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, 2008

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

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

As of the last business day of the Company's most recently completed second fiscal quarter, the aggregate market value of voting and non-voting common equity held by non-affiliates* was $5,970,000.

As of March 17, 2009, the registrant had 61,944,901 common shares outstanding.

* Without asserting that any of the issuer's directors or executive officers, or the entities that own 38,252,448 shares of common stock are affiliates, the shares of which they are beneficial owners have been deemed to be owned by 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 terms or other comparable terminology, we are identifying forward-looking statements. Forward-looking statements involve risks and uncertainties, which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. These factors include our research and development activities, distributor channels, compliance with regulatory impositions; and our capital needs. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

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

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

General

Chembio Diagnostics, Inc. (referred to collectively with its subsidiaries as the "Company") and its subsidiaries develop, manufacture and market rapid diagnostic tests that detect infectious diseases. The Company's main products presently commercially available are three rapid tests for the detection of HIV antibodies in whole blood, serum and plasma samples, all of which employ lateral flow technology, and two of which were approved by the FDA in 2006. In addition, we have a fourth rapid HIV test, developed on our patented Dual Path Platform (DPP®) technology, for the detection of antibodies to HIV in oral fluid samples, as well as whole blood, serum and plasma samples. The products which employ lateral flow technology are manufactured and sold under a non-exclusive license we have from Inverness Medical Innovations, Inc. ("Inverness"), which is also our exclusive marketing partner for the FDA-approved products in the United States (as well as Europe and Asia for the product that is known as the "barrel" format product) under its Clearview® brand. Inverness launched its marketing of these products in the United States in February 2007. Chembio's two HIV STAT-PAK® rapid HIV tests (in cassette and dipstick formats) are marketed outside the United States through different partners and channels under our license from Inverness.

On March 13, 2007, we were issued United States patent #7,189,522 for our Dual Path Platform (DPP®) rapid test system. Additional patent protection for DPP® is pending worldwide. DPP® enables Chembio to participate in the growing point–of-care diagnostics market with a patent-protected point-of-care platform technology. DPP® devices enable the development of products whose performance we believe exceeds that of comparable tests developed with lateral flow technology. As stated above we have completed development of an oral fluid HIV test on this new platform and are currently pursuing the commercialization of this product in several markets. We have also developed and/or are developing several other products on DPP®. We believe that DPP® provides significant advantages as a point-of-care platform particularly where challenging sample matrices, such as oral fluid, are involved, or where multiplexing is desired. We are developing all of our new products using this platform. Our strategy for the development of this platform technology is also dual; we have entered and are seeking to enter exclusive collaborations with large marketing partners for whom we will develop and manufacture products on the DPP® and we are developing our own products that we may choose to market through selected distribution partners either under a Chembio, DPP® or other brand.

Our products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, and medical professionals. Our products are sold either under our DPP®, STAT-PAK® or SURE CHECK® registered trademarks and/or the private labels of our marketing partners, such as is the case with the Inverness Clearview® label for our rapid HIV tests in the United States.

Rapid HIV Tests

The major component of our revenue growth in 2008 was increased sales of our rapid HIV tests and related components. A large percentage of individuals that are HIV positive worldwide are unaware of their status. Part of the reason for this is that even those that do get tested in public health settings will often not return or call back for their test results if samples have to be sent out to a laboratory which can take at least several days to process. The increased availability, greater efficacy and reduced costs for anti-retroviral treatments (ARVs) for HIV is also having a tremendous impact on the demand for testing, as the stigma associated with the disease is lessened, and the ability to resume normal activities is substantially improved, providing a positive message to those potentially infected. All four of our rapid HIV tests are qualitative "yes/no" tests for the detection of antibodies to HIV 1 & 2 with results available within approximately 15 minutes. The tests differ principally only in the method of sample collection and test procedure, flexibility with different sample types, and cost of manufacture. Prior to our agreement with Inverness, our rapid HIV tests had been marketed under either our SURE CHECK® or STAT-PAK® trademarks. Pursuant to our agreement with Inverness Medical Innovations, Inc., the SURE CHECK® product (which incorporates a proprietary barrel format) is now being marketed by Inverness as Clearview® Complete HIV 1/2 and the cassette format of our HIV 1/2 STAT-PAK (we also have a third product known as HIV 1/2 STAT-PAK dipstick) is now being marketed by Inverness in the United States as Clearview® HIV 1/2 STAT-PAK®. We continue to market our STAT-PAK® cassette and dipstick outside the United States through other marketing channels. In addition, in 2008 we amended the agreement with Inverness, which previously had global exclusivity for the barrel format product, to a non-exclusive in Africa and Latin America. We will begin to market our DPP® oral fluid test globally (including in the United States) as we establish required regulatory clearances and authorizations, which we expect to receive during this year for certain markets in the developing world, though there is no assurance that this will occur.

Regulatory Status:

Rapid HIV Tests

The FDA approved our Pre-Market Applications (hereinafter "PMA"; see "Governmental Regulations" and Glossary) for our SURE CHECK HIV 1/2 (and also now Inverness' Clearview® Complete HIV 1/2) and HIV 1/2 STAT-PAK (now Inverness' Clearview® HIV 1/2 STAT-PAK in the United States only) products on May 25, 2006. A Clinical Laboratory Improvement Act ("CLIA") waiver was granted by the FDA for the HIV 1/2 STAT-PAK on November 20, 2006. Labeling changes to the Inverness Clearview® brands for both products were approved during the first quarter of 2007. CLIA waiver for the Clearview® Complete HIV 1/2 was granted on October 22, 2007. CLIA waiver is required in order to market the products for use in hospital emergency rooms, public health clinics and physicians' offices, where the level of training is traditionally less than the training at clinical laboratories and laboratories in hospitals. These settings constitute the largest portion of the available market for our products. Our third lateral flow rapid HIV test, HIV 1/2 STAT-PAK Dipstick and our DPP® oral fluid HIV test, though not FDA approved, qualify under FDA export regulations to sell, subject to any required approval by the importing country, to customers outside the United States. The dipstick product is our most competitively priced version of our three rapid HIV tests, and was designed primarily for resource-constrained, donor-funded markets that have large test volume needs. Although we have received approval from a number of potential importing countries for three of our lateral flow HIV tests, Brazil, Mexico, Nigeria, Ethiopia and Uganda are the countries in which we have realized significant sales. As a result of favorable evaluations of our HIV 1/2 STAT-PAK and HIV 1/2 STAT-PAK Dipstick products by the World Health Organization (the "WHO"), these products are qualified for procurement by programs funded by the United Nations and their partners' programs. All three of our lateral flow HIV tests have qualified for procurement under the President's Emergency Plan for AIDS Relief ("PEPFAR"). During the first quarter of 2009 we submitted our oral fluid DPP® HIV 1/2 test, to these same agencies for inclusion in these programs. We also have other evaluations ongoing for this new product and anticipate commencement of clinical trials in the United States in support of a PMA during this year.

Partners Involved in Marketing Our Products

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

We have appointed distributors internationally so that we are positioned to service those markets. Our focus is on those countries that have received or will receive funding commitments for HIV prevention and treatment, of which rapid HIV testing is an essential part. The most significant program globally that funds HIV testing is the United States PEPFAR program, which primarily is focused in 15 countries in sub-Saharan Africa that are at the epicenter of the disease. During 2008 we shipped approximately 2.4 million test kits to Nigeria, 1.6 million test kits to Uganda, and approximately 600,000 test kits to Ethiopia, or a total of approximately 4.6 million tests, mostly through the PEPFAR procurement agency known as the Partnership for Supply Chain Management ("PSCM"). Lesser volumes were shipped to several other countries in Asia, and Latin America. We also shipped HIV test kit components to the Oswaldo Cruz Foundation for the manufacture of tests in Brazil pursuant to our 2004 technology transfer agreement.

Effective in January 2009, Nigeria changed from a parallel testing algorithm to a serial algorithm, and in this change our test's designation in two of their new protocols was changed to that of a confirmatory test and a tie-breaker test in the third protocol. This designation has resulted in a dramatic reduction of sales to this country which decrease we anticipate will likely continue for at least several months. During 2008, the implementation of our HIV 1/2 STAT-PAK® as the confirmatory test in Ethiopia's serial testing algorithm resulted in significantly increased sales to that country, which increases we anticipate may continue during 2009. We do not presently anticipate however that the increased sales in Ethiopia will in any case fully offset the decrease in Nigeria.

