIV Tests above).

The agreements with Alere have allowed the Company to participate in the growth of the rapid HIV test market in the United States in an OEM (Original Equipment Manufacturer) capacity. This collaboration has been successful as it has allowed the company to invest in its product development, regulatory and manufacturing activities, and to avoid investing in a United States marketing organization.

We have appointed distributors internationally for our lateral flow HIV tests. Our largest markets for our lateral flow HIV rapid tests outside the United States are certain countries in Africa and Mexico.

Our DPP® HIV test was approved by ANVISA in June 2010. This approval was granted to our Brazilian partner, the Oswaldo Cruz Foundation ("FIOCRUZ"), pursuant to one of six technology transfer, supply and license agreements we have entered with this public health organization since 2004 (See OEM DPP® products).

OTHER LATERAL FLOW RAPID TESTS

The Company entered the rapid test market segment with lateral flow technology and for many years our revenues were almost entirely based on this technology, primarily pregnancy tests before we developed the HIV lateral flow tests. Because of the limited license we entered into with Alere to manufacture and market only certain applications of lateral flow technology, we developed our own patent-protected rapid point-of-care technology platform, DPP®, that does not require a lateral flow license, all of our other products and products under development are based on the DPP®. Revenues from products based on lateral flow technologies other than our HIV tests were 3.9% of sales in 2010, substantially all of which are primarily attributable to our niche product line relating to veterinary tuberculosis and Chagas. We developed the veterinary tuberculosis tests as a result of and development program we did pursuant to a National Institute Health grant. This grant work enabled us to have our facility approved for the manufacture of products regulated by the United States Department of Agriculture. We are pursuing new opportunities in the veterinary diagnostics field in order to leverage this capability together with our development capabilities and proprietary point-of-care platform, DPP®.

OTHER DPP® PRODUCTS

Our strategy with respect to our DPP® technology has evolved as the Company has evolved. Initially, following the issuance of our DPP® patent in the United States in 2007, our strategy entirely involved efforts in developing third party funded OEM research and development contracts and grants. This strategy enabled us to conserve our own capital resources, while at the same time acquire important know-how and experience with the platform while also developing third party references and implicit endorsements of the technology. As our capabilities to develop and manufacture DPP® products expanded, and as our financial position has improved, so have our strategic options expanded and improved. While we will continue to employ the strategy of seeking OEM development and manufacturing agreements as a way to participate in markets that we cannot and/or choose not serve (e.g., veterinary) , we believe that we can also develop our own branded line of products, and we plan to do this in the public health area. This brand will be launched with our DPP® HIV Screening Assay in the United States market in 2012, to be followed by our Syphilis test (See RECENT DEVELOPMENTS AND CHEMBIO'S PLAN OF OPERATIONS FOR THE NEXT TWELVE MONTHS).

Following is a discussion of the OEM DPP® products for which we have completed our development activity pursuant to our OEM contracts with FIOCRUZ, Bio-Rad Laboratories, and the Battelle Memorial Institute. The status of those OEM and Chembio-branded products that are still under development are described in Part II Item 7.

OEM DPP® Products
Oswaldo Cruz Foundation OEM DPP® Agreements

During 2008 we signed four agreements and in 2010 one additional agreement with the Oswaldo Cruz Foundation (FIOCRUZ) in Brazil relating to products based on our DPP® technology. FIOCRUZ is the leading public health organization in Brazil and it is affiliated with Brazil's Ministry of Health and has basic research and educational divisions as well as extensive manufacturing facilities that manufacture drugs and vaccines, as well as diagnostic products.

During 2010, two of the products under agreement with FIOCRUZ, the DPP® HIV Screening Assay and the 5-band multiplex point-of-care confirmation test for HIV 1&2, were approved by ANVISA. We believe that FIOCRUZ is seeking to have these products used in a new serial testing algorithm to be deployed by the Ministry of Health in

Brazil; an evaluation concerning this new algorithm is underway. During the fourth quarter of 2010, we shipped $537,500 of DPP® HIV Screening Assays to FIOCRUZ. Under the two agreements we have for the recently approved products, there is a potential for aggregate sales of $13.5 million. The agreements between the Company and FIOCRUZ are unique examples of technology transfer collaborations between a private sector rapid test manufacturer and a public health organization. The other products under agreement with FIOCRUZ are for DPP® products for Leishmaniasis, Leptospirosis and Syphilis. These products are still pending regulatory approval in Brazil and their status is briefly discussed in Part II Item 7.

All of the agreements with FIOCRUZ contemplate a technology transfer license to FIOCRUZ for the manufacture of the subject products over stipulated periods of time. These technology transfers, and the provision by Chembio of the information and training that is required for this to occur, are subject to Chembio receiving orders for a minimum amount of products for manufacture by Chembio; thereafter Chembio may receive royalty payments for a defined period based on product sold by FIOCRUZ to the public health programs in Brazil. During 2010 Chembio received $92,000 of royalties from FIOCRUZ pursuant to the 2004 agreement with FIOCRUZ.

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

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

Battelle/CDC DPP® Influenza Immunity Test – In December 2009 Chembio entered into a milestone-based development agreement for the development and initial supply of a multiplex, rapid point-of-care ("POC") influenza immunity test. The agreement contemplated a period of approximately nine months in which the development activity was 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. The objective of the project was 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. Development work with respect to the contract development specification is substantially completed and our contract partners are assessing the prototype product and determining potential additional funded development activity.

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

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 Markets

Rapid HIV Tests

A large percentage of individuals that are HIV positive worldwide are unaware of their status. Part of the reason for this is that even those that do get tested in public health settings will often not return or call back for their test results if samples have to be sent out to a laboratory which can take at least several days to process. However, the increased availability, greater efficacy and reduced costs for anti-retroviral treatments (ARVs) for HIV has increased the demand for testing, as the stigma associated with the disease is lessened, and the ability to resume normal activities is substantially improved, providing a positive message to those potentially infected.

There are approximately 53,000 new diagnoses of HIV infection in the United States each year, according to the CDC. In time, most of these infections progress to AIDS. The CDC estimates that approximately 1.1 million individuals in the U.S. are living with HIV, with an estimated 250,000 Americans, or more than 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 from samples that have to be sent out to a laboratory and that 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 6-7 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 today 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 are that an HIV test should be given as a routine test like any other for all patients between 13 and 64 years of age, regardless of risk, with an opt-out screening option and focused testing procedural (pre and post test counseling) guidelines. Adoption of the 2006 CDC recommendations by a number of states continues to have an increasing impact.

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

Oral fluid testing is an established alternative to blood testing for diagnostic tests, including HIV tests. It is also often patient preferred, providing a more comfortable test. In certain public health clinics, staffs choose not to handle blood specimens; thus, oral sample collection provides a viable alternative. The most well-established market for oral fluid HIV testing is the United States. There is also now an 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.

Rapid Syphilis Tests

Recent data indicate that approximately 70,000-100,000 new cases of syphilis are occurring annually in the U.S. Syphilis can be treated with antibiotics, but untreated 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 in the United States require two different tests (called non-treponemal and treponemal markers), each requiring trained personnel in laboratory settings and several days to receive back results, in order to confirm an active, previously untreated case.

Development of the POC market for syphilis testing is expected to be comparable to the development of the POC market for HIV testing, as there is a significant public health value to being able to provide results at the point-of-care. There are several ways to assess the market opportunity for this unique rapid test, although we believe the U.S. rapid test market opportunity 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.

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

Marketing Strategy

Our marketing strategy is to:

- Support, review and assess the marketing and distribution efforts of our rapid HIV tests by Alere. Alere, which is a leading marketer of point-of-care diagnostic products, has significantly expanded its distribution footprint since we signed our agreement with them, and although we believe that this will enhance opportunities for Alere to market our rapid HIV tests, the product line is a very small one for them notwithstanding the strong growth they have enjoyed with respect to our products.

- Leverage our DPP® intellectual property and regulated product development and manufacturing experience to continue creating new collaborations where Chembio can be the exclusive development and manufacturing partner supporting leading marketing organizations.

- Establish strong distribution relationships for our Chembio-branded products in the U.S and abroad and establish a direct sales and marketing organization that is focused in the public health market segment.

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 2010 and 2009, $4.1 million ($2.6 million, net of Qualified Therapeutic Discovery Project ("QTDP") grants) and $2.9 million, respectively, were spent on research and development (including regulatory activities). These expenses were in part underwritten by funding from R&D and milestones revenues of $2.8 million in 2010 and $1.3 million in 2009. 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, 2010, we employed 118 people, including 115 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") before marketing can begin. PMA's must demonstrate, among other matters, that the medical device provides a reasonable assurance of safety and effectiveness. A PMA application is typically a complex submission, including the results of non-clinical and clinical studies. Preparing a PMA application is a much more expensive, detailed and time-consuming process as compared with a 510(K) pre-market notification. The Company has approved PMAs for the two rapid HIV tests now marketed by Alere Medical as Clearview® Complete HIV 1-2 and Clearview® HIV 1-2 STAT PAK®. FDA approval of our DPP® HIV screening assay for use with oral fluid or blood samples 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 Alere Medical as Clearview® Complete HIV 1/2 and Clearview® HIV 1/2 STAT PAK®. The CLIA waiver was granted by the FDA for HIV 1/2 STAT-PAK on November 20, 2006 and for the Clearview® Complete HIV 1/2 on October 22, 2007.

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

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

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

Environmental Laws

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

Intellectual Property

Intellectual Property Strategy

Our intellectual property strategy is to: (1) build our 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.

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

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

Trademarks

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

Trade Secrets and Know-How

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

Lateral Flow Technology and Reagent Licenses

As part of our agreements in 2006 with Alere for the marketing of our HIV tests, we were granted non-exclusive licenses to certain lateral flow technology for certain products manufactured and marketed by Chembio including but not limited to our HIV tests. Although we believe our DPP® is outside of the scope of all lateral flow patents of which we are aware, we consult with patent counsel, and seek licenses and/or redesigns of products that we believe to be in the best interests of the Company and our stockholders. Because of the costs and other negative consequences of time-consuming patent litigation, we often attempt to obtain a license on reasonable terms. Nevertheless there is no assurance that the Alere lateral flow patents we have licensed will not be challenged or that other patents containing claims relevant to the Company's lateral flow or DPP® products will not be granted and that licenses to such patents, will be available on reasonable terms, if any. Alere has aggressively enforced its lateral flow intellectual property, although some of the main patents will expire within the next few years.

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

The peptides used in our rapid HIV tests 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 Adaltis' bankruptcy, during the third quarter of 2009 we bought out all of our remaining obligations under that agreement. We also have licensed the antigens used in other tests including our Syphilis, Tuberculosis, Leptospirosis 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.

Glossary

AIDS	Acquired Immunodeficiency Syndrome. AIDS is caused by the Human Immunodeficiency Virus, HIV.
ALGORITHM (parallel or serial)	For rapid HIV testing this refers both to method or protocol (in developing countries to date) for using rapid tests from different manufacturers in combination to screen and confirm patients at the point-of-care, and may also refer to the specific tests that have been selected by an agency or ministry of health to be used in this way. A parallel algorithm uses two screening tests from different manufacturers and a tie-breaker test only if there is a discrepancy between the screening tests results. A serial algorithm only uses a second confirmatory test if there is a positive result from the screening test, meaning that the number of confirmatory tests used is equal to the positivity rate in the testing venue. A tie-breaker test resolves discrepancies between the screen and the confirmatory test.
ANTIBODY	A protein which is a natural part of the human immune system produced by specialized cells to neutralize antigens, including viruses and bacteria that invade the body. Each antibody producing cell manufactures a unique antibody that is directed against, binds to and eliminates one, and only one, specific type of antigen.
ANTIGEN	Any substance which, upon entering the body, stimulates the immune system leading to the formation of antibodies. Among the more common antigens are bacteria, pollens, toxins, and viruses.
	Anti-Retroviral Treatments for AIDS
ANVISA	The National Health Surveillance Agency of Brazil
ARVs	Anti-retroviral medications developed to fight AIDS
CDC	United States Centers for Disease Control and Prevention
CLIA waiver	Clinical Laboratory Improvement Act designation that allows simple tests to be performed in point-of-care settings such as doctor's offices, walk-in clinics and emergency rooms.
DIAGNOSTIC	Pertaining to the determination of the nature or cause of a disease or condition. Also refers to reagents or procedures used in diagnosis to measure proteins in a clinical sample.
EITF	Emerging Issues Task Force
FASB	Financial Accounting Standards Board
FIOCRUZ	The Oswaldo Cruz Foundation of Brazil
FDA	United States Food and Drug Administration
FDIC	Federal Deposit Insurance Corporation
FAS	Financial Accounting Standard
IgG	IgG or Immunoglobulin are proteins found in human blood. This protein is called an "antibody" and is an important part of the body's defense against disease. When the body is attacked by harmful bacteria or viruses, antibodies help fight these invaders.
NGO	Non-Governmental Organization
OTC	Over-the-Counter
PEPFAR	The President's Emergency Plan for AIDS Relief
PMA	Pre-Marketing Approval –FDA approval classification for a medical device that is not substantially equivalent to a legally marketed device or is otherwise required by statute to have an approved application. Rapid HIV tests must have an approved PMA application before marketing of such a product can begin.
PROTOCOL	A procedure pursuant to which an immunodiagnostic test is performed on a particular specimen in order to obtain the desired reaction.