We are pursuing new opportunities for distribution of our existing lateral flow HIV tests and new DPP® oral fluid HIV test in a number of markets globally. As stated earlier, during 2008 we amended our agreement with Inverness so that we may now market the barrel product under Chembio's trademark, SURE CHECK® HIV 1/2 directly throughout South America and Africa, subject to the payment of royalties to Inverness in accordance with our license to their lateral flow patents.

OTHER RAPID TESTS

We also have commercially available lateral flow tests for Chagas Disease and also a line of tests for the detection of tuberculosis in humans and certain animal species. However, these products represented less than 4% of our product revenues during 2008 and are not part of the central focus of our current business and growth strategy.

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.

Lateral flow technology involves a sample flowing from the point of application on a test strip to provide a test result, indicated with a labeling reagent that allows the result to be visually or otherwise detected, on a portion of a strip downstream from either the point of application of the sample. Lateral flow technology is well established and widely applied in the development of rapid diagnostic tests. The functionality of our lateral flow tests is based on the ability of an antibody to bind with a specific antigen (or vice versa) and for the binding to become visible through the use of the colloidal gold and/or colored latex that we use in our products. The colloidal gold or the colored latex produces a colored line if the binding has occurred (the test line), in which case it means there has been a reactive or positive result. In any case, a separate line (the control line) will appear to confirm that the test has been validly run in accordance with the instructions for use.

On March 13, 2007, we were issued United States patent number #7,189,522 describing a Dual Path Immunoassay system which we believe provides several advantages over lateral flow technology for certain applications (See "Intellectual Property"). The Dual Path Platform technology, or DPP®, uniquely provides for the sample application and migration toward the test zone area to be from an independent strip. This system enables improved sample control, multiplexing and certain other advantages. DPP® is providing the Company with significant new product development and licensing opportunities, and we are devoting all of our research and development efforts toward these programs.

The sensitivity of a test indicates how strong the sample must be before it can be detected by the test. The specificity of a test measures the ability of the test to analyze, isolate, and detect only the matters targeted by the test. The sensitivity and specificity of our rapid HIV tests during our clinical trials undertaken in connection with our FDA PMAs were 99.7% and 99.9%, respectively. 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.

Our HIV tests are qualitative (reactive/non-reactive) tests. We have developed proprietary techniques that enable us to achieve high levels of sensitivity and specificity [see definition above] in our diagnostic tests using our proprietary colloidal gold conjugates and buffer systems. These techniques include the methods we employ in manufacturing and fusing the reagents with the colored latex, or colloidal gold, blocking procedures used to reduce false positives, and methods used in treating the materials used in our tests to obtain maximum stability and resulting longer shelf life. We also have extensive experience with a variety of lateral flow devices, including the sample collection device used in our SURE CHECK rapid HIV test which eliminates the need for transferring finger-stick whole blood samples from the fingertip onto a test device, because the collection of the sample is performed within a tubular test chamber that contains the lateral flow test strip. The whole blood sample is absorbed directly onto the test strip through a small opening in one end of the test chamber and an absorbent pad positioned just inside this same end of the test chamber.

During 2007 and 2008 we entered collaborations with companies that have developed hand held and desktop readers that can objectively measure, quantify, record and report test results. Certain of the products we have and/or are developing for our customer in Brazil, the Oswaldo Cruz Foundation, will incorporate some of these readers, and we are developing other products that may be used with or will require use of a reader.

Target Market

Rapid HIV Tests

The marketing of our FDA-approved and CLIA-waived rapid HIV tests in the United States was launched by Inverness during the first quarter of 2007, and we estimate to have approximately a 10% share of the U.S. rapid HIV test market. In the United States, the need for rapid HIV tests has been developing first in the public health and hospital emergency room segments, and also in the physicians' office laboratories. Of the estimated 25-30 million HIV tests performed in clinical settings in the United States, rapid HIV tests now account for approximately 20-25% of this market, or approximately 5-6 million tests of this total. We believe that the total number of HIV tests will continue to grow, and that the share available to rapid HIV tests will also grow.

The pace of the implementation of recommendations that were made in late 2006 by the United States Centers for Disease Control ("CDC") for routine HIV testing of all individuals between the ages of 13 and 64 will be a major factor in the rate of growth of the rapid HIV testing market in the United States. Endorsement of these recommendations by opinion leaders in the professional medical community are gradually helping to increase the demand for HIV testing in the United States. In addition, the revelation in a study disclosed in 2008 by CDC that annual new HIV cases in the US, which disproportionately impact African-Americans, had been under-reported for years by approximately 40%, underscored the need for improved prevention efforts in the United States. Although the most recent efforts to increase federal funding for STD prevention in the federal stimulus package were unsuccessful, we still believe that there is a good prospect that the current Congress and Administration will seek to increase these programs through other legislative appropriations.

In the international market, PEPFAR, the large United States funded international AIDS relief program focused on fifteen countries, was reauthorized last year for up to $48 billion for FY2009-2012 (up from $15 billion in 2004-2008); the appropriation for 2009 is approximately $5.5 billion, of which approximately 12% or $900 million is allocated to the Global Fund, the other large international program created in 2001 to combat HIV/AIDS, TB and Malaria. PEPFAR, The Global Fund and other global initiatives have succeeded in making life-saving treatments available now to well in excess of one million individuals. We believe that this is likely to have the effect of further encouraging more people to get tested, because with the availability of treatment, there is a clear reason to be tested. Other programs such as UNAIDS are significant participants in the global effort to prevent further transmission and save the lives of those already infected, as well as care for their families that are impacted.

Marketing Strategy

Our marketing strategy is to:

- Support, review and assess the marketing and distribution efforts of our rapid HIV tests by Inverness Medical Innovations, Inc. Inverness, which is a leading marketer of point-of-care diagnostic products, has significantly expanded its distribution footprint since we signed our agreement with Inverness, and we believe that this will enhance opportunities for Inverness to market our rapid HIV tests. In particular, Inverness has been very active in acquiring point-of-care product lines serving hospital emergency rooms and physicians' offices.
- Leverage our DPP® intellectual property and regulated product development and manufacturing experience to create new collaborations where Chembio can be the exclusive development and manufacturing partner with world class marketing partners.
- Develop a small number of Chembio or DPP® branded products that capitalize on the advantages of this newly patented point-of-care technology and select distribution partners for such products.

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 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 enhances our ability to develop more profitable collaborative relationships and to license out the technology.

We believe our regulatory certifications are also a strong asset for developing new products and collaborations. There are only two companies besides Chembio that have approved PMA's for lateral flow rapid tests, all HIV tests: Trinity Biotech (Ireland) and Orasure Technologies, Inc. (PA). We believe that this is a significant competitive advantage when considering new products and collaborations. During 2006 and 2007 we obtained CLIA waivers for each of our FDA PMA approved HIV tests. These products therefore represent two of the four CLIA-waived rapid HIV tests. During 2007 and 2008 we received facility and product licenses from the USDA, became certified under ISO 13.485, and received our initial CE mark (for our Chagas product). We anticipate receiving CE marks for our HIV products during the first half of 2009.

Our access to capital is much less than that of several of our competitors, and to the extent we would need to access large amounts of capital, this is a competitive disadvantage. We believe however that our access to capital is likely to increase if we continue our trend of improved operating results, and in the meantime we are focused on minimizing our capital requirements. Establishment of strategic collaborations for our DPP® technology also may provide us with access to funding that is potentially less dilutive or non-dilutive. The simplification of our capital structure that was completed in December 2007 should also improve our access to capital (See Management's Discussion and Analysis of Financial Condition and Results of Operations – Overview).

To date, we believe we have been competitive in the industry in attracting and retaining qualified personnel. Because of the greater financial resources of many of our competitors, we may not be able to compete effectively for the same individuals to the extent that a competitor uses its substantial resources to attract any such individuals. Also, in order to control costs and conserve resources, we have implemented layoffs and salary reductions that larger companies with greater resources may not need to implement.

We have been able to obtain patent protection by entering into licensing arrangements for reagents and lateral flow technologies. The March 2007 issuance by the United States Patent & Trademark Office of our Dual Path Platform™ patent gives us our first patent protection for our own rapid test platform, which we believe enhances our competitive position. Additional protection of this intellectual property is pending worldwide.

Competitive factors specifically related to our HIV tests are product quality, delivery, sensitivity, specificity, ease-of-use, shelf life and price. Other factors can be sample size required, the presence of a true IgG control, and time to result. During the last few years, the competitive features of certain products produced by some international competitors have improved. Most of these companies, whose products are not and in most cases probably could not be FDA approved, typically have substantially lower costs of labor, regulatory approval and compliance, and intellectual property (if any) as compared with Chembio. Price has become an increasingly important factor since U.S. procurement rules still operate under a waiver of Buy America provisions, described below. Also, as described below, in most of the donor-funded markets in the developing world technical committees controlled by host governments are empowered to make final decisions as to which products will be used in screening programs. The leading competitors in the international rapid HIV test market are Trinity Biotech (Ireland), Inverness (U.S.) and Standard Diagnostics (Korea). Uni-Gold® HIV, marketed by Trinity Biotech of Ireland and Determine®, marketed by Inverness Medical, are the market leaders in the developing world, particularly sub-Saharan Africa, which is where most of the funding for rapid HIV tests is being allocated from donor funded programs such as PEPFAR. Neither the Trinity or Inverness products are FDA-approved, although Trinity does manufacture in Ireland an FDA-approved rapid HIV test, Uni-Gold Recombigen, for marketing in the United States. Inverness' Orgenics subsidiary in Israel also has a rapid HIV test, Double-Check Gold, as does its subsidiary in China, ABON; neither of these products is FDA-approved. As such, while Inverness is our exclusive marketing partner in the United States, it is also a principal competitor to our rapid HIV tests outside the United States. Furthermore, in 2006 Trinity Biotech settled litigation with Inverness, and as part of that settlement it committed to have ABON, an Inverness subsidiary, to manufacture all of Trinity's Uni-Gold® HIV products primarily for the African market. Standard Diagnostics of Korea also has a low-cost product that is very competitive against each of the other competitors in the developing world. There are a number of additional competitors, including several based in China and India of varying quality, that produce competitive rapid HIV tests.

Under a now long-established waiver of Buy America provisions, products procured with US taxpayer funds need not be FDA approved or even made in the US so long as they meet reduced quality standards as compared to what would be required for an FDA approved product. Under the waiver guidelines, all manufacturers are invited by PEPFAR to be considered for procurement with United States taxpayer funds. The waiver, which was initially made available because of a dearth of suitable US-made or FDA approved products when PEPFAR was originally authorized, has continued even though there are now several products, including Chembio's, that are FDA approved. Also, in addition to competing against approximately thirty non-FDA approved, non-US made products that can be purchased under U.S. procurement rules, in order to realize sales in the markets where the donor (mostly U.S.) funds are allocated, the product must additionally be selected by a country's ministry of health or their designees to be part of a national testing protocol or "algorithm". The algorithms typically use multiple rapid tests in sequence or in parallel to screen and confirm patients at the point-of-care and are increasingly allowing for multiple tests to be qualified in these algorithms. Chembio's sales in Africa and certain other markets are therefore based on the fact that its test has been one of those selected. A product's designation in a donor-funded country's algorithm is largely followed by most of the implementing agencies and organizations, resulting in the selection process being critical to participation in donor funded procurements in such market, and limiting the impact of marketing activities once these selections have been made. The selection process in each of these countries is not predictable and is based upon a number of factors, including but not limited to product performance, price, and supply chain.

In the developed world, particularly the United States and Europe, the competitive landscape and market dynamics are quite different. Due to the costs of and quality system requirements associated with US FDA regulatory approval, there are currently only two companies besides Chembio that have products that are both FDA PMA-approved and also CLIA-waived: Orasure Technologies (Bethlehem, PA) with OraQuick®, and Trinity Biotech Ltd. (Ireland) with Uni-Gold® Recombigen. The regulatory costs for FDA approval and fewer number of products in turn results in very different (higher) pricing in the US market as compared with the developing world, with prices in the US averaging $8-12 per test to end user. This compares to approximately $1.00 per test in the developing world. As the requirements for the PMA and CLIA waiver are difficult, costly, risky and time-consuming, particularly relative to the size of the market, and because such approval is not required for participation in PEPFAR under the above-described waiver guidelines, we do not anticipate that Inverness has any plan to submit any of its products produced outside the U.S. to the FDA. Further, our agreements with Inverness provide that in the event one of those submissions is made (or if Inverness acquires a competitive product in the United States), we have the right to terminate our agreement with Inverness or make Inverness' marketing rights non-exclusive. In either case, we would retain a license under the Inverness lateral flow patents to market the products under a Chembio brand and/or through third party distribution partners.

Orasure has an estimated market share in the U.S. of approximately 70% with its Oraquick ® product. This product's main advantages are that it was the first test to market and also that, at least for certain market segments (primarily public health), it can be performed with oral fluid samples, as compared with only blood samples, which is the case for our products as well as Trinity's. The main disadvantage of the Orasure product is its relatively higher price. Also, Orasure's claimed sensitivity with oral fluid samples is lower than with blood samples, and combined with some limited reports of performance (false positive) problems on oral fluid samples, this has created some opportunities for Inverness with our product, as well as for Trinity.

Orasure markets its products directly through its own sales organization to the public health market, has made a significant investment in that market, and has nearly 100% of the three largest states in this market (New York, California and Florida) that together constitute the majority of public health HIV testing in the US. For the hospital market segment Orasure had an exclusive marketing arrangement with Abbott Diagnostics, but as of January 2009 they terminated this agreement and are expanding their direct sales organization to market directly to the hospital market segment as well. Trinity also relies on its own sales force to market its product, and does not have any other rapid tests to sell to distributors. The Uni-Gold product that is marketed by Trinity accounts for an estimated 10% of the market. This product does not detect HIV-2, while our products and Orasure's both do. Though HIV-2 is a rare strain of HIV, it is an advantage to be able to detect, though there is a cost of 15% of Net Sales to the license for this claim. Trinity's product also requires a much larger sample size, and does not have a true IgG control. This means that a control line, which is intended to confirm that the test procedure has been performed correctly, will appear on their product so long as any liquid material is applied to its sampling area; Chembio's (and Orasure's) control line will appear only if a biological sample is applied. The shelf life of our HIV products is 24 months, which is twice that of both the Uni-Gold and Orasure products.

We believe that Inverness, as a leading marketer of a broad range of point-of-care tests sold into all U.S. market segments, has a superior marketing organization as compared to either of our U.S. market competitors who are much smaller than Inverness. Inverness has made a significant investment in its launch of our products, in the training of a large marketing organization in the US, and in the acquisition of complementary product lines and sales organizations. For example, Inverness has significantly augmented its access to emergency room departments in hospitals through its acquisition of Bio-Site, which was the leading company in point-of-care tests for cardiac monitoring, and whose sales force can now add our product to its product portfolio for this important market segment. We believe that this is an example of the distribution advantages of our marketing partner.

Chembio's HIV Tests

One of our two product formats, the "barrel" format now marketed by Inverness as Clearview® Complete HIV 1-2, is a unique product format inasmuch as it is a unitized product, meaning that all components necessary to perform a single test are contained in a single pouch. This "barrel" format provides for a proprietary method of collecting finger-stick whole blood samples that eliminates the need for the step that all other devices require of transferring the sample from the fingertip to the sample well of the test. Also, the buffer solution in the barrel format is in a unitized vial that is pierced by the barrel tip to initiate the sample migration up the test strip contained inside the "barrel", and thereby creates a closed system that helps to minimize possible exposure to potentially infectious samples.

Our other FDA PMA approved rapid HIV test, marketed by Inverness as Clearview® HIV 1-2 STAT PAK®, is a rectangular-shaped lateral flow plastic cassette format test wherein the sample is transferred from the sample source (finger tip in the case of finger-stick whole blood samples) to the sample port in the cassette by means of a transfer loop. Though this step is not required in the barrel format, the cassette is less costly to manufacture, is a more familiar format to customers that have performed other standard design lateral flow tests, and is a more flexible format that utilizes the same procedure for all approved sample matrices (venous whole blood, finger-stick whole blood, serum and plasma). To date this format has accounted for almost all of the sales we have had through Inverness. However this is in part due to the fact that the barrel format was not CLIA waived until October 2007, approximately a year later than the cassette product, and we anticipate more sales of this product in the future, though still less than the cassette.