REAGENT	A chemical added to a sample under investigation in order to cause a chemical or biological reaction which will enable measurement or identification of a target substance.
RETROVIRUS	A type of virus which contains the enzyme Reverse Transcriptase and is capable of transforming infected cells to produce diseases in the host such as AIDS.
SAB	Staff Accounting Bulletin
SENSITIVITY	Refers to the ability of an assay to detect and measure small quantities of a substance of interest. The greater the sensitivity, the smaller the quantity of the substance of interest the assay can detect. Also refers to the likelihood of detecting the antigen when present.
SPECIFICITY	The ability of an assay to distinguish between similar materials. The greater the specificity, the better an assay is at identifying a substance in the presence of substances of similar makeup.
USDA	U.S Department of Agriculture
WHO	World Health Organization

ITEM 1A. RISK FACTORS

You should carefully consider each of the following risk factors and all of the other information provided in this Annual Report. The risks described below are those we currently believe may materially affect us. An investment in our Common Stock involves a high degree of risk, and should be considered only by persons who can afford the loss of their entire investment.

Risks related to our industry, business and strategy

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

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

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

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

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

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

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

The diagnostic industry is focused on the testing of biological specimens in a laboratory or at the point-of-care and is highly competitive and rapidly changing. Our principal competitors often have considerably greater financial, technical and marketing resources than we do. Several companies produce diagnostic tests that compete directly with our testing product line, including but not limited to, Orasure Technologies, Alere Medical and Trinity Biotech. As new products enter the market, our products may become obsolete or a competitor's products may be more effective or more effectively marketed and sold than ours. 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 will enhance our competitive position in HIV rapid testing and other fields. During 2010 we made significant progress toward the commercialization of this product. However we still have technical, manufacturing, regulatory and marketing challenges to meet before we will know whether we can successfully commercialize products incorporating this technology. There can be no assurance that we will overcome these challenges.

We have granted Alere exclusive rights to market our SURE CHECK® HIV 1/2 in the United States and non-exclusive rights in the rest of the world and exclusive rights to market our HIV 1/2 STAT PAK® in the U.S. only. Alere has no rapid HIV tests that are approved for marketing in the U.S., we are not aware of any rapid HIV products that Alere is even contemplating for the U.S., and Alere is obligated to inform us of any such products as soon as it is able to do so. Alere 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 Alere products, and we specifically acknowledge in our agreements with Alere the existence of such other products. Moreover, except for a product in the HIV barrel field as defined in our agreement with Alere, Alere 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 Alere or change the agreement to a non-exclusive agreement, and Alere 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 Alere 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, Alere 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 Alere 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.

We plan to introduce our DPP® oral fluid HIV test, which test also can be used with blood samples, in the U.S. market under a Chembio brand once it is FDA approved, currently anticipated in 2012 but for which there can be no assurance. Under our 2006 Agreement with Alere, Alere has a right of first negotiation for the right to market any new rapid HIV antibody detection test that we develop. In accordance with this provision in our agreement, we presented this product to Alere in 2007 and in 2007 Alere waived its right of first negotiation under the agreement. While such waiver does not prevent Alere from reconsidering the marketing of this product, we have no reason to believe that they will. Also, although we believe that the main market opportunity for the DPP® HIV product is for those customers that have a clear preference for an oral fluid HIV test the product is also likely to compete with our FDA approved rapid HIV tests being marketed by Alere. Therefore this could have a material and adverse effect on our business with Alere.

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

Although we own our DPP® patent, we own no issued patents covering lateral flow technology, and the field of lateral flow technology is complex and characterized by a substantial amount of litigation, so the risk of potential

patent challenges is ongoing for us in spite of our DPP® patent.

Although we have been granted non-exclusive licenses to the lateral flow patents owned by Alere, there is no assurance that its lateral flow patents will not be challenged or that licenses from other parties may not be required, if available at all. In addition, certain of the Alere patents will expire in the next couple of years which expiration could open the market to certain competitors. In the event that it is determined that a license is required and it is not possible to negotiate a license agreement under a necessary patent, we may be able to modify our HIV rapid test products and other products such that a license would not be necessary. However, 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 we have been profitable for two consecutive years. Nevertheless, prior to 2009 we sustained significant operating losses since 2004. At December 31, 2010, we had a stockholders' equity of $5.8 million and a working capital surplus of $4.6 million. The Company estimates that its resources are sufficient to fund its needs through the end of 2011 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; (2) the extent to which, if any, that revenue level improves operating cash flows; (3) the Company's investments in research and development, facilities, marketing, regulatory approvals, and other investments it may determine to make; and (4) the Company's investment in capital equipment and the extent to which it improves cash flow through operating efficiencies. There are no assurances that the Company will remain profitable or generate positive cash flow in 2011 or, in the alternative, be successful in raising sufficient capital to fund its needs through 2011.

The launch of our DPP® products in Brazil, increased revenues from Alere, increased sales to developing world markets, and continued strength in our contract development and grant revenues are all critical for us to continue to fund our new product regulatory approval and commercialization programs. If we fail to meet any of these objectives, we may not generate revenues in the amounts necessary to fund our planned research, development and regulatory expenses in 2011.

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

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

If we are unable to increase our revenues from international sales, our operating results will be materially harmed.

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

Chembio has a policy in place prohibiting its employees, distributors and agents from engaging in corrupt business practices, including activities prohibited by the United States Foreign Corrupt Practices Act (FCPA). Nevertheless, because we work through independent sales agents and distributors (and do not have any employees or subsidiaries) outside the United States, we do not have control over the day-to-day activities of such independent agents and distributors. In addition, in the donor- funded markets in Africa where we sell our products, there is significant oversight from PEPFAR, the Global Fund, and advisory committees comprised of technical experts concerning the development and establishment of national testing protocols. This is a process that includes an overall assessment of a product which includes extensive product performance evaluations, a manufacturer's quality systems, as well as price and delivery. In Brazil where we have six product collaborations with FIOCRUZ, those programs that our products are or may be deployed in are all funded by the Brazilian Ministry of Health. Although FIOCRUZ is affiliated with

the Brazilian Ministry of Health, it is not its exclusive supplier. However because each of our collaborations with FIOCRUZ incorporates a technology transfer aspect, we believe we have a competitive advantage versus other suppliers to the Brazilian Ministry of Health, assuming other aspects of our product offering through FIOCRUZ are otherwise competitive in comparison. We have no knowledge or reason to know of any activities by our employees, distributors or sales agents of any actions which could be in violation of the FCPA, although there can be no assurance of this.

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

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

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

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

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

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

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

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

We have entered into employment contracts with our President, Lawrence Siebert, and our Senior Vice President of Research and Development, Javan Esfandiari. Due to the specific knowledge and experience of these executives regarding the industry, technology and market, the loss of the services of either one of them would likely have a material adverse effect on the Company. The contract with Mr. Siebert provides that Mr. Siebert will serve as the Chief Executive Officer and President of the Company through May 11, 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 in part on our ability to participate in large testing programs in the U.S. and worldwide and we may not be able to do so.

We believe it to be in our best interests to meaningfully participate in large testing programs. Participation in these programs requires alignment and engagement with the many other participants in these programs including the World Health Organization, U.S. Center for Disease Control, U.S. Agency for International Development, foreign governments and their agencies, non-governmental organizations, and HIV service organizations. If we are unsuccessful in our efforts to participate in these programs, our operating results could be materially harmed.

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

From the inception of Chembio Diagnostic Systems, Inc. in 1985 through the period ended December 31, 2008, we incurred net losses and we have only become profitable during the last two years. While we anticipate growth in our

product revenues in 2011 as compared with 2010, there can be no assurance of this. Moreover in 2011 we expect to make substantial expenditures for regulatory submissions, product development and other purpose that may make it more difficult to maintain profitability in 2011. Our ability to continue profitability in the future will primarily depend on our ability to increase sales of our products, reduce production and other costs and to successfully introduce new products and enhanced versions of our existing products into the marketplace. If we are unable to increase our revenues at a rate that is sufficient to achieve profitability, or adequately control and reduce our operating costs, our operating results would be materially harmed.

To the extent that we are unable to obtain sufficient product liability insurance or that we incur product liability exposure that is not covered by our product liability insurance, our operating results could be materially harmed.

We may be held liable if any of our products, or any product which is made with the use or incorporation of any of the technologies belonging to us, causes injury of any type or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or usage. We have obtained product liability insurance we have never received a product liability claim, and have generally not seen product liability claims for screening tests that are accompanied by appropriate disclaimers. Nevertheless, in the event there is a claim, this insurance may not fully cover our potential liabilities. In addition, as we attempt to bring new products to market, we may need to increase our product liability coverage which would be a significant additional expense that we may not be able to afford. If we are unable to obtain sufficient insurance coverage at an acceptable cost to protect us, we may be forced to abandon efforts to commercialize our products or those of our strategic partners, which would reduce our revenues.

Risks related to our Common Stock

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

In the past, our Common Stock has been classified as penny stock. Penny stocks generally are equity securities with a price of less than $5.00 and trade on the over-the-counter bulletin board market (OTCBB). 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 2008, 2009 and 2010 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 45,000 shares per day over the three months ended March 1, 2011. If limited trading in our stock continues, it may be difficult for investors to sell their shares in the public market at any given time at prevailing prices.

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

As of March 1, 2011, our named executive officers, directors and 5% stockholders beneficially owned approximately 28.3% of our voting power. For the foreseeable future, to the extent that these parties vote similarly, they may be able to exercise significant control over many matters requiring approval by the board of directors or our stockholders. As a result, they may be able to:

- control the composition of our board of directors;
- control our management and policies;
- determine the outcome of significant corporate transactions, including changes in control that may be beneficial to stockholders; and
- act in each of their own interests, which may conflict with, or be different from, the interests of each other or the interests of the other stockholders.

ITEM 2. PROPERTIES

Our administrative offices and research facilities are located in Medford, New York. We lease approximately 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 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.

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

Until February 23, 2011, our common stock was 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 2010	High Bid	Low Bid
First Quarter	$.33	$.20
Second Quarter	$.28	$.159
Third Quarter	$.29	$.21
Fourth Quarter	$.49	$.225

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

On February 24, 2011, and since that date, our stock has not been quoted on the OTC Bulletin Board, and is now being quoted on the OTCQB, which is the second of the three tiers of the OTC Market Group. The situation is in a state of flux and we are trying to determine what market we believe is best for our stock, considering the relative costs, liquidity, market strategy, etc. The other markets that we will consider are (1) the higher tier of the OTC Market Group called OTC-QX; (2) the NYSE-AMEX, and; (3) NASDAQ.

Our stock is no longer trading on the OTC Bulletin Board because the market maker that had filed originally to quote our stock on the OTC Bulletin Board is no longer providing quotes on the OTC Bulletin Board. It is our understanding that a large number of other market makers also have ceased to provide quotes on the OTC Bulletin Board and that 300 to 500 other companies have ceased being quoted on the OTC Bulletin Board during the past few months for the same reason.

This change has nothing to do with Chembio or the quality of our company. It is solely related to the desire of the market makers to save costs related to providing quotes on the OTC Bulletin Board.

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 2008, 2009 and 2010 exceeded $6 million per year. However, there can be no assurance that transactions in our common stock will not be subject to the Penny Stock Rule in the future.

Holders

As of March 1, 2011, there were approximately 1,350 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, 2010. 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, all years shown conform to this presentation.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
SELECTED HISTORICAL FINANCIAL DATA

Statement of Operations Data:										
	December 31, 2010		December 31, 2009		December 31, 2008		December 31, 2007		December 31, 2006	
TOTAL REVENUES	$16,704,703		$13,834,248		$11,049,571		$9,230,948		$6,502,480	
GROSS MARGIN	$8,100,699	48%	$5,860,405	42%	$3,851,721	35%	$2,795,710	30%	$1,608,272	25%
OPERATING COSTS:										
Research and development expenses	$2,586,308	15%	$2,883,696	21%	$2,605,343	24%	$1,906,653	21%	$1,401,472	22%
Selling, general and administrative expenses	$2,940,721	18%	$2,659,382	19%	$3,317,046	30%	$3,765,221	41%	$4,786,993	74%
	$5,527,029		$5,543,078		$5,922,389		$5,671,874		$6,188,465	
INCOME (LOSS) FROM OPERATIONS	$2,573,670		$317,327		$(2,070,668)		$(2,876,164)		$(4,580,193)	
OTHER INCOME (EXPENSES):	(14,503)		(8,267)		121,898		249,272		(414,827)	
NET INCOME (LOSS)	$2,559,167	15%	$309,060	2%	$(1,948,770)	-18%	$(2,626,892)	-28%	$(4,995,020)	-77%
Dividends accreted/payable in stock to preferred	$-		-		-		5,645,310		3,210,046	

stockholders and a beneficial conversion feature								
NET INCOME (LOSS) ATTRIBUTABLE TO COMMON STOCKHOLDERS	$2,513,344	$309,060	-1,948,770	-18%	-8,272,202	-90%	-8,205,066	-126%
Basic income (loss) per share	$0.04	$(0)	$(0.03)		$(0.57)		$(0.80)	
Diluted income (loss) per share	$0.04	$(0)	$(0.03)		$(0.57)		$(0.80)	
Weighted average number of shares outstanding, basic	$62,102,861	$61,946,435	$61,266,954		$14,608,478		$10,293,168	
Weighted average number of shares outstanding, diluted	$70,920,915	$75,041,932	$61,266,954		$14,608,478		$10,293,168	
Balance Sheet Data:								
Working capital	$4,560,277	$1,493,970	$1,663,914		$3,228,724		$5,113,233	
Total assets	$9,086,174	$6,315,250	$5,914,941		$6,584,997		$7,906,577	
Total liabilities	$3,277,230	$3,227,336	$3,337,609		$2,322,171		$2,297,193	
Shareholders' equity (deficit)	$5,808,944	$3,087,914	$2,577,332		$4,262,826		$(939,807)	

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 1/2 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.