Research and Development

During 2008 and 2007, $2.6 million and $1.9 million, respectively, were spent on research and development activities. Substantially all of our new product development activities involve employment of our Dual Path Platform (DPP®) technology for which we were awarded a U.S patent in 2007. We believe that this platform enables us to pursue many new product development and licensing opportunities. The DPP® technology can provide improved features on certain tests developed with it that include higher sensitivity, earlier detection, improved performance with more challenging sample types (such as oral fluid), and the improved ability to detect multiple analytes (multiplexing) in one test device.

During 2008 we made substantial progress in developing a portfolio of products based on the DPP® technology. These activities include completing development of certain products and making significant progress toward the development of additional products. These activities are further explained in Part II Item 7.

Regulatory Activities

We continue to make progress on obtaining a Community European (CE) marking for our products to indicate conformity with European Union health, safety and environmental requirements. We have submitted the HIV 1/2 STAT-PAK® technical file to our notified body and should complete all required steps for CE Marking of this product during the second quarter of 2009. Under our agreement with Inverness we are to obtain a CE Marking for the Clearview® Complete HIV 1/2. We are prepared to submit the technical file for this product on behalf of Inverness once we received final proposed labeling from Inverness.

We are also pursuing registrations of our lateral flow and DPP® HIV products in a number of other jurisdictions, and also pursing registrations with the USDA of additional claims for our veterinary tuberculosis products.

During 2008 we received FDA approval for the lowering of the age limits that the tests are approved for from 18 years to 13 years of age. This lowering of the lower age limit put our approved product claims in line with the 2006 CDC recommendations for routine test of all individuals between the ages of 13 and 64, and we believe that this additional marketing claim for the product will assist Inverness in certain market opportunities with our products.

Employees

At December 31, 2008, we employed 114 people, including 110 full-time employees. Effective May 2006, we entered into an employment agreement with Lawrence Siebert, President and Chairman. Effective March 2007, we entered into an employment agreement with Javan Esfandiari, Executive Vice-President of Research and Development.

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.

Most point-of-care diagnostic products are regulated as medical devices by the FDA Centers of Device and Radiological Health, though some are regulated by the FDA Center of Biologics Evaluation and Research. 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. An applicant must submit a 510(k) application at least 90 days before marketing of the affected product commences. Although FDA clearance may be granted within that 90-day period, in some cases as much as a year or more may be required before clearance is obtained, if at all.

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 PMA application before marketing can begin. PMA's must demonstrate, among other matters, that the medical device provides a reasonable assurance of safety and effectiveness. A PMA application is typically a complex submission, including the results of non-clinical and clinical studies. Preparing a PMA application is a much more expensive, detailed and time-consuming process as compared with a 510(K) pre-market notification. Once a PMA has been submitted, the FDA is required to review the submission within a statutory period of time. However, the FDA's review may be, and often is, much longer, often requiring one year or more, and may include requests for additional data. The Company has approved PMAs for the two rapid HIV tests now marketed by Inverness Medical as Clearview® Complete HIV 1-2 and Clearview® HIV 1-2 STAT PAK®.

Every company that manufactures medical devices distributed in the United States must comply with the FDA's Quality System Regulations. These regulations govern the manufacturing process, including design, manufacture, testing, release, packaging, distribution, documentation and purchasing. Compliance with the Quality System Regulations is required before the FDA will approve an application, and these requirements also apply to marketed products. Companies are also subject to other post-market and general requirements, including compliance with restrictions imposed on marketed products, compliance with promotional standards, record keeping and reporting of certain adverse reactions or events. The FDA regularly inspects companies to determine compliance with the Quality System Regulations and other post-approval requirements. Failure to comply with statutory requirements and the FDA's regulations can lead to substantial penalties, including monetary penalties, injunctions, product recalls, seizure of products, and criminal prosecution.

The Clinical Laboratory Improvement Act of 1988 ("CLIA") prohibits laboratories from performing in vitro tests for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of, the health of human beings unless there is in effect for such laboratories a certificate issued by the United States Department of Health and Human Services (via the FDA) applicable to the category of examination or procedure performed. Although a certificate is not required for the Company, it considers the applicability of the requirements of CLIA in the design and development of its products. The statutory definition of "laboratory" is very broad, and many of our customers are considered labs. A CLIA waiver will remove certain quality control and other requirements that must be met for certain customers to use the Company's products and this is in fact critical to the marketability of a product into the point-of-care diagnostics market. The Company has received a CLIA waiver for each of the two rapid HIV tests now marketed by Inverness Medical as Clearview® Complete HIV 1/2 and Clearview® HIV 1/2 STAT PAK®. The CLIA waiver was granted by the FDA for HIV 1/2 STAT-PAK on November 20, 2006 and for the Clearview® Complete HIV 1/2 on October 22, 2007.

In addition, the FDA regulates the export of medical devices that have not been approved for marketing in the United States. The Federal Food, Drug and Cosmetic Act contains general requirements for any medical device that may not be sold in the United States and is intended for export. Specifically, a medical device intended for export is not deemed to be adulterated or misbranded if the product: (1) complies with the specifications of the foreign purchaser; (2) is not in conflict with the laws of the country to which it is intended for export; (3) is prominently labeled on the outside of the shipping package that it is intended for export; and (4) is not sold or offered for sale in the United States. Some medical devices face additional statutory requirements before they can be exported. If an unapproved device does not comply with an applicable performance standard or PMA requirement, is exempt from either such requirement because it is an investigational device, or is a banned device, the device may be deemed to be adulterated or misbranded unless the FDA has determined that exportation of the device is not contrary to the public health and safety and has the approval of the country to which it is intended for export. However, the Federal Food, Drug and Cosmetic Act does permit the export of devices to any country in the world, if the device complies with the laws of the importing country and has valid marketing authorization in one of several "listed" countries under the theory that these listed countries have sophisticated mechanisms for the review of medical devices for safety and effectiveness.

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

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

Environmental Laws

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

Intellectual Property

Intellectual Property Strategy

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

Trade Secrets and Know-How

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

Lateral Flow Technology and Reagent Licenses

As part of our agreements in 2006 with Inverness for the marketing of our HIV tests, we were granted non-exclusive licenses to their lateral flow technology for certain products manufactured and marketed by Chembio including but not limited to our HIV tests. Although we believe our DPP® is outside of the scope of lateral flow patents, we consult with patent counsel, and seek licenses and/or redesigns of products that we believe to be in the best interests of the Company and our stockholders. Because of the costs and other negative consequences of time-consuming patent litigation, we often attempt to obtain a license on reasonable terms. Nevertheless there is no assurance that Inverness' lateral flow patents will not be challenged or that other patents containing claims relevant to the Company's products will be not be granted and that licenses to such patents, if any, will be available on reasonable terms, if any. Inverness has aggressively enforced its lateral flow intellectual property, and in 2008 brought a patent infringement lawsuit against Orasure. Orasure has claimed that their Oraquick product does not infringe the Inverness patent and that the Inverness patent is invalid. The lawsuit is in the discovery phase.

In the event that it is determined that a license to any patent is required and it is not possible to negotiate a license agreement under a necessary patent, we may be able to modify the applicable product such that a license would not be necessary. However, this alternative could delay or limit our ability to sell these products in the United States and/or other markets, and/or increase penalties, all of which would adversely affect our results of operations, cash flows and business.

The DPP® technology provides us with our own intellectual property and we believe it also enables tests to be developed with improved sensitivity as compared with comparable tests on lateral flow platforms. The Company has signed and anticipates signing new development projects based upon the DPP® technology that will provide new manufacturing and marketing opportunities. We have several other patents issued or pending related to other point-of-care technologies or applications thereof. The DPP® patent protection is being prosecuted in many foreign jurisdictions as well.

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, which was recently amended to reduce the royalty rate. We also have licensed the antigens used in other tests including our Chagas, Tuberculosis and Leishmaniasis tests. In prior years we concluded license agreements related to intellectual property rights owned by the United States associated with HIV- 1, and during the first quarter of 2008 we entered into a sub-license agreement for HIV-2 with Bio-Rad Laboratories N.A., the exclusive licensee of the Pasteur Institute's HIV-2 intellectual property estate.