All of the Company's products other than its lateral flow tests (see PRODUCTS and Our Rapid Test Technologies) are based on the Company's patented Dual Path Platform (DPP®) technology. The Company has had a very active research and development effort and has significantly increased its spending on research and development programs during the last three years. However, third party funding from research and development contracts and grants have more than offset these increased research and development expenses (excluding the $654,000 of 2010 clinical trials expenses and also excluding the benefit of the $1.467MM in QTDP grants awarded in 2010). These externally funded R&D programs have been instrumental in a number of very important ways: first, it has helped the Company to avoid raising capital during 2008-2010, which was a very difficult period for fundraising. Second, it has resulted in significant third party validations of our DPP® technology. Third, it has subsidized the Company in developing an increasing capability to develop, manufacture, validate, and scale up current and future DPP® products and product features.

Research and development activity has been completed on seven DPP® products to date. Four were completed during 2007-2009 and three were completed during 2010.

The four DPP® products completed prior to 2010 are as follows:

1) DPP® HIV 1/2 Confirmatory Test – See OEM DPP® Products, Oswaldo Cruz Foundation OEM DPP® Agreements
2) DPP® HIV 1/2 Screening Test – See Regulatory Status below and OEM DPP® Products, Oswaldo Cruz Foundation Agreements
3) DPP® Syphilis Screen & Confirm Test – See Regulatory Status below and OEM DPP® Products, Oswaldo Cruz Foundation Agreements
4) DPP® Canine Leishmaniasis – See Regulatory Status and OEM DPP® Products, Oswaldo Cruz Foundation Agreements

Of the three DPP® products we completed development of during 2010, two relate to agreements we have with the Oswaldo Cruz Foundation ("FIOCRUZ") for the Brazilian public health market. These are the DPP® products for Leptospirosis and a new Syphilis product (this is a single-parameter, treponemal-only version we developed for FIOCRUZ; our agreement further contemplates providing our Screen & Confirm product as soon as practicable. The third product we completed development of during 2010 is the multiplex product developed pursuant to a funded product development agreement we entered in 2008 with Bio-Rad Laboratories, Inc. (see OEM DPP® Products).

During 2010 we also completed the prototype of a six-parameter influenza immune-status product as per the specifications in a funded development contract we signed in December 2009 with the Battelle Memorial Institute (See OEM DPP® Products).

As we look forward in 2011, the Company has a number of ongoing and new development programs that employ the DPP® technology. These product development activities are further described below.

DPP® Influenza – We have developed a prototype multiplex test for FLU A/B Antigen Detection and we are on schedule to complete development and validation of this product by the end of the second quarter of 2011. Achievement of this plan will enable us begin clinical testing during the upcoming 2011-12 Flu season, submit the 510(k) application to the FDA in early 2012, and launch the product in the U.S. market in mid-2012.

DPP® Leptospirosis – In 2009 we were awarded a 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. As of March 1, 2011, we have identified several novel leptospiral proteins cloned from a variety of strains that are prevalent in different countries. These antigens will supplement the current test prototype and thus enhance the potential for its use worldwide as a universal point-of-care test for leptospirosis.

DPP® Tuberculosis – In February 2011 we were awarded an SBIR Phase II grant from the NIH to continue development of a simple, rapid, accurate, and cost-effective serological test for active tuberculosis that can be utilized in resource-limited settings. Chembio developed a prototype of this test in the Phase I work in collaboration with the Infectious Disease Research Institute ("IDRI"), a Seattle-based biotechnology research organization dedicated to technologies that address diseases in the developing world; this collaboration will continue in this second phase of the research and development grant as well. The grant is effective March 1, 2011. The prototype test developed during the Phase I work uses the Dual Path Platform (DPP®) technology together with selected antigens from a large panel of novel recombinant antigens identified at IDRI. The Phase I studies demonstrated the feasibility of developing a rapid and accurate test for tuberculosis with required diagnostic performance characteristics (sensitivity >80%, specificity >95%). In Phase II, the proposed rapid (15 minutes) point-of-care DPP® test for tuberculosis will be fully

developed, optimized, and evaluated in multi-center clinical trials in several countries, followed by validation of production protocols, preparation for regulatory approval and commercialization

DPP® Hepatitis C and DPP® Hepatitis C (HCV) /HIV Oral Fluid Antibody Tests – In 2010 we received data from a study sponsored by the CDC that assessed the performance of our HCV product. The data confirmed that we had achieved good performance with this HCV antibody detection test prototype. We have recently been invited to participate in some additional CDC studies this year with this and certain other related prototype products that we have in development in this area. We have also determined however that the market opportunity for a point-of-care HCV antibody only (i.e., without antigen detection) test is very limited, and so in addition to improving our antibody detection test, we are also working on including antigen detection as well in a new DPP® format that we have in development, which format incorporates some of our platform enhancements (see below). We believe this could result in a more commercially viable market opportunity for this market.

Platform Enhancements - During 2010 and increasingly during 2011 we are improving and enhancing the capabilities of our DPP® technology. For example, we are further simplifying the procedure to run certain kinds of tests developed with DPP® and we are also making antibody and antigen detection available in a single test device. This is possible utilizing DPP® without certain limitations that are presented when this is attempted with lateral flow technology. We have also fully integrated the new automated assembly system into our manufacturing operation, which will make all of our production, both lateral flow and DPP®, more cost effective.

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.

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.

Regulatory Activities

Regulatory Approvals in Brazil through the Oswaldo Cruz Foundation (FIOCRUZ) – We have five active projects with FIOCRUZ. Two have obtained regulatory approval (See OEM DPP® Products, Oswaldo Cruz Foundation OEM). The three that are pending regulatory approval are updated as follows.

DPP® Canine Leishmaniasis:
In January 2011 FIOCRUZ was requested by MAPA for the second time to provide additional information. This will further delay the approval process and based upon recent experience it is difficult to predict timing. We believe there is strong support for this product within FIOCRUZ based on our discussions with them.

DPP® Leptospirosis:
Chembio has sent three production lots of this product to FIOCRUZ and FIOCRUZ is completing preparation of the technical file in order to submit it to ANVISA. FIOCRUZ estimates ANVISA approval will be granted during the second quarter of 2011.

DPP® Syphilis Treponemal:
Chembio has sent three production lots of this product to FIOCRUZ and FIOCRUZ is completing preparation of the technical file in order to submit it to ANVISA. FIOCRUZ estimates ANVISA approval will be granted during the second quarter of 2011.

DPP® HIV 1/2 Screening Assay for Oral Fluid – During 2010 we made significant progress toward commercializing this product. In March 2010, we obtained approval of this product from the United States PEPFAR program, and more recently we commenced clinical trials in the United States in support of, a planned Pre-Marketing Approval (PMA) application to the FDA. We have enrolled about half of the patients of the clinical protocol and are planning on completing this clinical trial this summer. We recently submitted a request to file a modular PMA to the FDA. This modular PMA approach provides a mechanism of submitting preclinical data and manufacturing information for review while still collecting, compiling and analyzing clinical data. The modular PMA is a compilation of three sections ("modules"); the first, second and third modules are being planned for submission to FDA in the first, second and third quarter, respectively.

DPP® Syphilis Screen & Confirm – We are completing the validation lots intended for clinical studies in the United States. Clinical studies are being scheduled for 2nd Quarter 2011 to support the FDA pre-market clearance (510k). The completion of these lots will also allow us to finish the required studies for self-certification of a CE Mark which we anticipate to file in 2nd quarter 2011.

CE Mark for Lateral Flow HIV tests – In order to meet the final requirement of the Common Technical Specifications we are required to collect data on blood donors at a blood donation center within the European Community. We experienced setbacks as many of the European blood centers experienced budget cutbacks resulting in reduced resources. We have currently identified a blood donation center in Europe and are in the process of scheduling with

the site, which is anticipated to start the study sometime in the 2nd/3rd Quarter 2011.

Recent Events

During the fourth quarter of 2010 the Company was awarded $1.467 million in Qualified Therapeutic Discovery Project grants (“QTDP”) under Section 48D of the Internal Revenue Code, as enacted under the Patient Protection and Affordable Care Act of 2010. This was for six of the seven projects the Company submitted for consideration. This was reflected as a reduction in research and development expenses.

In November 2010, the Company entered into a new Technology Transfer Agreement with the Oswaldo Cruz Foundation of Brazil ("FIOCRUZ") relating to its DPP(R) point-of-care tests for Syphilis. Under the agreement, the Company will transfer technology to FIOCRUZ for two DPP® syphilis products. The transfer is anticipated to occur over a three-year period, requiring purchases by FIOCRUZ from the Company of these products and related components aggregating a minimum of $5.7 million over that period and also requiring a total of approximately $1.8 million of additional revenues to the Company during the fourth and fifth years This is the sixth technology transfer agreement, each covering a different product, entered into between Chembio and FIOCRUZ since 2004.

RESULTS OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2010 AS COMPARED WITH THE YEAR ENDED DECEMBER 31, 2009

Net income:

Net income for the year ended December 31, 2010 increased to $2,513,300 from 309,060 for the year ended December 31, 2009. The primary factors for this increase are described below.

Revenues:

Selected Product Categories:	For the years ended			
	December 31, 2010	December 31, 2009	$ Change	% Change
HIV	$ 12,111,560	$ 10,792,947	$ 1,318,613	12.22 %
DPP	628,101	619,530	8,571	1.38 %
Other	776,698	960,016	(183,318)	-19.10 %
Net Product Sales	13,516,359	12,372,493	1,143,866	9.25 %
License and royalty revenue	432,238	121,896	310,342	254.60 %
R&D, milestone and grant revenue	2,756,106	1,339,859	1,416,247	105.70 %
Total Revenues	$ 16,704,703	$ 13,834,248	$ 2,870,455	20.75 %

Revenues for our lateral flow HIV tests and related components during the year ended December 31, 2010 increased by $1.32 million over the same period in 2009. This was primarily attributable to increased sales to Ethiopia of $2.40 million, to $3.69 million in 2010, as compared with $1.29 million in 2009. This increase was partially offset by reduced sales to Brazil of lateral flow HIV tests, which decreased by 64.2%, or $1.47 million to $.82 million in 2010, as compared with $2.29 million in 2009. Sales of our DPP® products in 2010 were similar to levels in 2009. However most of the DPP® product sold in 2010 related to products that were approved for sale in Brazil as compared to products sold in 2009 which were used by FIOCRUZ in submissions to regulatory agencies for approval. The increase in R&D, milestone and grant revenue was primarily due to $1.55 million earned as a result of the completion of certain milestones. The milestones include $125,000 earned in June 2010 as a result of the completion of the milestone in our Bio-Rad agreement, $804,000 from Battelle for influenza immunity test and milestone fees of $400,000 and $225,000 from FIOCRUZ that were triggered upon the approval of the Company's DPP® HIV 1/2 Screening Assay and its DPP® HIV 1/2 Confirmatory rapid tests, respectively. R&D revenues also include funds, recognized on an "as expenses are incurred" basis, from Phase II NIH grant for Leptospirosis, which was effective as of June 1, 2009. License and royalty revenue includes fee payments of $340,000 from Bio-Rad pursuant to the License Agreement we signed with them in January 2009 and for royalties from Brazil under our 2004 technology transfer and license agreement.

Gross Margin:

Gross Margin related to Net Product Sales:	For the years ended			
	December 31, 2010	December 31, 2009	$ Change	% Change
Gross Margin per Statement of	$ 8,100,699	$ 5,860,405	$ 2,240,294	38.23 %

Operations									
Less: R&D, milestone, grant, license and royalties		3,188,344			1,461,755		1,726,589	118.12	%
Gross Margin from Net Product Sales	$	4,912,355		$	4,398,650	$	513,705	11.68	%
Gross Margin %		36.34	%		35.55	%			

The increase in our gross margin was primarily due to the increase in non-product revenues (see revenue items other than product sales - see revenues above). The increase in our product gross margin resulted primarily from reduced royalty expense due to product sold in 2010 to countries where a lower rate applies than in 2009.