Corporate History

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

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

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

Glossary

AIDS	Acquired Immunodeficiency Syndrome. AIDS is caused by the Human Immunodeficiency Virus, HIV.
ALGORITHM (parallel or serial)	For rapid HIV testing this refers both to method or protocol (in developing countries to date) for using rapid tests from different manufacturers in combination to screen and confirm patients at the point-of-care, and may also refer to the specific tests that have been selected by an agency or ministry of health to be used in this way. A parallel algorithm uses two screening tests from different manufacturers and a tie-breaker test only if there is a discrepancy between the screening tests results. A serial algorithm only uses a second confirmatory test if there is a positive result from the screening test, meaning that the number of confirmatory tests used is equal to the positivity rate in the testing venue. A tie-breaker test resolves discrepancies between the screen and the confirmatory test.
ANTIBODY	A protein which is a natural part of the human immune system produced by specialized cells to neutralize antigens, including viruses and bacteria that invade the body. Each antibody producing cell manufactures a unique antibody that is directed against, binds to and eliminates one, and only one, specific type of antigen.
ANTIGEN	Any substance which, upon entering the body, stimulates the immune system leading to the formation of antibodies. Among the more common antigens are bacteria, pollens, toxins, and viruses.
ARVs	Anti-Retroviral Treatments for AIDS
CD-4	The CD4+ T-lymphocyte is the primary target for HIV infection because of the affinity of the virus for the CD4 surface marker. Measures of CD4+ T-lymphocytes are used to guide clinical and therapeutic management of HIV-infected persons.
CDC	United States Centers for Disease Control and Prevention
CLIA waiver	Clinical Laboratory Improvement Act designation that allows simple tests to be performed in point-of-care settings such as doctors offices, walk-in clinics and emergency rooms.
DIAGNOSTIC	Pertaining to the determination of the nature or cause of a disease or condition. Also refers to reagents or procedures used in diagnosis to measure proteins in a clinical sample.
EITF	Emerging Issues Task Force
FASB	Financial Accounting Standards Board
FDA	United States Food and Drug Administration
FDIC	Federal Deposit Insurance Corporation
FAS	Financial Accounting Standard
HIV	Human Immunodeficiency Virus. HIV (also called HIV-1), a retrovirus, causes AIDS. A similar retrovirus, HIV-2, causes a variant disease, sometimes referred to as West African AIDS. HIV infection leads to the destruction of the immune system.
IgG	IgG or Immunoglobulin are proteins found in human blood. This protein is called an “antibody” and is an important part of the body’s defense against disease. When the body is attacked by harmful bacteria or viruses, antibodies help fight these invaders.
MOH	Ministry of Health
MOU	Memoranda of Understanding
NGO	Non-Governmental Organization
OTC	Over-the-Counter
PEPFAR	The President’s Emergency Plan for AIDS Relief
PMA	Pre-Marketing Approval –FDA approval classification for a medical device that is not substantially equivalent to a legally marketed device or is otherwise required by statute to have an approved application. Rapid HIV tests must have an approved PMA application before marketing of such a product can begin.
PROTOCOL	A procedure pursuant to which an immunodiagnostic test is performed on a particular specimen in order to obtain the desired reaction.
REAGENT	A chemical added to a sample under investigation in order to cause a chemical or biological reaction which will enable measurement or identification of a target substance.
RETROVIRUS	A type of virus which contains the enzyme Reverse Transcriptase and is capable of transforming infected cells to produce diseases in the host such as AIDS.
SAB	Staff Accounting Bulletin
SENSITIVITY	Refers to the ability of an assay to detect and measure small quantities of a substance of interest. The greater the sensitivity, the smaller the quantity of the substance of interest the assay can detect. Also refers to the likelihood of detecting the antigen when present.
SPECIFICITY	The ability of an assay to distinguish between similar materials. The greater the specificity, the better an assay is at identifying a substance in the presence of substances of similar makeup.
SPUTUM	Expectorated matter; saliva mixed with discharges from the respiratory passages
TB	Tuberculosis (TB) is a disease caused by bacteria called Mycobacterium tuberculosis. The bacteria usually attack the lungs. But, TB bacteria can attack any part of the body such as the kidney, spine, and brain. If not treated properly, TB disease can be fatal. TB is spread through the air from one person to another. The bacteria are put into the air when a person with active TB disease of the lungs or throat coughs or sneezes. People nearby may breathe in these bacteria and become infected.
UNAIDS	Joint United Nations Program on HIV/AIDS
USAID	United States Agency for International Development
USDA	U.S Department of Agriculture
WHO	World Health Organization

ITEM 1A. RISK FACTORS

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

Risks related to our industry, business and strategy

Because we may not be able to obtain necessary regulatory approvals for some of our products, we may not generate revenues in the amounts we expect, or in the amounts necessary to continue our business.

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

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

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

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

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

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

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

The diagnostic industry is focused on the testing of biological specimens in a laboratory or at the point-of-care and is highly competitive and rapidly changing. Our principal competitors often have considerably greater financial, technical and marketing resources than we do. Several companies produce diagnostic tests that compete directly with our testing product line, including but not limited to, Orasure Technologies, Inverness Medical and Trinity Biotech. As new products enter the market, our products may become obsolete or a competitor's products may be more effective or more effectively marketed and sold than ours. Although we have no specific knowledge of any competitor's product that will render our products obsolete, if we fail to maintain and enhance our competitive position or fail to introduce new products and product features, our customers may decide to use products developed by our competitors, which could result in a loss of revenues and cash flow.

We are developing an oral fluid rapid HIV test as well as other applications utilizing our Dual Path Platform technology, which we believe could enhance our competitive position in HIV rapid testing and other fields. During 2008 we completed development of our initial DPP® products for the detection of antibodies to HIV 1 & 2 in oral fluid as well as blood samples, and a product for the detection of canine leishmaniasis. However we still have technical, manufacturing, regulatory and marketing challenges to meet before we will know whether we can successfully commercialize products incorporating this technology. There can be no assurance that we will overcome these challenges.

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

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

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 pending patent applications.

Although we have been granted non-exclusive licenses to the lateral flow patents owned by Inverness Medical Innovations, Inc. , there is no assurance that their lateral flow patents will not be challenged or that licenses from other parties may not be required, if available at all. In the event that it is determined that a license is required and it is not possible to negotiate a license agreement under a necessary patent, we may be able to modify our HIV rapid test products and other products such that a license would not be necessary. However, this alternative could delay or limit our ability to sell these products in the U.S. and other markets, which would adversely affect our results of operations, cash flows and business.

During 2008 Inverness and Church & Dwight commenced a patent infringement suit against Orasure Technologies, Inc. based on Orasure's alleged infringement of one of Church & Dwight's and Inverness' (the parties have joint rights to this patent) main patents covering lateral flow technology. Orasure has alleged that it does not infringe such patent and that such patent is invalid. A judgment adverse to Inverness stating that Orasure's product does not infringe the Inverness patent or invalidating the Inverness patent, which patent Inverness has successfully used to restrict competition in selected product areas core to Inverness' business, could potentially open up the US rapid HIV test market to other competitors, and thereby have a material and adverse effect on our business. A settlement by Inverness with Orasure, depending on its terms, could also have a material effect on our business, which effect could be beneficial or detrimental.

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 preliminary studies using well characterized samples. We believe that this new platform is outside of the scope of currently issued patents in the field of lateral flow technology, thereby offering the possibility of a greater freedom to operate. However there can be no assurance that our patents or our products incorporating the patent claims will not be challenged at some time in the future.

New developments in health treatments or new non-diagnostic products may reduce or eliminate the demand for our products.

The development and commercialization of products outside of the diagnostics industry could adversely affect sales of our products. For example, the development of a safe and effective vaccine to HIV or treatments for other diseases or conditions that our products are designed to detect, could reduce, or eventually eliminate, the demand for our HIV or other diagnostic products and result in a loss of revenues.

We may not have sufficient resources to effectively introduce and market our products, which could materially harm our operating results.

Introducing and achieving market acceptance for our rapid HIV tests and other new products will require substantial marketing efforts and will require us or our contract partners, sales agents, or distributors to make significant expenditures of time and money. In some instances we will be significantly or totally reliant on the marketing efforts and expenditures of our contract partners, sales agents, distributors. If they do not have or commit the expertise and resources to effectively market the products that we manufacture, our operating results will be materially harmed.

The success of our business depends, in addition to the market success of our products, on our ability to raise additional capital through the sale of debt or equity or through borrowing, and we may not be able to raise capital or borrow funds in amounts necessary to continue our business, or at all.

Our revenues and gross margins have increased significantly in recent periods, and our operating and net losses have decreased significantly in recent periods. Nevertheless we have sustained significant operating losses in 2008, 2007 and 2006. At December 31, 2008, we had a stockholders' equity of $2.58 million and a working capital surplus of $1.66 million**.** The Company estimates that its resources are sufficient to fund its needs through the end of 2009 and beyond or that, in the alternative, it could raise additional capital although the terms under which that capital could be raised would likely be very dilutive to current shareholders. The Company's liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenues (the Company received $340,000 in 2009 for license fees for which we need to meet certain milestones to earn); (2) the extent to which, if any, that revenue level improves operating cash flows; (3) the Company's investments in research and development, facilities, marketing, regulatory approvals, and other investments it may determine to make; and (4) the investment in capital equipment (including production equipment of $323,500 that the Company has contracted for) and the extent to which it improves cash flow through operating efficiencies. There are no assurances that the Company will become profitable or generate positive cash flow by the end of 2009 or, in the alternative, be successful in raising sufficient capital to fund its needs through 2009.

Our objective of increasing international sales is critical to our business plan and if we fail to meet this objective, we may not generate revenues in the amounts we expect, or in amounts necessary to continue our business.

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

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

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

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

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

We seek to protect our proprietary products under trade secret and copyright laws, enter into license agreements for various materials and methods employed in our products, and enter into strategic relationships for distribution of the products. These strategies afford only limited protection. We currently have no foreign patents, though we are seeking patent protection in several foreign jurisdictions for our DPP® technology. We have licenses to reagents (antigens and peptides) used in several of our products and products under development We also have a license to manufacture, use and sell products used to screen for antibodies to HIV-2. In addition, our SURE CHECK®, DPP® and STAT-PAK® trademarks have been registered in the U.S. Despite our efforts to protect our proprietary assets, and respect the intellectual property rights of others, we participate in several markets where intellectual property rights protections are of little or no value. This can place our products and our company at a competitive disadvantage.

During 2008 and in the first quarter of 2009 we terminated a number of employees who have had access to proprietary and confidential information. In connection with the termination of several of these employees whose positions were terminated, individuals executed severance agreements that include strong covenants by these former employees to keep our proprietary information confidential. Despite these and other efforts we make to protect our confidential information, 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 had a term of two years ending May 2008, which the board of directors extended for one year, and the contract with Mr. Esfandiari has a term of three years ending March 2010. We have obtained a key man insurance policy for Mr. Esfandiari.

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

We believe it to be in our best interests to meaningfully participate in the PEPFAR Program, UN Global Fund initiatives and other programs funded by large donors. We have initiated several strategies to participate in these programs. 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.

We have a history of incurring net losses and we cannot be certain that we will be able to achieve profitability.

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

We expect to continue to make substantial expenditures for sales and marketing, regulatory submissions, product development and other purposes, though within reasonable limitations that we believe are necessary in order to continue our making progress toward profitability without requiring additional capital. Our ability to achieve profitability in the future will primarily depend on our ability to increase sales of our products, reduce production and other costs and successfully introduce new products and enhanced versions of our existing products into the marketplace. If we are unable to increase our revenues at a rate that is sufficient to achieve profitability, or adequately control and reduce our operating costs, our operating results would be materially harmed.

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

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

Risks related to our Common Stock

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

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

At the present time, transactions in our Common Stock are not subject to the "penny stock" rules because our average revenue for 2006, 2007 and 2008 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 16,000 shares per day over the three months ended March 16, 2009. If limited trading in our stock continues, it may be difficult for investors to sell their shares in the public market at any given time at prevailing prices.

Our management and larger stockholders exercise significant control over our Company and may approve or take actions that may be adverse to your interests.

As of March 17, 2009, our named executive officers, directors and 5% stockholders beneficially owned approximately 63.7% of our voting power. For the foreseeable future, to the extent that our current stockholders vote similarly, they will be able to exercise control over many matters requiring approval by the board of directors or our stockholders. As a result, they will be able to:

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

ITEM 2. PROPERTIES

Our administrative offices and research facilities are located in Medford, New York. We lease approximately 18,200 square feet of industrial space for $11,987 per month. The space is utilized for research and development activities (approximately 2,660 square feet), offices (approximately 1,820 square feet) and production (approximately 13,720 square feet). The lease term expires on April 30, 2009, and the Company has an option to renew for an additional two years. 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.

As of the filing date of this Annual Report, the Company is in discussion for a lease extension for its administrative offices and research facilities. The principle terms being discussed are as follows: (a) a lease term of five years; (b) an initial rent of $11,350 per month; (c) the monthly rent for year two of the lease will increase by the lower of (i) the change in the consumer price index, or (ii) five percent; and (d) the monthly rent for years three through five of the lease will increase each year by the lower of (i) the change in the consumer price index, or (ii) two and one half percent. Although the Company believes that the extension will be entered into on terms that are substantially similar to the terms being discussed, there is no assurance that this will occur.

ITEM 3. LEGAL PROCEEDINGS

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

PART II

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

Market Information

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

Fiscal Year 2008	**High Bid**	**Low Bid**
First Quarter	$0.30	$0.11
Second Quarter	$0.26	$0.08
Third Quarter	$0.28	$0.15
Fourth Quarter	$0.21	$0.10
Fiscal Year 2007	**High Bid**	**Low Bid**
First Quarter	$0.93	$0.61
Second Quarter	$0.65	$0.47
Third Quarter	$0.65	$0.37
Fourth Quarter	$0.57	$0.26

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 2006, 2007 and 2008 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 January 15, 2009, there were approximately 875 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.

Equity Compensation Plan Information

Combined Equity Compensation Plans - Information as of December 31, 2008

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders[1]	2,416,650[1]	$0.366	4,566,350
Equity compensation plans not approved by security holders	--	--	--
Total	2,416,650	$0.366	4,566,350

1 The “Number of Securities to be Issued Upon Exercise of Outstanding Warrants and Rights” represents 1,983,000 from the 1999 Stock Option Plan and 433,650 under the 2008 Stock Incentive Plan. The “Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans” represents shares issuable under the 2008 Stock Incentive Plan. The Company currently has no intention to issue additional securities under the 1999 Stock Option Plan.

ITEM 6. SELECTED FINANCIAL DATA

Presented in this table are selected financial data for the past five years ending December 31, 2008. Prior year’s financial statements have been reclassified to conform to current year presentation (See discussion in ITEM 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS, Gross Margin). As of the year ended December 31, 2008 the Company reclassified its royalty and license expenses to cost of goods sold, instead of selling, general and administrative expenses.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
SELECTED FINANCIAL DATA

Statement of Operations Data:

	December 31, 2008		December 31, 2007		December 31, 2006		December 31, 2005		December 31, 2004	
TOTAL REVENUES	$ 11,049,571		$ 9,230,948		$ 6,502,480		$ 3,940,730		$ 3,305,932	
GROSS PROFIT	3,851,721	35%	2,795,710	30%	1,608,272	25%	944,648	24%	623,242	19%
OVERHEAD COSTS:										
Research and development expenses	2,605,343	24%	1,906,653	21%	1,401,472	22%	1,364,898	35%	1,508,849	46%
Selling, general and administrative expenses	3,317,046	30%	3,765,221	41%	4,786,993	74%	2,877,737	73%	2,217,755	67%
	5,922,389		5,671,874		6,188,465		4,242,635		3,726,604	
LOSS FROM OPERATIONS	(2,070,668)		(2,876,164)		(4,580,193)		(3,297,987)		(3,103,362)	
OTHER INCOME (EXPENSES):	121,898		249,272		(414,827)		45,987		4,471	
NET LOSS	(1,948,770)	-18%	(2,626,892)	-28%	(4,995,020)	-77%	(3,252,000)	-83%	(3,098,891)	-94%
Dividends accreted/payable in stock to preferred stockholders and a beneficial conversion feature	-		5,645,310		3,210,046		3,517,022		1,943,073	
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	$ (1,948,770)	-18%	$ (8,272,202)	-90%	$ (8,205,066)	-126%	$ (6,769,022)	-172%	$ (5,041,964)	-153%
Basic and diluted loss per share	$ (0.03)		$ (0.57)		$ (0.80)		$ (0.88)		$ (0.85)	
Weighted average number of shares outstanding, basic and diluted	61,266,954		14,608,478		10,293,168		7,705,782		5,966,769	
Balance Sheet Data:										
Working capital	$ 1,663,914		$ 3,228,724		$ 5,113,233		$ 4,707,957		$ (504,825)	
Total assets	5,914,941		6,584,997		7,906,577		7,074,644		1,373,760	
Total liabilities	3,337,609		2,322,171		2,297,193		1,963,703		1,950,413	
Shareholders' equity (deficit)	2,577,332		4,262,826		(939,807)		1,052,703		(523,964)	