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, 2010	December 31, 2009	$ Change	% Change
Clinical and Regulatory Affairs:				
Wages and related costs	$ 424,038	$ 321,830	$ 102,208	31.76 %
Consulting	30,525	35,560	(5,035)	-14.16 %
Share-based compensation	11,881	12,916	(1,035)	-8.01 %
Clinical trials	654,253	69,499	584,754	841.38 %
Other	74,254	32,056	42,198	131.64 %
Total Regulatory	$ 1,194,951	$ 471,861	$ 723,090	153.24 %
R&D Other than Regulatory:				
Wages and related costs	$ 1,889,702	$ 1,541,295	$ 348,407	22.60 %
Consulting	19,430	88,600	(69,170)	-78.07 %
Share-based compensation	73,656	62,180	11,476	18.46 %
Materials and supplies	635,911	462,806	173,105	37.40 %
Other	239,534	256,954	(17,421)	-6.78 %
Total other than Regulatory	$ 2,858,233	$ 2,411,835	$ 446,398	18.51 %
	$ 4,053,184	$ 2,883,696	$ 1,169,488	40.56 %
Less: QTDP grant	1,466,876	-	1,466,876	100.00 %
Total Research and Development	$ 2,586,308	$ 2,883,696	$ (297,388)	-10.31 %

Expenses for Clinical & Regulatory Affairs for the year ended December 31, 2010 increased by $723,000 as compared to the same period in 2009. This was primarily due to expenses we incurred in 2010 for clinical trials conducted for our DPP® HIV Screen Assay. In addition, wages and related costs also contributed to the increase.

R&D expenses other than Clinical & Regulatory Affairs increased by $446,000 in the year ended December 31, 2010 as compared with the same period in 2009 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.

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

Research and development expenses, before the QTDP grant, net of revenues from R&D, milestones and grants (see sub-heading Revenues above) was $1,297,000 for the year ended December 31, 2010 ($4,053,000 less $2,756,000, this includes clinical trials of $654,000 and does not include the QTDP reduction) compared to $1,174,000 ($2,884,000 less $1,340,000, this includes clinical trials of $69,000) for the same period in 2009.

Selling, General and Administrative Expense:

Selected expense lines:	For the years ended			
	December 31, 2010	December 31, 2009	$ Change	% Change
Wages and related costs	$ 1,076,446	$ 1,075,532	$ 914	0.08 %
Consulting	215,391	165,371	50,020	30.25 %
Commissons	183,762	302,515	(118,753)	-39.26 %
Share-based compensation	64,429	98,356	(33,927)	-34.49 %
Marketing materials	17,627	22,779	(5,152)	-22.62 %
Investor relations/investment bankers	197,183	72,888	124,295	170.53 %
Legal, accounting and SOX 404 compliance	563,277	470,843	92,434	19.63 %
Travel, entertainment and trade shows	59,003	61,316	(2,313)	-3.77 %
Other	563,603	389,782	173,821	44.59 %
Total S, G &A	$ 2,940,721	$ 2,659,382	$ 281,339	10.58 %

Selling, general and administrative expenses for the year ended December 31, 2010 increased by 10.6% as compared with the same period in 2009. This was primarily due to the recording of $94,000 in Brazilian tax withholdings on the milestone payments, an increase in investor relations and an increase in legal, accounting and SOX 404 expenses for compliance and for pursuing possible strategic opportunities, partially offset by a decrease in commissions as a result of lower sales in Brazil.

Other Income and Expense:

	For the years ended			
	December 31, 2010	December 31, 2009	$ Change	% Change
Other income (expense)	$ (3,923)	$ (6,696)	$ 2,773	-41.41 %
Interest income	4,147	9,032	(4,885)	-54.09 %
Interest expense	(14,727)	(10,603)	(4,124)	38.89 %
Total Other Income and (Expense)	$ (14,503)	$ (8,267)	$ (6,236)	75.43 %

Other income and (expense) for the year ended December 31, 2010 decreased approximately $6,200 to $14,500 as compared with $8,300 for the same period in 2009, primarily as a result of an increase in interest expense due to the term loan with HSBC and a decrease in interest income due to a decrease in interest rates in interest-bearing accounts, both of which were partially offset by a lower loss on the sale of an asset in 2009 compared to a retirement of an asset in 2010.

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED DECEMBER 31, 2010 AS COMPARED WITH THE THREE MONTHS ENDED DECEMBER 31, 2009

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

	December 31, 2010	December 31, 2009
REVENUES:		
Net product sales	$ 5,179,226	$ 3,127,454
License and royalty revenue	31,480	38,186
R&D, milestone and grant revenue	456,136	385,801
TOTAL REVENUES	5,666,842	3,551,441
Cost of product sales	3,175,984	1,920,636
GROSS MARGIN	2,490,858	1,630,805
OPERATING EXPENSES:		
Research and development expenses	(236,147)	755,837
Selling, general and administrative expenses	797,006	657,309
	560,859	1,413,146
INCOME FROM OPERATIONS	1,929,999	217,659
OTHER INCOME (EXPENSES):		
Other expense	-	-
Interest income	1,400	1,949
Interest expense	(4,800)	(2,394)
	(3,400)	(445)
INCOME BEFORE INCOME TAXES	1,926,599	217,214
Provision for income taxes	45,823	-
NET INCOME	$ 1,880,776	$ 217,214
Basic earnings per share	$ 0.03	$ 0.00
Diluted earnings per share	$ 0.03	$ 0.00

Weighted average number of shares outstanding, basic	62,204,742	61,950,988
Weighted average number of shares outstanding, diluted	70,513,280	75,365,550

See accompanying notes to consolidated financial statements

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Net Income:

Net income, on an unaudited basis, increased to $1,880,800 for the three months ended December 31, 2010 from $217,200 for the three months ended December 31, 2009. The primary factors for this increase are described below.

Revenues:

Selected Product Categories:	For the three months ended			
	December 31, 2010	December 31, 2009	$ Change	% Change
HIV	$ 4,379,098	$ 2,963,671	$ 1,415,427	47.76 %
DPP	621,580	-	621,580	100.00 %
Other	178,548	163,783	14,765	9.01 %
Net Product Sales	5,179,226	3,127,454	2,051,772	65.61 %
License and royalty revenue	31,480	38,186	(6,706)	-17.56 %
R&D, milestone and grant revenue	456,136	385,801	70,335	18.23 %
Total Revenues	$ 5,666,842	$ 3,551,441	$ 2,115,401	59.56 %

Revenues for our lateral flow HIV tests during the three months ended December 31, 2010 increased by approximately 48% or $1,415,000 over the same period in 2009. This was primarily attributable to increased sales in Africa which increased by $1,638,000 to $2,537,000, and partially offset by a decrease in sales to North America of $93,000. The increase in DPP® revenues was principally due to sales of our DPP® HIV Screen test. The increase in R&D revenues was primarily due to revenue from our contract development agreement with Bio-Rad and IDRI. 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, 2010	December 31, 2009	$ Change	% Change
Gross Margin per Statement of Operations	$ 2,490,858	$ 1,630,805	$ 860,053	52.74 %
Less: R&D, milestone, grant, license and royalties	487,616	423,987	63,629	15.01 %
Gross Margin from Net Product Sales	$ 2,003,242	$ 1,206,818	$ 796,424	65.99 %
Gross Margin %	38.68 %	38.59 %		

The increase in our product gross margin resulted primarily from reduced royalty expense due to product sold in 2010 to countries where a lower rate applies than in 2009.

Research and Development:

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

Selected expense lines:	For the three months ended			
	December 31, 2010	December 31, 2009	$ Change	% Change
Clinical and Regulatory Affairs:				
Wages and related costs	$ 145,265	$ 96,284	$ 48,981	50.87 %
Consulting	-	5,610	(5,610)	-100.00 %
Share-based compensation	2,122	4,667	(2,545)	-54.53 %
Clinical trials	253,461	23,448	230,013	980.95 %
Other	5,845	7,852	(2,007)	-25.56 %
Total Regulatory	406,693	137,861	268,832	195.00 %
R&D Other than Regulatory:				
Wages and related costs	583,285	420,088	163,197	38.85 %
Consulting	240	25,052	(24,812)	-99.04 %
Share-based compensation	10,950	9,722	1,228	12.63 %
Materials and supplies	158,041	102,491	55,550	54.20 %
Other	71,520	60,623	10,897	17.97 %
Total other than Regulatory	$ 824,036	617,976	206,060	33.34 %
	$ 1,230,729	$ 755,837	$ 474,892	62.83 %
Less: QTDP grant	1,466,876	-	1,466,876	100.00 %
Total Research and Development	$ (236,147)	$ 755,837	$ (991,984)	-131.24 %

Expenses for Clinical & Regulatory Affairs for the three months ended December 31, 2010 increased by $269,000 as compared to the same period in 2009. This was primarily due to expenses we incurred in 2010 for clinical trials conducted for our DPP® HIV Screen Assay. In addition, wages and related costs also contributed to the increase.

R&D expenses other than Clinical & Regulatory Affairs increased by $206,000 in the year three months December 31, 2010 as compared with the same period in 2009 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.

On November 1, 2010, the Company was notified by the IRS that it received awards in the total amount of $1.467 million relating to six “Qualifying Therapeutic Discovery Projects” under the U.S. Patient Protection and Affordable

Care Act of 2010 (P.L. 111-148), a program that was created as part of the major United States federal health care reform legislation enacted earlier this year. The $1.467 million reduced R&D expenses in the fourth quarter of 2010.

Research and development expenses, before the QTDP grant, net of revenues from R&D, milestones and grants (see sub-heading Revenues above) was $775,000 for the year three months December 31, 2010 ($1,231,000 less $456,000, this includes clinical trials of $253,000 and does not include the QTDP reduction) compared to $370,000 ($756,000 less $386,000, this includes clinical trials of $23,000) for the same period in 2009.

Selling, General and Administrative Expenses:

Selected expense lines:	For the three months ended			
	December 31, 2010	December 31, 2009	$ Change	% Change
Wages and related costs	$ 332,824	$ 324,131	$ 8,693	2.68 %
Consulting	43,377	22,250	21,127	94.95 %
Commissons	83,526	15,952	67,574	423.61 %
Share-based compensation	11,549	30,414	(18,865)	-62.03 %
Marketing materials	3,917	5,419	(1,502)	-27.72 %
Investor relations/investment bankers	36,411	35,839	572	1.60 %
Legal, accounting and SOX 404 compliance	123,048	123,500	(452)	-0.37 %
Travel, entertainment and trade shows	9,676	13,849	(4,173)	-30.13 %
Other	152,678	85,955	66,723	77.63 %
Total S, G &A	$ 797,006	$ 657,309	$ 139,697	21.25 %

Selling, general and administrative expenses for the three months ended December 31, 2010 increased by 21.3% as compared with the same period in 2009. This was primarily due to an increase in commissions for the increased sales made to Brazil of our DPP® products, increase in consulting and an increase in board fees, partially offset by a decrease in share-based compensation.

Other Income and (Expense):

	For the three months ended			
	December 31, 2010	December 31, 2009	$ Change	% Change
Other income	$ -	$ -	$ -	100.00 %
Interest income	1,400	1,949	(549)	-28.17 %
Interest expense	(4,800)	(2,394)	(2,406)	100.50 %
Total Other Income and (Expense)	$ (3,400)	$ (445)	$ (2,955)	664.04 %

Other income and (expenses) for the three months ended December 31, 2010 decreased approximately $3,000 as compared with the same period in 2009, primarily from an increase in interest expense due to the term loan with HSBC and a decrease in interest income due to a decrease in interest rates in interest-bearing accounts.

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LIQUIDITY AND CAPITAL RESOURCES

	For the three months ended			
	December 31, 2010	December 31, 2009	$ Change	% Change
Net cash provided by operating activities	$ 1,016,850	$ 251,927	$ 810,746	321.82 %
Net cash used in investing activities	(182,292)	(376,988)	194,696	-51.65 %
Net cash provided by financing activities	233,558	(18,926)	252,484	-1334.06 %
NET INCREASE IN CASH AND CASH EQUIVALENTS	$ 1,068,116	$ (143,987)	$ 1,257,926	-873.64 %

The Company had an increase in cash for the year ended December 31, 2010 which is primarily attributable to cash provided by operations and cash provided by financing activities ($250,000 term loan from HSBC). The decrease in the 2009 period is primarily attributable to the cash used in investing activities, which includes the purchase of fixed assets. The increased cash from operations in 2010 was primarily attributable to net income along with non-cash expenses aggregating $2,986,000. Net income includes the reduction of R&D expenses from the QTDP grants of $1,467,000, which if not granted in 2010, would result in the cash from net income, along with non-cash expenses, aggregating $1,519,000. In addition, operating activities included increase in accruals and payables of $150,000, a decrease in inventories of $207,000, a decrease in prepaid expenses of $62,000 and a decrease in other assets of $93,000, which were offset by an increase in receivables of $2,185,000 and a decrease in deferred revenue of $296,000. The decrease in deferred revenue was primarily due to the achievement of a milestone for which payment was received in January 2009 and for which there was no counterpart in 2010. The Company's non-cash expenses totaled $554,000, which consisted of $284,000 from depreciation expense, $170,000 in share-based compensation expense and $100,000 in the amortization of licenses. Investing activities represent the Company's investment in fixed assets. The cash provided from financing activities is primarily due to the term loan from HSBC of $250,000.

The increase in accounts receivable was due to the Company making most of the quarter's sales in December and has collected 67% as of March 1, 2011.

In addition on January 3, 2011, the Company made payment to Bio-Rad for the $875,000 due under the HIV-2 license agreement.