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," "anticipates," "believes," "estimates," "predicts," "potential," "continues" or the negative of these terms or other comparable terminology. Although we believe that the expectations reflected-in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

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

The following management discussion and analysis relates to the business of the Company, including its subsidiaries, which develop, manufacture, and market rapid diagnostic tests that detect infectious diseases. The Company's main products presently commercially available are three rapid tests for the detection of HIV antibodies in whole blood, serum and plasma samples, all of which employ lateral flow technology and two of which were approved by the FDA in 2006. In addition, we have a fourth rapid HIV test, more recently developed on our patented Dual Path Platform (DPP®) technology, for the detection of antibodies to HIV in oral fluid samples, as well as in whole blood, serum and plasma samples. The products which employ lateral flow technology are manufactured and sold under a non-exclusive license we have from Inverness Medical Innovations, Inc. ("Inverness"), which is also our exclusive marketing partner for the FDA-approved products in the United States (as well as Europe and Asia for the product that is known as the "barrel" format product) under its Clearview® brand. Inverness launched its marketing of these products in the United States in February 2007. Chembio's two HIV STAT-PAK® rapid HIV tests (in cassette and dipstick formats) are marketed outside the United States through different partners and channels under our license from Inverness.

Rapid HIV tests represented nearly 90% of the Company's product revenues in 2008. The Company also has other rapid tests that together represented approximately 10% of sales in 2008. The Company's products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments. Chembio's products are sold under the Company's STAT PAK® or SURE CHECK ® registered trademarks or under the private labels of its marketing partners, for example the Clearview® label owned by Inverness Medical Innovations, Inc.

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. In 2008 the Company completed development of its first two products that employ the DPP® technology and it has a number of additional products under development that employ the DPP® technology. These product development activities are further explained below.

Oswaldo Cruz Foundation Agreements

During 2008 we signed four agreements with the Oswaldo Cruz Foundation (FIOCRUZ) in Brazil relating to products for Leptospirosis, Leishmaniasis, screening for HIV 1/2 with oral fluid samples, and confirmation of HIV 1. We have completed development of two of the products (Leishmaniasis and HIV oral fluid screening test), and substantially completed development of the other two. All four of these products are or will be undergoing regulatory approval evaluations in Brazil; we expect that all of these products will be approved by ANVISA for distribution by FIOCRUZ in Brazil during 2009, triggering initial orders as well as approximately $1MM in technology transfer fee payments to the Company in 2009. We received purchase orders from FIOCRUZ in the fourth quarter of 2008 for approximately $500,000 of the Leishmaniasis product; however due to the delay in FIOCRUZ receiving necessary import authorizations for the second and larger portion of this order, approximately $380,000 of this amount could not be shipped in December and was instead shipped during the first quarter of 2009. Also, based upon additional features that we are adding to the HIV confirmatory test, we are finalizing a revised agreement for this product which we believe will provide us with a larger market opportunity for this product in Brazil subject to regulatory approval and other conditions.

On April 16, 2008, we announced a new development agreement with Bio-Rad Laboratories N.A.., a part of Bio-Rad Laboratories Inc, a leading in-vitro diagnostic and life science company. The agreement with Bio-Rad is for the development of a new multiplex product that is being developed on DPP® and which would be marketed by Bio-Rad under a limited exclusive license from Chembio to Bio-Rad that is limited to this field of application. Our agreement with Bio-Rad contemplated that we would enter into a license agreement effective no later than December 2008 subject to Bio-Rad being satisfied with development progress and other conditions. We in fact did enter into this license agreement in January 2009 with a December 31, 2008 effective date and have received a $340,000 payment for this license. Development of this product is anticipated to continue through 2009, funded by Bio-Rad at a cost of $125,000 every six months. The agreement is terminable at any time by Bio Rad and, under certain circumstances, some or all of the $340,000 license fee is refundable.

DPP® HIV Oral Fluid Test Status

Having completed development of this product in 2008 for international sales, we are now in the initial stages of commercializing it to participate in the US and global markets. We are initially pursuing approval and registration of this product in the large markets globally including but not limited to those markets where we have been successful with our current lateral flow tests that only use finger-stick whole blood and other blood matrices (venous whole blood, serum and plasma). Our product is being included in a study in Africa that is being conducted by a governmental organization interested in the possibility of expanded use of oral fluid based tests. We are also negotiating an agreement with a large global in-vitro diagnostic products company that would have exclusive marketing rights to this product in the United States market under a co-branding of the product that would include the DPP® trademark in the name of the product. (See RECENT DEVELOPMENTS AND CHEMBIO'S PLAN OF OPERATIONS FOR THE NEXT TWELVE MONTHS).

Progress on DPP® Syphilis Screen and Confirm Multiplex Test

During 2008 and 2009 year to date, we made substantial progress on this product, with extensive collaborative efforts with the CDC and others. We are currently evaluating whether this product meets the performance objectives for the US market while we continue to assess and focus on the market opportunity for this product in the United States.

Other DPP® Development Projects

Our patented DPP® technology, combined with our development and manufacturing experience and know-how, has enabled us to attract and enter into and pursue third-party-funded product development opportunities that in turn add further to our capabilities while subsidizing some of our R&D personnel and overall overhead costs. This allows us to maintain a larger R&D staff than we could otherwise justify, which also gives us some flexibility in how and when we allocate resources. Included in our research and development organization is a technical team that we created in 2008. This team is able to transfer products from R&D into production and assist in validation, is involved in supporting our manufacturing organization when the need arises, and is also able to assist in pure development activities. Creation of this team was an important accomplishment in 2008.

Chembio continues to work with commercial, governmental and private organizations in order to obtain research grants and other funding for development projects. In this regard, we have entered into a development agreement with Bio-Rad, which, subject to continued achievement of milestones and other conditions, could result in approximately $200,000 of development funds for Chembio in 2009. We also have DPPÒ grants from governmental agencies for $55,000 for leprosy research and $110,000 for Human TB Serology research in 2009. Our four technology transfer, supply and license agreements with Oswaldo Cruz Foundation of Brazil could result in as much as $1,050,000 of advance royalty payments. In addition to the projects described, Chembio has applied for other research grants and is working on entering into a number of other development agreements.

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

We continue to make progress on obtaining a Community European (CE) marking for our products to indicate conformity with European Union health, safety and environmental requirements. We have submitted the HIV 1/2 STAT-PAK® technical file to our notified body and should complete all required steps for CE Marking of this product during the second quarter of 2009. Under our agreement with Inverness we are to obtain a CE Marking for the Clearview® Complete HIV 1/2. We are prepared to submit the technical file for this product on behalf of Inverness once we have received final proposed labeling from Inverness.

We are pursuing registrations of our lateral flow and DPP® HIV products in a number of other jurisdictions, and also pursing registrations with the USDA of additional claims for our veterinary tuberculosis products.

Recent Events

During the quarter ended December 31, 2008, Inverness Medical Innovations, Inc. (“Inverness”) notified the Company that Inverness had entered into a contract with Bio-Rad Laboratories, Inc. (“Bio-Rad”) for royalties on Bio-Rad’s patent for the detection of HIV-2 antibodies. The agreement also provided for Inverness to pay past royalties. The agreements between the Company and Inverness provide that the Company is to share in these past royalties and Inverness requested it be reimbursed for the Company’s share of these past royalties. The Company and Inverness have agreed that this liability, which is approximately $500,000, is to be paid from future revenues over approximately the next 18 months.