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

Chembio achieved record financial results in 2010 in every respect. The Company recorded a nearly 21% increase in total revenues in 2010 versus 2009. This increase was on the strength of a 118% increase of non-product revenues to a total of $3.19 million (license, royalty, R&D, milestone and grant revenues) versus $1.46 million in 2009, and also due to a 9.2% increase in Net Product Sales to $13.52 million from $12.37 million in 2009. Fourth quarter 2010 Total Revenues of $5.67 million represented an increase of 65% compared with the same period in 2009, and also represented an increase of 25.8% over the Company's previous record quarterly revenues which were $4.51 million in the third quarter of 2010. The Net Product sales in the fourth quarter included strong performance from both international and US market sales of our lateral flow products, as well as from the first commercial shipment of our

DPP® HIV oral fluid HIV test to FIOCRUZ in Brazil.

These strong top line results produced record gross profits, both in dollars and also as a percentage of sales. Our 2010 gross profit dollars increased over 38% from last year's record gross profit dollars of $5.86 million, to $8.10 million or 49% of Total Revenues. Fourth quarter Gross profit was $2.49 million, also a record, and this was primarily based on the strength of our Net Product Sales in the quarter.

The record non-product revenues are attributable to continued progress in a number of development programs, all based on our DPP® technology, including significant accomplishments which further validated our platform and our capability to develop diagnostic products serving large markets and/or important health care objectives. These accomplishments include two regulatory approvals in Brazil, completion of performance specifications for multiplex products we were contracted to develop for Bio-Rad Laboratories, Inc. and for the US government's contractor for pandemic flu preparedness, and several evaluations that were completed on our DPP® HIV Screening Assay for use with oral fluid or blood samples.

Operating Expenses as reported in our audited results, which include Research & Development (R&D) Expenses as well as Selling, General and Administrative Expenses ("SGA") were essentially unchanged from 2009. However these audited numbers include three uncommon expense items as compared to prior periods that need to be pointed out. First, SG&A expenses in 2010 included approximately $275,000 of expenses incurred in connection with two specific potential strategic opportunities, including approximately $100,000 for legal fees, including patent research and due diligence, $100,000 for outside directors' Special Committee fees, $37,500 for a valuation consultant deposit, $25,000 for investment consulting fees and $12,500 in various other expenses. One of these potential opportunities, which was unsolicited, involved due diligence, travel and negotiation, and preparation of an written agreement which was not finalized, and the other involved travel and extensive negotiations and due diligence. Both opportunities involved numerous meetings, conferences and discussions by and with management, Chembio's outside directors and counsel, both for internal strategy sessions and with the proposed strategic partner. Neither of the potential opportunities ultimately resulted in any material agreement. The Company's senior management and board believes strongly in the value that has been created and the opportunities there are for further increasing shareholder value, particularly once it begins to commercialize the products in its development and clinical pipeline. Second, we recorded the benefit of the $1.467 million we received in Qualified Therapeutic Discovery Project (QTDP) grants in the fourth quarter of 2010, which amount was accounted for as a reduction in R&D Expense in that period. Finally, we expended approximately $650,000 of clinical trial expenses in 2010 related to our oral fluid HIV test PMA, including $250,000 in the fourth quarter. The $275,000 in strategic investigation costs in SG&A expenses, $1.467 million QTDP benefit (expense reduction), and the $650,000 clinical trial expense each had a material impact on our 2010 net income.

Our operating results in 2011 are likely to benefit from continued growth in sales to those customers and markets that we participated in during 2010, although there can be no assurance of this. We have recently reviewed the 2010 results with the marketing team we work with at Alere and we believe they are well positioned to deliver additional growth this year. We believe that Alere achieved at least 25% revenue growth with our products on their books in 2010 versus 2009, however due to inventory level changes at Alere this fact is not reflected in our 2010 results. Based on the two product approvals we received in Brazil in 2010, as well as three product approvals that are pending in Brazil, we anticipate significant revenues from this customer in 2011 as well, though there can be no assurance of this. We have additional opportunities in other markets for our products that we are developing which, if realized, would provide additional revenues for our products.

The $2.9 million Phase II grant award we received from the NIH in February, which is effective March 1, 2011, will help to subsidize our Operating Expenses, while also advancing the specific research and development aims of such grant. Chembio is budgeted to receive approximately 63.5% of the awarded amount, or approximately $1,842,700, if award funding continues over the full three years as is expected; IDRI would receive the balance as a subcontractor to Chembio. The grant award budget is approximately equal in each grant year, or approximately $967,000 per year. As in all such grants, award funding in the second and third years is subject to satisfactory progress and availability of funds.

We believe that the above-described anticipated product sales, as well as proceeds already received and/or anticipated from development fees, grants (including the QTDP grants), and milestone fees will be sufficient to fund our clinical and regulatory programs, which may exceed $2.0 million in costs during 2011, however there can be no assurance of this. Accordingly we need to manage all aspects of our costs to ensure that we do not compromise the timetable for commercializing our new products. The automated assembly equipment we installed and validated in 2010 is fully operational and should help us to reduce our manufacturing costs or offset other increases, as it already did in 2010. We believe certain quality control measures that we have implemented will also help to increase production yields, also lowering unit costs. We will nonetheless continually assess our Operating Expenses so as to ensure that our expenditures are aligned with our strategy and within our means. Our cash position, working capital, and shareholder equity is stronger than ever. As of March 1, 2011 we had a cash balance in excess of the balance reflected in our 2010 audited statements as a result of our collection, in January and February, of large accounts receivable balances reflected on our December 31 balance sheet, and even after paying off the $875,000 balance due to Bio-Rad Laboratories, Inc., which occurred in early January. We also have a $250,000 line of credit with our bank which has

a zero balance.

We have made significant progress in completing the requirements for submitting our Pre-Marketing Approval (PMA) Application to the FDA for our DPP® HIV Screening Assay and the rate of progress is accelerating. We are approximately halfway through the clinical trials for this product and the trials are proceeding well. We recently submitted the first module in our PMA application to the FDA, we plan to submit our second module during the second quarter, and the third and final module during the third quarter. This timetable, if maintained, could result in an approval before the end of this year, although approval in 2012 is a much more likely scenario, although there can be no assurance even of this. We have also made significant progress in our Syphilis and Flu programs, even though we are delayed from the timetable we had previously anticipated. We are very excited about the opportunity we have to potentially be the first dual marker (treponemal and non-treponemal) POCT for syphilis in the United States.

We believe that our strategy of developing a core public health brand, initially with our DPP® HIV Oral Fluid test and our DPP® Syphilis Screen & Confirm test, supplemented by OEM opportunities in all other market segments, is sound, based upon what we have in our pipeline today. Recent studies published by the CDC confirm the value of our dual marker DPP® Syphilis Screen & Confirm test, and we believe that there are sales opportunities in the U.S. and international rapid HIV test markets for our DPP® oral fluid HIV test that are not available to our lateral flow whole blood tests. We may identify other product opportunities that cause us to modify this strategy.

We will also need to begin to develop our sales and marketing organization, and brand, as we get closer to commercialization of our products. While this is a costly investment, it should enable us to retain a larger portion of our unit selling prices which, if that occurs, will result in our having higher sales and gross margins, though also higher marketing expenses.

Critical Accounting Policies and Estimates

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

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

Revenue Recognition –

We recognize revenue for product sales in accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 104, "Revenue Recognition" ("SAB 104"). Under SAB 104, revenue is recognized when there is persuasive evidence of an arrangement, delivery has occurred or services have been rendered, the sales price is determinable, and collectability is reasonably assured. Revenue typically is recognized at time of shipment. Sales are recorded net of discounts, rebates and returns.

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

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

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 $14,000.

Allowance for doubtful accounts –

Our policy is to review our accounts receivable on a periodic basis, no less than monthly. On a quarterly basis an analysis is made of the adequacy of our allowance for doubtful accounts and adjustments are made accordingly. The current allowance is approximately 1% of accounts receivable. For example each additional 1% of accounts receivable that becomes uncollectible would reduce such balance of accounts receivable by approximately $40,000.

Income Taxes –

Income taxes are accounted for under Financial Accounting Standards Board ("FASB") authoritative guidance ("Guidance") which requires the asset and liability method of accounting for deferred income taxes. Deferred tax assets

and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities. Deferred tax assets or liabilities at the end of each period are determined using the tax rate expected to be in effect when taxes are actually paid or recovered. For example, even though we have become profitable, we may be unable to utilize our deferred tax asset, which approximates $7,246,000 at December 31, 2010.

The Guidance also requires that a valuation allowance be established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence needs to be considered, including a company's current and past performance, the market environment in which the company operates, length of carryback and carryforward periods and existing contracts that will result in future profits.

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.

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

The 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.

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, 2010.

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

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

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

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors and Executive Officers

Lawrence A. Siebert (54), 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 (54), Chief Financial Officer. Mr. Larkin was appointed as Chief Financial Officer of Chembio Diagnostics, Inc. upon consummation of the merger in 2004. Mr. Larkin oversees our financial activities and information systems. Mr. Larkin has been the Chief Financial Officer of Chembio Diagnostic Systems Inc. since September 2003. Prior to joining Chembio Diagnostic Systems Inc., Mr. Larkin served as CFO at Visual Technology Group from May 2000 to September 2003, and also led their consultancy program that provided hands-on expertise in all aspects of financial service, including the initial assessment of client financial reporting requirements within an Enterprise Resource Planning (Manufacturing) environment through training and implementation. Prior to joining VTG, he served as CFO at Protex International Corporation from May 1987 to January 2000. Mr. Larkin holds a BBA in Accounting from Dowling College and is a member of the American Institute of Certified Public Accountants.

Javan Esfandiari (44), 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 (57), 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 (48), 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 (60), 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 also served as Chairman of the Board of Directors’ Special Committee for handling certain strategic opportunities. Dr. Meller has been the president of CommSense Inc., a healthcare business development company, since 2001. CommSense Inc. works with clients in Europe, Asia, North America, and the Middle East on medical information technology, medical records, pharmaceutical product development and financing, health services operations and strategy, and new product and new market development. From 1999 until 2001 Dr. Meller was the executive vice president, North America, of NextEd Ltd., a leading internet educational services company in the Asia Pacific region. Dr. Meller also was a limited partner and a member of the Advisory Board of Crestview Capital Master LLC, which 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 (54), Director. Ms. Davis was elected to the Company's Board of Directors in May 2007, and currently serves on the Board of Director's Audit, Compensation and Nominating And Corporate Governance Committees, including as Chairman of each of the Audit Committee and the Nominating And Corporate Governance Committee. Ms. Davis also served on the Boards' Special Committee for handling certain strategic opportunities. Since January 2007, Ms. Davis has been the owner of Davis Design Group LLC, a company that provides analytical and visual tools for public policy design. Previously, from February 2005 to December 2006, she served as the Chief Executive Officer of Global Access Point, a start-up company with products for data transport, data processing, and data storage network and hub facilities. From October 2003 to January 2005, Ms. Davis was Lieutenant Governor of the State of Indiana, and from January 2000 to October 2003 was Controller of the City of Indianapolis. From 1989 to 2003, Ms. Davis held leadership positions with agencies and programs in the State of Indiana including State Budget Director, Secretary of Family & Social Services Administration, and Deputy Commissioner of Transportation. From 1982 to 1989 Ms. Davis held increasingly senior positions with Cummins Engine, where she managed purchasing, manufacturing, engineering, and assembly of certain engine product lines. Ms. Davis also led the startup of and initial investments by a $50 million Indiana state technology fund, serves on the not-for-profit boards of Noble of Indiana, University of Evansville Institute of Global Enterprise, Purdue College of Science Dean's Leadership Council and Indiana University School of Public and Environmental Affairs Dean's Advisory Council. She has a Masters of Business Administration from Harvard Business School and a Bachelor of Science in Mechanical Engineering from the Massachusetts Institute of Technology. Ms. Davis has varied experience in business, political and financial areas made her an excellent candidate for serving on the board.

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, 2010, 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 May 18, 2010 that covered one report and one transaction and one Form 4/A filed on December 20, 2010 covering one report with one transaction that were not reported on a timely basis; (ii) one Form 4 for Lawrence Siebert filed on December 21, 2010 that covered one report and two transactions; (iii) one Form 4 for Javan Esfandiari filed on March 18, 2010 that covered one report and one transaction; and (iv) one Form 4 for Katherine Davis that covered one report and two 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 and our two most highly compensated executive officers other than our principal executive officer whose annual compensation exceeded $100,000.

Name / Principal Position	Year	Salary1 ($)	Bonus2 ($)	Option Awards3 ($)	Stock Awards ($)	All Other Compensation5 ($)	Total ($)
Lawrence A. Siebert4	2010	$ 265,000	$ 99,375	$ -	$ -	$ 7,200	$ 371,575
CEO	2009	265,000	110,200	37,950	-	7,200	420,350
Javan Esfandiari	2010	$ 230,192	$ 80,850	$ 66,030	$ -	$ 4,800	$ 381,872
VP-R&D	2009	230,192	29,400	28,200	5,000	4,883	297,675
Tom Ippolito	2010	$ 185,815	$ 42,656	$ -	$ -	$ -	$ 228,471
VP-Regulatory	2009	181,500	35,600	21,150	-	140	238,390

1 Salary is total base salary.
2 Bonuses earned in 2010 and 2009 were partially based on reaching certain objectives, which included revenue dollar levels and operating profit levels, additional amounts earned were discretionary.
3 The estimated fair value of any option or common stock granted was determined in accordance with ASC 718, "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 through May 11, 2012. On June 15, 2006, Mr. Siebert and the Company entered into an Employment Agreement, effective May 10, 2006, which was to terminate on May 10, 2008, extended in 2008 to May 10, 2009. Pursuant to the Employment Agreement, Mr. Siebert serves as the President and Chief Executive Officer of the Company and received an initial salary of $240,000 per year, which had been increased to $265,000 per year until Mr. Siebert agreed to a 15 percent reduction, to $225,000, effective January 19, 2009. Mr. Siebert's salary was restored to $265,000 per annum effective in July 2009. Mr. Siebert also is eligible for a bonus of up to 50% of his salary, consisting of (i) a bonus of up to 25% of his salary that is at the complete discretion and determination of the board of directors, and (ii) a bonus of up to an additional 25% of his salary that will be determined based upon revenue and earnings performance criteria established each year by the board of directors. Mr. Siebert is eligible to participate in any profit sharing, stock option, retirement plan, medical and/or hospitalization plan, and/or other benefit plans except for disability and life insurance that the Company may from time to time place in effect for the Company's executives during the term of Mr. Siebert's employment agreement. If Mr. Siebert's Employment Agreement is terminated by the Company without cause, or if Mr. Siebert terminates his Employment Agreement for a reasonable basis, as defined in the Employment Agreement, including within 12 months of a change in control, the Company is required to pay as severance Mr. Siebert's salary for six months. Mr. Siebert has agreed for a period of two years after the termination of his employment with the Company not to induce customers, agents, or other sources of distribution of the Company's business under contract or doing business with the Company to terminate, reduce, alter, or divert business with or from the Company. The terms of the extended May 11, 2009 and May 11, 2008 Employment Agreements are identical to the June 15, 2006 Employment Agreement,

except that under the May 11, 2008 extended Employment Agreement, Mr. Siebert received additional consideration in the form of incentive stock options to purchase 250,000 shares of the Company’s common stock exercisable at $0.13 per share, which was the closing price of the Company's common stock on June 3, 2008. The incentive stock options are immediately exercisable and they expire on the June 3, 2013.

Mr. Esfandiari. The Company entered into an employment agreement dated March 4, 2010, and to be effective March 5, 2010 (the "Employment Agreement"), with Mr. Esfandiari to continue as the Company's Senior Vice President of Research and Development for an additional term of three years through May 5, 2013. Mr. Esfandiari's salary under the Employment Agreement is $245,000 for the first year, $255,000 for the second year, and $265,000 for the final year. Mr. Esfandiari is eligible for a cash bonus of up to 50% of his base salary for each respective year, 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, options to purchase 100,000 shares vest on the effective date, options to purchase an additional 100,000 shares of the stock options vest on the second anniversary of the Employment Agreement, and options to purchase an additional 100,000 shares of the stock options vest on the third anniversary of the Employment Agreement. Mr. Esfandiari is eligible to participate in any profit sharing, stock option, retirement plan, medical and/or hospitalization plan, and/or other benefit plans except for disability and life insurance that the Company may from time to time place in effect for the Company’s executives during the term of Mr. Esfandiari’s employment agreement. If Mr. Esfandiari’s employment agreement is terminated by the Company without cause, or if Mr. 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. The Compensation Committee determined that 40% of the executive's bonus will be quantitative factors, based on the budget. 60% will be based on other factors; with one-half of the 60% (or 30%) based on management objectives, and the other one-half of the 60% (or 30%) will be discretionary. The plan, during 2010 for the 40%, called for a sliding percentage of the executive's salary, from zero to 5% for attaining 85% to 100% of revenue goals, and from zero to 5% of the executive's salary for attaining between zero percent to 150% of the designated operating profit goals. The Company achieved 93% of its revenue goals for 2010, resulting in a bonus of 2.75 of each executive's salary, and achieved greater than 95% of its operating profit goal, resulting in a bonus of 2.25% of salary, for a total of 5% of salary. In addition, the Compensation Committee approved 7.5% of salary in discretionary bonuses for the subject executives and 7.5% in management objectives, bringing the total plan bonus to approximately 20% of salary. In addition, outside of the plan, the compensation committee awarded an additional 2.75% in bonuses in recognition outstanding overall efforts and accomplishments, making the total bonus for 2010 equal to 22.75% of base pay. Goals for 2011 have not yet been established.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END 2010

	Option Awards					Stock Awards		
Name	Number of Securities Underlying Unexercised Options Excerciseable (#)	Number of Securities Underlying Unexercised Options Unexcersable (#)	Option Exercise Price ($)	Option Expiration Date	Option Vesting Date	Number of Shares of Stock That Have Not Vested (#)	Market Value of Shares of Stock That Have Not Vested ($)	Foot-note
Lawrence A. Siebert		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	$ 69,500	$ -	$ 69,500
Gary Meller	86,500	$ -	86,500

1 Fees earned or paid in cash represents a yearly fee and fees for meeting expenses: (a) Ms. Davis received an $18,000 annual fee as a member of the board of directors, a $2,500 annual fee as audit committee chairman, $40,000 as a member of a special committee and $9,000 in meeting fees paid during 2010; (b) Mr. Meller received an $18,000 annual fee as a member of the board of directors, $60,000 as a member of a special committee and $9,000 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.

Director Compensation

All non-employee directors are paid an $18,000 annual retainer in semi-annual payments, and once every five years, on the date of the annual meeting of stockholders that directors are elected or re-elected (every 5 years), receive stock options to acquire, subject to vesting as described below, 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. Directors also may be paid for serving ad hoc committees of the Board. In fact, when the Board established its Special Committee in 2010 to handle the possible sale of the Company, the Chairman of the Committee was paid $12,000 per month, and the other director-member of the Committee was paid $8,000 per month.

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, 2010. No member of the Compensation Committee serves as an executive officer of any other public company during the year ended December 31, 2010. No interlocking relationship exists between the members of our Compensation Committee and the Board or compensation committee of any other company.

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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, 2011.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Owner	Percent of Class
Siebert, Lawrence (1) 3661 Horseblock Road Medford, NY 11763	6,871,715	10.93%
Esfandiari, Javan (2) 3661 Horseblock Road Medford, NY 11763	977,573	1.55%
Larkin, Richard (3) 3661 Horseblock Road Medford, NY 11763	359,338	0.58%
Ippolito, Tom (4) 3661 Horseblock Road Medford, NY 11763	140,000	0.22%
Bruce, Richard (5) 3661 Horseblock Road Medford, NY 11763	210,075	0.34%

Meller, Gary (6) 3661 Horseblock Road Medford, NY 11763	598,000	0.96%
Davis, Katherine L. (7) 3661 Horseblock Road Medford, NY 11763	238,366	0.38%
GROUP (8)	9,395,067	14.58%
Alere, Inc. 51 Sawyer Road, Suite 200 Waltham, MA 02453	5,367,840	8.62%
Crestview Capital Offshore Fund, Inc. 95 Revere Drive, Suite A Northbrook, IL 60062	3,177,950	5.11%

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 (62,240,483) of the Company's common stock outstanding as of March 1, 2011. 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 2010, 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 2010.

(1) Includes 618,333 shares issuable upon exercise of options exercisable within 60 days. Does not include 266,667 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(2) Includes 707,500 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.
(3) Includes 204,166 shares issuable upon exercise of options exercisable within 60 days. Does not include 183,334 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(4) Includes 140,000 shares issuable upon exercise of options exercisable within 60 days. Does not include 150,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(5) Includes 185,000 shares issuable upon exercise of options exercisable within 60 days. Does not include 150,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(6) Includes 198,000 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)

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Equity Compensation Plan Information

Combined Equity Compensation Plans - Information as of December 31, 2010

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column (a)
	(a)	(b)	(c)
Equity compensation plans approved by security holders1	5,530,5681	$0.156	1,571,350
Equity compensation plans not approved by security holders	--	--	--
Total	5,530,568	$0.156	1,571,350

1 The "Number of Securities to be Issued Upon Exercise of Outstanding Warrants and Rights" represents 2,130,250 from the 1999 Stock Option Plan and 3,400,318 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.

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, Alere notified the Company that Alere 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 Alere to pay past royalties. On June 25, 2009, the Company and Alere 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 Alere for the amount of HIV-2 royalties that Alere paid when Alere 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 Alere of approximately $525,000 as of December 31, 2008. Under the agreement Alere 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. As of December 31, 2010 this balance was fully paid.

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 Gary Meller and Katherine L. Davis currently qualify as independent directors. We do not list the "independent" definition we use on our internet website.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

All fees discussed below were paid to ParenteBeard LLC.

Audit Fees

For the years ended December 31, 2010 and 2009, the Company's independent accounting firm billed the Company $154,620 and $160,000, 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, 2010 and 2009, 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, 2010 and 2009, the independent accounting firm billed the Company $9,415 and $20,000, respectively, for professional services for tax compliance, tax advice and tax planning.

All Other Fees

For the years ended December 31, 2010 and 2009, the independent accounting firm billed the Company $19,208 and none 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)
4.1	Form of Common Stock Warrant issued pursuant to the January 26, 2005 Securities Purchase Agreement. (6)
4.2	Amended Form of Common Stock Warrant issued pursuant to the January 26, 2005 Securities Purchase Agreement. (8)
4.3	Registration Rights Agreement, dated as of January 26, 2005, by and among the Registrant and the purchasers listed therein. (8)
4.4	Form of Warrant, dated June 29, 2006, issued pursuant to Company and purchasers of the Company's Secured Debentures. (6)
4.5	Registration Rights Agreement, dated June 29, 2006. (3)
4.6	Registration Rights Agreement, dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (5)
4.7	Form of Common Stock Warrant issued pursuant to the Securities Purchase Agreements dated September 29, 2006 (5).
4.8	Amended Form of Common Stock Warrant issued pursuant to the Securities Purchase Agreements dated October 5, 2006. (5)
4.9	Amended Form of Common Stock Warrant issued to Placement Agents pursuant to the October 5, 2005 Securities Purchase Agreement. (8)
4.10*	Form of Employee Option Agreement. (8)
4.11	1999 Equity Incentive Plan. (9)
4.12	2008 Stock Incentive Plan. (10)
4.21	Rights Agreement, dated March 8, 2010 (11)
4.22	Form of Warrant (to be filed by amendment)
10.1*	Employment Agreement dated June 15, 2006 with Lawrence A. Siebert. (4)
10.2*	Employment Agreement dated March 5, 2010 with Javan Esfandiari. (12)
10.3	Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of January 26, 2005, by and among the Registrant and the purchasers listed therein. (6)
10.4	Amendment No. 1 to Securities Purchase Agreement, dated as of January 28, 2005 by and among the Registrant and the purchasers listed therein. (7)
10.5	Security Purchase Agreement, dated June 29, 2006, among the Company and purchasers of the Company's Secured Debentures. (3)
10.6	Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (5)
10.7	Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (5)
10.8	Letter of Amendment to Securities Purchase Agreements dated as of September 29, 2006 by and among the Registrant and the Purchasers listed therein. (5)
10.9	HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Alere and StatSure. (5)
10.1	HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (5)
10.11	Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (5)
10.12	Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (5)
10.13	Secured Term Note, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (13)

10.14	Secured Revolving Demand Note, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (13)
10.15	Loan and Security Agreement, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (13)
14.1	Ethics Policy (14)
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 (File No. 333-85787) filed with the Commission on August 23, 1999 and the Registrant's Forms 8-K filed on May 14, 2004, December 20, 2007 and April 18, 2008.
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 Current Report on Form 8-K filed with the Commission on January 31, 2005.
7	Incorporated by reference to the Registrant’s registration statement on Form SB-2 filed with the Commission on March 28, 2005.
8	Incorporated by reference to the Registrant’s annual report on Form 10-KSB filed with the Commission on March 12, 2008.
9	Incorporated by reference to the Registrant’s definitive proxy statement on Schedule 14A filed with the Commission on May 11, 2005.
10	Incorporated by reference to the Registrant’s definitive proxy statement on Schedule 14A filed with the Commission on April 14, 2008.
11	Incorporated by reference to the Registrant’s registration statement on Form 8-A filed with the Commission on March 11, 2010.
12	Incorporated by reference to the Registrant’s registration statement on Form S-1/A filed with the Commission on March 11, 2010.
13	Incorporated by reference to the Registrant’s Quarterly Report on Form 10-Q filed with the Commission on July 29, 2010.
14	Incorporated by reference to the Registrant’s annual report on Form 10-KSB filed with the Commission on March 30, 2006.
(*)	An asterisk (*) beside an exhibit number indicates the exhibit contains a management contract, compensatory plan or arrangement which is required to be identified in this registration statement.

SIGNATURES

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

CHEMBIO DIAGNOSTICS, INC.

Date: March 3, 2011 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 3, 2011
/s/ Richard J. Larkin Richard J. Larkin	Chief Financial Officer (Principal Financial & Accounting Officer)	March 3, 2011
/s/ Gary Meller Dr. Gary Meller	Director	March 3, 2011
/s/ Katherine L. Davis Katherine L. Davis	Director	March 3, 2011

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

Index to Consolidated Financial Statements

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To The Board of Directors and Stockholders of
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, 2010 and 2009 and the related consolidated statements of operations, stockholders' equity and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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 audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Chembio Diagnostics, Inc. and Subsidiary as of December 31, 2010 and 2009, and the consolidated results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

PARENTEBEARD LLC

/s/ PARENTEBEARD LLC

New York, New York
March 3, 2011

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

	December 31, 2010	December 31, 2009
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	$ 2,136,351	$ 1,068,235
Accounts receivable, net of allowance for doubtful accounts of $35,000 and $20,000 for 2010 and 2009, respectively	3,946,398	1,776,327
Inventories	1,349,161	1,555,903
Prepaid expenses and other current assets	204,824	266,637
TOTAL CURRENT ASSETS	7,636,734	4,667,102
FIXED ASSETS, net of accumulated depreciation	813,214	580,213
OTHER ASSETS:		
License agreements, net of current portion	600,000	700,000
Deposits on manufacturing equipment	-	338,375
Deposits and other assets	36,226	29,560
TOTAL ASSETS	$ 9,086,174	$ 6,315,250
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	$ 2,055,943	$ 1,906,163
Current portion of loans payable	55,817	9,600
Deferred research and development revenue	65,000	360,833
License fee payable	875,000	875,000
Current portion of obligations under capital leases	24,697	21,536
TOTAL CURRENT LIABILITIES	3,076,457	3,173,132
OTHER LIABILITIES:		
Loans payable - net of current portion	186,197	14,931
Obligations under capital leases - net of current portion	14,576	39,273
TOTAL LIABILITIES	3,277,230	3,227,336

COMMITMENTS AND CONTINGENCIES				
STOCKHOLDERS' EQUITY:				
Preferred stock – 10,000,000 shares authorized, none outstanding		-		-
Common stock - $.01 par value; 100,000,000 shares authorized, 62,238,983 and 61,979,901 shares issued and outstanding for 2010 and 2009, respectively		622,390		619,799
Additional paid-in capital		39,658,617		39,453,522
Accumulated deficit		(34,472,063)		(36,985,407)
TOTAL STOCKHOLDERS' EQUITY		5,808,944		3,087,914
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$	9,086,174	$	6,315,250

See accompanying notes to consolidated financial statements

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

	December 31, 2010	December 31, 2009
REVENUES:		
Net product sales	$ 13,516,359	$ 12,372,493
License and royalty revenue	432,238	121,896
R&D, milestone and grant revenue	2,756,106	1,339,859
TOTAL REVENUES	16,704,703	13,834,248
Cost of product sales	8,604,004	7,973,843
GROSS MARGIN	8,100,699	5,860,405
OPERATING EXPENSES:		
Research and development expenses	2,586,308	2,883,696
Selling, general and administrative expenses	2,940,721	2,659,382
	5,527,029	5,543,078
INCOME FROM OPERATIONS	2,573,670	317,327
OTHER INCOME (EXPENSES):		
Other expense	(3,923)	(6,696)
Interest income	4,147	9,032
Interest expense	(14,727)	(10,603)
	(14,503)	(8,267)
INCOME BEFORE INCOME TAXES	2,559,167	309,060
Provision for income taxes	45,823	-
NET INCOME	$ 2,513,344	$ 309,060
Basic earnings per share	$ 0.04	$ 0.00
Diluted earnings per share	$ 0.04	$ 0.00
Weighted average number of shares outstanding, basic	62,102,861	61,946,435
Weighted average number of shares outstanding, diluted	70,920,915	75,041,932

See accompanying notes to consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2010 AND 2009

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount	Amount	Amount	Amount
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	-	-	-	309,060	309,060
Balance at December 31, 2009	61,979,901	$ 619,799	$ 39,453,522	$ (36,985,407)	$ 3,087,914
Warrants and options:					
Excercised	259,082	2,591	35,020		37,611
Stock option compensation			170,075		170,075
Net income				2,513,344	2,513,344
Balance at December 31, 2010	62,238,983	$ 622,390	$ 39,658,617	$ (34,472,063)	$ 5,808,944

See accompanying notes to consolidated financial statements

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

	December 31, 2010	December 31, 2009
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS:		
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers	$ 14,534,632	$ 12,871,921
Cash paid to suppliers and employees	(13,507,202)	(12,618,423)
Interest received	4,147	9,032
Interest paid	(14,727)	(10,603)
Net cash provided by operating activities	1,016,850	251,927
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of fixed assets	-	13,750
Acquisition of fixed assets	(182,292)	(390,738)
Net cash used in investing activities	(182,292)	(376,988)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from option exercises	37,611	-
Proceeds from loan	250,000	4,550
Payment of loan obligation	(32,517)	(4,697)
Payment of capital lease obligation	(21,536)	(18,779)
Net cash provided by financing activities	233,558	(18,926)
INCREASE IN CASH AND CASH EQUIVALENTS	1,068,116	(143,987)
Cash and cash equivalents - beginning of the period	1,068,235	1,212,222
Cash and cash equivalents - end of the period	$ 2,136,351	$ 1,068,235
RECONCILIATION OF NET INCOME TO NET CASH PROVIDED BY OPERATING ACTIVITIES:		

Net income	$ 2,513,344	$ 309,060
Adjustments:		
Depreciation and amortization	283,743	362,338
Provision for doubtful accounts`	15,000	9,699
Loss on retirement/sale of fixed asset	3,923	6,696
Share based compensation	170,075	198,220
Changes in assets and liabilities:		
Accounts receivable	(2,185,071)	(976,723)
Inventories	206,742	263,134
Prepaid expenses and other current assets	61,813	(42,732)
Deposits and other assets	93,334	238,260
Accounts payable and accrued liabilities	149,780	360,833
Deferred research and development revenue	(295,833)	(476,858)
Net cash provided by operating activities	$ 1,016,850	$ 251,927
Supplemental disclosures for non-cash investing and financing activities:		
Deposits on manufacturing equipment transferred to fixed assets	$ 338,375	$ -
Purchase of fixed asset through a loan	-	29,228

See accompanying notes to consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2010 AND 2009

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 90% of the Company's product revenues in 2010. The Company also has other rapid tests that together represented approximately 10% of sales in 2010. The Company's products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments both domestically and internationally. Chembio's products are sold under the Company's STAT PAK®, SURE CHECK® or DPP® registered trademarks, or under the private labels of its marketing partners, for example the Clearview® label owned by Alere, Inc. ("Alere"), which is the Company's exclusive marketing partner for its rapid HIV lateral flow test products in the United States. These products employ lateral flow technologies that are proprietary and/or licensed to the Company. All of the Company's products that are currently being developed are based on its patented Dual Path Platform (DPP®), which is a unique diagnostic point-of-care platform that has certain advantages over lateral flow technology. In 2009 and 2010 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 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, short-term portion of 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 a maturity of three months or less when purchased to be cash equivalents.

(e) Concentrations of Credit Risk:

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of temporary cash investments and trade receivables. The Company places its temporary cash instruments with well-known financial institutions and, at times, may maintain balances in excess of the $250,000 FDIC Insurance limit. The Company monitors the credit ratings of the financial institutions to mitigate this risk. The Company maintains four accounts with a well established multi-national bank and as of December 31, 2010 and 2009 had approximately an aggregate of $1,866,000 and $818,000, respectively 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 for accounts receivable.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2010 AND 2009

(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, based on the expected lifespan of our then current HIV products. 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, 2010 is $600,000 and is reflected in other assets.

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

Long-lived assets to be held and used are analyzed for impairment whenever events or changes in circumstances indicate that the related carrying amounts may not be recoverable. The Company evaluates at each balance sheet date whether events and circumstances have occurred that indicate possible impairment. If there are indications of impairment, the Company uses future undiscounted cash flows of the related asset or asset grouping over the remaining life in measuring whether the assets are recoverable. In the event such cash flows are not expected to be sufficient to recover the recorded asset values, the assets are written down to their estimated fair value. We believe that the carrying values of our long-lived tangible and intangible assets were realizable at December 31, 2010 and 2009, respectively.

(j) Revenue Recognition:

The Company recognizes revenue for product sales in accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 104, “Revenue Recognition” (“SAB 104”). Under SAB 104, revenue is recognized when there is persuasive evidence of an arrangement, delivery has occurred or services have been rendered, the sales price is determinable, and collectability is reasonably assured. Revenue typically is recognized at time of shipment. Sales are recorded net of discounts, rebates and returns.

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

On June 15, 2010, the Company adopted Financial Accounting Standards Board (“FASB”) issued authoritative guidance (“guidance”) prospectively for the recognition of revenue under the milestone method. The Company applies the milestone method of revenue recognition for certain collaborative research projects defining milestones at the inception of the agreement.

Any projects or grants funded in advance are deferred until earned. As of December 31, 2010 and 2009, an aggregate of $65,000 and $361,000, respectively of advanced revenues was unearned.

(k) Research and Development:

Research and development (R&D) costs are expensed as incurred. During the fourth quarter of 2010 the Company was awarded $1,466,875 in Qualified Therapeutic Discovery Project grants (“QTDP”) for the years 2010 and 2009 under Section 48D of the Internal Revenue Code, as enacted under the Patient Protection and Affordable Care Act of 2010. This was reflected as a reduction of R&D costs for the year ended December 31, 2010.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2010 AND 2009

(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 FASB Guidance. The Guidance 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 the Guidance 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 FASB Guidance. The 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.

The Guidance 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. The Guidance 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:

	For the years ended	
	December 31, 2010	December 31, 2009
Basic	62,102,861	61,946,435
Diluted	70,920,915	75,041,932

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, 2010 and 2009 reflects the potential dilution from the exercise or conversion of other securities into common stock. The following securities, presented on a common share equivalent basis, have been used in the diluted per share computations:

	For the years ended	
	December 31, 2010	December 31, 2009
1999 and 2008 Plan Stock Options	5,638,310	4,451,129

Other Stock Options	124,625	124,625
Warrants	3,055,119	8,519,743
	8,818,054	13,095,497

(o) Recent Accounting Pronouncements Affecting the Company:

Revenue Arrangements with Multiple Deliverables

In October 2009, the FASB issued authoritative guidance ("guidance") that amends existing guidance for identifying separate deliverables in a revenue-generating transaction where multiple deliverables exist, and provides guidance for allocating and recognizing revenue based on those separate deliverables. The guidance is expected to result in more multiple- deliverable arrangements being separable than under current guidance. This guidance is effective for the Company beginning January 1, 2011. The Company is evaluating the impact, if any this guidance may have on its consolidated financial statements.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2010 AND 2009

Intangibles – Goodwill and Other

In December 2010, the FASB amended the existing guidance to modify Step 1 of the goodwill impairment test for a reporting unit with a zero or negative carrying amount. Upon adoption of the amendment, an entity with a reporting unit that has a carrying amount that is zero or negative is required to assess whether it is more likely than not that the reporting unit's goodwill is impaired. If the entity determines that it is more likely than not that the goodwill of the reporting unit is impaired, the entity should perform Step 2 of the goodwill impairment test for the reporting unit. Any resulting goodwill impairment should be recorded as a cumulative-effect adjustment to beginning retained earnings in the period of adoption. Any goodwill impairments occurring after the initial adoption of the amendment should be included in earnings. This guidance is effective for the Company beginning January 1, 2011. The Company is currently assessing the impact, if any, this may have on their consolidated financial statements.

Broad Transactions – Business Combination

In December 2010, the FASB amended the existing guidance to require a public entity, which presents comparative financial statements, to disclose revenue and earnings of the combined entity as though the business combination that occurred during the current year had occurred as of the beginning of the comparable prior annual reporting period only.

The amendment also expanded the required supplemental pro forma disclosures to include a description of the nature and amount of material, nonrecurring pro forma adjustments directly attributable to the business combination, which are included in the reported pro forma revenue and earnings. The amendments are effective for the Company beginning January 1, 2011. The Company is currently assessing the impact, if any, this may have on their consolidated financial statements.

NOTE 3— INVENTORIES:

Inventories consist of the following at:

	December 31, 2010	December 31, 2009
Raw materials	$ 785,693	$ 1,031,567
Work in process	235,548	184,081
Finished goods	327,920	340,255
	$ 1,349,161	$ 1,555,903

NOTE 4— FIXED ASSETS:

Fixed assets consist of the following at December 31:

	December 31, 2010	December 31, 2009
Machinery and equipment	$ 1,635,466	$ 1,222,216
Furniture and fixtures	207,485	212,106
Computer and telephone equipment	348,503	329,491

Leasehold improvements	482,215	400,589
Automobiles	29,228	29,228
	2,702,897	2,203,630
Less accumulated depreciation and amortization	(1,889,683)	(1,623,417)
	$ 813,214	$ 580,213

Included in fixed assets is $24,000 and $44,000, net of accumulated depreciation of $87,000 and $66,000 of assets held under capital leases as of December 31, 2010 and 2009, respectively. Depreciation expense for the 2010 and 2009 years aggregated $283,743 and $362,338, respectively.

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NOTE 5— ACCOUNTS PAYABLE AND ACCRUED LIABILITIES:

Accounts payable and accrued liabilities consist of the following at December 31,:

	December 31, 2010	December 31, 2009
Accounts payable – suppliers	$ 883,719	$ 662,739
Accrued commissions	114,451	43,931
Accrued royalties / license fees	352,285	612,709
Accrued payroll	162,740	114,234
Accrued vacation	129,732	99,057
Accrued bonuses	140,325	238,600
Accrued expenses – other	272,691	134,893
TOTAL	$ 2,055,943	$ 1,906,163

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 become fully earned and non-refundable based upon certain conditions being met in June of 2010. In addition, the Company recognizes income from R&D milestones when those milestones are reached and non-milestone contracts and grants when earned. Grants are invoiced after expenses are incurred. Any projects or grants funded in advance are deferred until earned. As of December 31, 2010 and 2009, an aggregate of $65,000 and $361,000 of advanced revenues was unearned.

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

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

The Term Note is payable at $4,775 of principal and interest per month in arrears. The payment was calculated by amortizing the $250,000 note over 60 months at an interest rate of 5.5% per annum. The Term Note matures June, 2015 and is secured under the terms of the Security Agreement.

The Demand Note allows the Company to draw on the line from time to time an amount up to an aggregate of $250,000 outstanding at any one time. The accrued interest on the Demand Note is payable monthly at an interest rate equal to one-quarter percent above prime per annum. The Company can repay any or all of the principal balance outstanding at any time. This is a demand note and is subject to annual reviews, as well as a 30-day clean-up, during which there can be no amounts outstanding.

The Security Agreement contains covenants that place annual restrictions on the Company’s assets and operations, including covenants relating to mergers, debt restrictions, capital expenditures, tangible net worth, net profit, leverage, fixed charge coverage, employee loan restrictions, distribution restrictions (common stock and preferred stock), dividend restrictions, restrictions on lease payments to affiliates, restrictions on changes in business, asset sale

restrictions, restrictions on acquisitions and intercompany transactions, restrictions on fundamental changes. The Security Agreement also requires that the Company maintain a minimum tangible net worth at all times of greater than $3,000,000 and EBITDA to CMLTD plus interest cannot be less than 1.25 to 1.00 for any fiscal year. (CMLTD is defined as any one-year period, the current scheduled principal payments required to be paid for the applicable period.). The Company was in compliance with all required financial covenants at December 31, 2010. The Security Agreement requires that the Demand Note has an annual 30-day clean-up, during which there can be no amounts outstanding.

The Company currently maintains its operating, payroll, and primary cash accounts at HSBC. The balance due on the Term Note as of December 31, 2010 was $228,000 and nothing was drawn down on the Demand Note as of December 31, 2010.

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Future minimum payments under the Term Note, excluding interest, as of December 31, 2010 were as follows:

Periods ending December 31,

2011	$45,911
2012	48,501
2013	51,236
2014	54,126
2015	28,121
	227,895
Less: current maturities	(45,911)
	$ 181,984

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, 2010 was $14,119.

Future minimum payments under this obligation, excluding interest as of December 31, 2010 were as follows:

Year ending December 31,

2011	$9,906
2012	4,213
	14,119
Less: current maturities	(9,906)
	$ 4,213

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. 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 which was paid on January 3, 2011. 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.

NOTE8—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, 2010 were as follows:

Year ending December 31,

2011	$28,572
2012	15,203
	43,775
Less imputed interest	(4,502)
Present value of future minimum lease payments	39,273
Less current maturities	(24,697)
	$ 14,576

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

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NOTE 9— RELATED PARTIES:

In September 2006, the Company entered into distribution and licensing agreements with Alere, Inc. ("Alere"). As of December 31, 2010 Alere owned 8.62% of the Company. See Note 15 where Alere is listed as customer 1.

During the quarter ended December 31, 2008, Alere notified the Company that they 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 Alere to pay past royalties. On June 25, 2009, the Company and Alere 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 included the Company's royalties owed under its agreements with Alere on lateral flow licenses. This amount was fully paid in 2010.

NOTE 10— INCOME TAXES:

The provision for income taxes for the years ended December 31, 2010 and 2009, are comprised of the following:

	2010	2009
Current		
Federal	$ 45,122	$ -
State	702	-
Total current provision	45,824	-
Deferred		
Federal	-	-
State	-	-
Total deferred provision	-	-
Total provision	$ 45,824	$ -

At December 31, 2010, the Company has unused net operating loss carry-forwards of approximately $19,000,000 which expire between 2018 and 2028. 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 $594,000 for the year ended December 31, 2010 which expires between 2011 and 2029.

As of December 31, 2010 and 2009, 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:

	2010	2009
Current assets		
Inventory	$ 198,000	$ 124,000
Less valuation allowance	(198,000)	(124,000)

Net current deferred asset	$ —	$ —
Noncurrent assets		
Net operating loss carry-forwards	$ 6,618,000	$ 7,490,000
Research and development credit	594,000	628,000
Other	34,000	176,000
Gross deferred tax assets	7,246,000	8,294,000
Less valuation allowances	(7,246,000)	(8,294,000)
Net deferred tax assets	$ —	$ —

The change in the valuation allowances between 2010 and 2009 are mainly due to the utilization of net operating loss carryfowards.

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

	Year Ending December 31,			
	2010		2009	
Federal income tax (benefit) at statutory rates	34.0	%	34.0	%
State income taxes, net of federal benefit	-	%	-	%
Nondeductible expenses	2.0	%	17.8	%
Change in valuation allowance	(34.4	) %	(52.3	) %
Other	.2	%	.5	%
Income tax (benefit)	1.8	%	-	%

Interest and penalties, if any, related to income tax liabilities are included in income tax expense. As of December 31, 2010, 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 2007 through 2009 are open and potentially subject to examination by the federal and New York state taxing authorities.

NOTE 11— STOCKHOLDERS' EQUITY:

(a) Common Stock

During 2010, options to purchase 259,082 shares of the Company's common stock were exercised at exercise prices ranging from of $.13 to $.22.

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

(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

In January 2010, certain warrants to purchase an aggregated 4,960,370 shares of common stock expired, at an average exercise price of $.474. In August 2010, certain warrants to purchase an aggregated 94,650 shares of common stock expired, at an average exercise price of $.687.

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

NOTE 12— RIGHTS AGREEMENT:

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

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

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

NOTE 13— 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.

The Company's results for the years ended December 31, 2010 and 2009 include share-based compensation expense totaling $170,000 and $198,000, respectively. Such amounts have been included in the Consolidated Statements of Operations within cost of goods sold ($20,000 and $25,000, respectively), research and development ($86,000 and $75,000, respectively) and selling, general and administrative expenses ($64,000 and $98,000, 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, 2010 and 2009 represents the estimated fair value of options outstanding which is being amortized on a straight-line basis over the requisite vesting period of the entire award.

The weighted average estimated fair value of stock options granted in the years ended December 31, 2010 and 2009 was $.22 and $.13 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.

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

	For the years ended	
	December 31, 2010	December 31, 2009
Expected term (in years)	4	1 to 4
Expected volatility	116.82%	123.81%
Expected dividend yield	n/a	n/a
Risk-free interest rate	1.43%	.54 - 1.95%

The Company granted 300,000 new options under the SIP plan during the year ended December 31, 2010 at an exercise price of $.27 per share.

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.

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, 2010 and 2009:

Stock Options	Number of Shares	Weighted Average	Weighted Average	Aggregate Intrinsic Value

		Exercise Price per Share	Remaining Contractual Term	
Outstanding at January 1, 2009	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
Granted	300,000	$0.27		
Exercised	(259,082)	$0.15		
Forfeited/expired/cancelled	(97,250)	$0.26		
Outstanding at December 31, 2010	5,530,568	$0.16	2.82 years	$ 1,497,063
Exercisable at December 31, 2010	2,963,893	$0.17	2.30 years	$ 767,893

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The following table summarizes information about stock options outstanding at December 31, 2010:

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 - $ 0.13	4,636,068	3.86	$ 0.130	$ 1,367,640	2,269,393	$ 0.130	$ 669,471
$ 0.14 - $ 0.22	404,500	3.13	0.220	46,500	404,500	0.220	82,923
$ 0.23 - $ 0.45	300,000	5.18	0.270	82,923	100,000	0.270	15,500
$ 0.46 - $ 0.88	190,000	2.15	0.501	-	190,000	0.501	-
Total	5,530,568	3.82	$ 0.157	$ 1,497,063	2,963,893	$ 0.171	$ 767,894

As of December 31, 2010, there was $102,000 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 .88 years. The total fair value of shares vested during the years ended December 31, 2010 and 2009, was $124,000 and $60,000, respectively.

NOTE 14— GEOGRAPHIC INFORMATION:

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

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

	For the years ended	
	December 31, 2010	December 31, 2009
Africa	$ 6,129,167	$ 3,351,115
Asia	120,212	165,293
Europe	107,060	111,755
Middle East	135,000	185,700
North America	5,977,108	6,129,789

South America	1,047,812	2,428,841
	$ 13,516,359	$ 12,372,493

Sales to Africa in 2010 were primarily to Ethiopia of approximately $3.69 million and Nigeria of approximately $.87 million. Sales in 2010 to North America were primarily from sales in the U.S of approximately $5.28 million and sales in 2010 to South America were primarily from sales in Brazil of approximately $.82 million.

During 2009, the Nigerian Ministry of Health reverted back to a parallel testing algorithm (wherein each patient is tested with two rapid tests from different manufacturers) and re-instated our designation in Nigeria as one of the screening tests. Consequently, our sales to Nigeria increased by $209,000 in 2010 as compared to 2009.

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NOTE 15— 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:

2011	$ 518,300
2012	373,750
2013	44,200
	$ 963,250

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 none and $1,534 for the years ended December 31, 2010 and 2009, respectively.

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

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,

2011	$	179,329
2012		179,329
2013		179,329
2014		59,776
	$	597,763

Rent expense was $174,200 and $145,300 for the years ended December 31, 2010 and 2009, respectively.

Economic Dependency:

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

	For the years ended				Accounts Receivable
	December 31, 2010		December 31, 2009		As of
	Sales	% of Sales	Sales	% of Sales	December 31, 2010
Customer 1	5,281,111	39	5,240,996	42	724,983
Customer 2	3,689,865	27	1,292,640	10	1,424,563
Customer 3	*	*	2,293,770	19	741,089

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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, 2010		December 31, 2009		As of
	Purchases	% of Purc.	Purchases	% of Purc.	December 31, 2010
Vendor 1	596,556	18	575,362	20	45,035

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

NOTE 16— COLLABORATIVE RESEARCH AND DEVELOPMENT ARRANGEMENTS:

In 2010 and 2009, the Company earned $2.8 million and $1.3 million, respectively from research revenues and milestones. The Company is now involved in additional feasibility and development contracts related to its DPP® technology. The total expended on R&D in 2010 and 2009, not including regulatory and QTDP, was approximately $2.9 million and $2.4 million, respectively. During the fourth quarter of 2010 the Company was awarded $1.47 million from the Qualified Therapeutic Discovery Project grant, which reduced 2010 R&D expenses to $1.4 million.

a. Bio-Rad:

On April 16, 2008, the Company entered into a development agreement (“Bio-Rad Agreement”) with Bio-Rad Laboratories, N.A. (“Bio-Rad”). The Bio-Rad Agreement is for the development of a new multiplex product (“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. The agreement with Bio-Rad contemplated that the Company would enter into a license agreement subject to the satisfaction of certain initial development milestones.

In accoradnace with guidance, management has concluded the Bio-Rad events recorded this year meet the definition of milestone events. The Company earned $615,000 and $0 for the years ended December 31, 2010 and 2009, respectively.

There are additional royalties and purchase commitments due to the Company to be executed in the future which will result in a larger revenue stream. Under the Bio-Rad agreement, the Company granted to Bio-Rad a royalty free license when the Company manufactures the product, and when Bio-Rad manufactures the product a seven percent royalty payment on net sales in those countries and other jurisdictions where Chembio has filed the relevant patent.

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b. Oswaldo Cruz Foundation/Fiocruz:

During 2008, the Company signed four Agreements with the Bio-Manguinhos unit of the Oswaldo Cruz Foundation of Brazil (“FIOCRUZ”) for the supply, license and transfer of certain products and related technologies from the Company to FIOCRUZ. The agreements are for the following rapid test products: i) DPP® HIV 1/2 Screen, ii) DPP® HIV 1/2 Confirmatory, iii) DPP® Leptospirosis and iv) DPP® Leishmaniasis. These Agreements provide for a staged technology transfer collaboration pursuant to which FIOCRUZ will ultimately be able to fully manufacture the applicable product for supply in Brazil provided certain minimum purchases of products and related components have occurred.

In accordance with guidance, management has concluded the FIOCRUZ events recorded this year meet the definition of milestone events. The Company earned $625,000 for the year ended December 31, 2010. Future milestone revenues expected from the agreements are $405,000.

There are additional royalties and purchase commitments due to the Company to be executed in the future which will result in a larger revenue stream.

c. Infectious Disease Research Institute (IDRI) Agreement:

In April 2009, Chembio entered into a development agreement for up to approximately $400,000 in connection with the development and initial supply of a low-cost, rapid point-of-care ("POC") test for infectious diseases. The agreement contemplates a period of approximately two years in which the development activity is to be completed. Chembio entered this agreement with IDRI.

As of December 31, 2010, the Company received $138,000 in research and development payments from this agreement and $65,000 is reflected in deferred revenue.

d. National Institutes of Health (NIH) Grant:

In June 2009, the Company received a $3 million, three-year grant from the United States National Institutes of Health to complete development of a test for Leptospirosis. Grants are invoiced after expenses are incurred.

e. Battelle/CDC DPP® Influenza Immunity Test:

In December 2009, Chembio entered into a 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.

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Based on the following events, in accordance with guidance, management has concluded the Battelle milestones recorded this quarter meet the definition of milestone events.

As of December 31, 2010, the Company recognized $803,900 in milestone revenues from this agreement.

Governmental Regulation:

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