For 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.

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

RESULTS OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2008 AS COMPARED WITH THE YEAR ENDED DECEMBER 31, 2007

Revenues:

Selected Product Categories:	For the years ended			
	December 31, 2008	December 31, 2007	**$ Change**	**% Change**
HIV	$ 9,192,297	$ 7,927,676	$ 1,264,621	15.95%
TB	281,555	111,403	170,152	152.74%
Other	881,916	725,798	156,118	21.51%
Net Product Sales	**10,355,768**	**8,764,877**	**1,590,891**	**18.15%**
Research grant income	693,803	466,071	227,732	48.86%
Total Revenues	**$ 11,049,571**	**$ 9,230,948**	**$ 1,818,623**	**19.70%**

Revenues for our HIV tests and related components during the year ended December 31, 2008 increased by $1.26 million over the same period in 2007. This was primarily attributable to increased sales in Brazil and sales to our distributor in the United States, offset by the reduction of sales to Mexico from 2007 that were not repeated in 2008. Sales of our TB product increased because of additional products being approved. The increase in research grant income was for grants and feasibility studies involving our patented DPP® technology of which $651,000 was received and $694,000 was earned in 2008, utilizing $43,000 in deferred revenues as of December 31, 2007. Sales to Africa (see Note 13 of the financial statements) were primarily from Nigeria of approximately $2.86 million. We have been advised recently that our designation in Nigeria as one of the screening tests has changed to that of the confirmatory test as this country moves from a parallel to a serial testing algorithm, which we expect will significantly reduce our sales to Nigeria in 2009.

Gross Margin:

Gross Margin related to Net Product Sales:	For the years ended			
	December 31, 2008	December 31, 2007	**$ Change**	**% Change**
Gross Margin per Statement of Operations	$ 3,851,721	$ 2,795,710	$ 1,056,011	37.77%
Less: Research grant income	693,803	466,071	227,732	48.86%
Gross Margin from Net Product Sales	**$ 3,157,918**	**$ 2,329,639**	**$ 828,279**	**35.55%**
Gross Margin %	**30.49%**	**26.58%**		

The increase in our gross margin resulted primarily from increased quantities of our product sales and increased average unit prices on product sales and component sales.

For the year ended December 31, 2008, the Company reclassified its royalty and license expenses to cost of goods sold. For all periods prior to the quarter ended December 31, 2008 these expenses were previously reflected in selling, general and administrative expenses. Without this reclassification of royalty and license expenses from SG&A expense to Cost of Goods Sold, the gross margin from product sales would have been $4.465 million, or 43.1%, and $3.396 million, or 38.7%, for the years ended December 31, 2008 and 2007, respectively.

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, 2008	December 31, 2007	**$ Change**	**% Change**
Clinical & Regulatory Affairs:				
Wages and related costs	$ 262,191	$ 188,050	$ 74,141	39.43%
Consulting	27,231	87,763	(60,532)	-68.97%
Clinical trials	138,792	29,664	109,128	367.88%
Other	60,821	(35,915)	96,736	-269.35%
Total Regulatory	**$ 489,035**	**$ 269,562**	**$ 219,473**	**81.42%**
R&D Other than Regulatory:				
Wages and related costs	$ 1,354,557	$ 959,679	$ 394,878	41.15%
Consulting	138,436	102,075	36,361	35.62%
Share-based compensation	84,935	189,843	(104,908)	-55.26%
Materials and supplies	307,662	268,566	39,096	14.56%
Other	230,718	116,928	113,790	97.32%
Total other than Regulatory	**$ 2,116,308**	**$ 1,637,091**	**$ 479,217**	**29.27%**
Total Research and Development	**$ 2,605,343**	**$ 1,906,653**	**$ 698,690**	**36.64%**

Expenses for Clinical & Regulatory Affairs for the year ended December 31, 2008 increased by $219,500 as compared to the same period in 2007. This was primarily due to an increase in expenses related to internal DPP testing, external clinical trials we contracted for in order to lower the age limitation of our FDA approved rapid HIV tests from 18 to 13 years of age, and also due to an increase in wages and related costs as we added to our regulatory staff, offset by a decrease in the use of consultants

Expenses other than Clinical & Regulatory Affairs increased by $479,200 in the year ended December 31, 2008 as compared with the same period in 2007 and were primarily related to an increase in personnel and material costs required to perform the work related to funded feasibility studies and grants received, all related to our patented DPP® technology, and to the establishment of a technical group within the R&D department in order to support product validations and transfers to production. These increases were partially offset by a decrease in the cost of share-based compensation related to the value of common stock and employee stock options issued to an employee pursuant to a contract.

Subject to the continuation of grant and feasibility income, the Company currently plans to continue research and development spending at levels that will, net of grant and feasibility study income, result in a net decrease in this spending category.

Selling, General and Administrative Expense:

Selected expense lines:	For the years ended December 31, 2008	December 31, 2007	$ Change	% Change
Wages and related costs	$ 1,261,511	$ 1,642,185	$ (380,674)	-23.18%
Consulting	187,494	232,184	(44,690)	-19.25%
Commissons	365,774	31,762	334,012	1051.61%
Share-based compensation	187,908	152,319	35,589	23.36%
Marketing materials	38,379	75,570	(37,191)	-49.21%
Investor relations	123,654	224,843	(101,189)	-45.00%
Legal, accounting and SOX 404 compliance	551,335	643,562	(92,227)	-14.33%
Travel, entertainment and trade shows	92,576	154,819	(62,243)	-40.20%
Other	508,415	607,977	(99,562)	-16.38%
Total S, G &A	**$ 3,317,046**	**$ 3,765,221**	**$ (448,175)**	**-11.90%**

Selling, general and administrative expenses for the year ended December 31, 2008 decreased by 12% as compared with the same period in 2007. Reduced personnel expenses, investor relations expenses, and professional fees were partially offset by increases in sales commissions that resulted from commissionable sales in Brazil that increased significantly in 2008 as compared with 2007. The decreased cost of professional fees (legal, accounting and section 404 of Sarbanes-Oxley) were related to the reduction of legal fees related to the Plan (see Recent Events above), which were almost all incurred in 2007. These decreased costs were partially offset by increased fees to our independent auditors.

Other Income and Expense:

Other Income and Expense	For the years ended December 31, 2008	December 31, 2007	$ Change	% Change
Other income	$ 95,812	$ 120,862	$ (25,050)	-20.73%
Interest income	34,403	145,289	(110,886)	-76.32%
Interest expense	(8,317)	(16,879)	8,562	-50.73%
Total Other Income and Expense	**$ 121,898**	**$ 249,272**	**$ (127,374)**	**-51.10%**

Other income for the year ended December 31, 2008 decreased 21% as compared with the same period in 2007 primarily as a result of a decrease in the net amounts received from New York State related to a program for qualified emerging technology companies. Interest income for the year ended December 31, 2008 decreased due to a decrease in available funds to invest in interest bearing accounts. Decreased interest expense in 2008 as compared with 2007 reflects the impact of lower interest payments for capital leases nearing the end of their terms

LIQUIDITY AND CAPITAL RESOURCES

	For the years ended			
	December 31, 2008	December 31, 2007	**$ Change**	**% Change**
Net cash used in operating activities	$ (1,194,227)	$ (1,345,796)	$ 151,569	-11.26%
Net cash used in investing activities	(397,462)	(410,425)	12,963	-3.16%
Net cash (used in) provided by financing activities	(23,458)	293,204	(316,662)	-108.00%
NET (DECREASE) IN CASH AND CASH EQUIVALENTS	**$ (1,615,147)**	**$ (1,463,017)**	**$ (152,130)**	**10.40%**

The Company had a decrease in cash for the year ended December 31, 2008 as compared to a lesser decrease in cash for the same period in 2007. The decrease during the 2008 and 2007 periods is primarily attributable to the cash used in operations.

The Company had a working capital surplus of $1,664,000 at December 31, 2008 and a working capital surplus of $3,229,000 at December 31, 2007. The Company estimates that its resources are sufficient to fund its needs through the end of 2009 and beyond or that, in the alternative, it could raise additional capital although the terms under which that capital could be raised would likely be very dilutive to current shareholders. The Company's liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenues (the Company received $340,000 in 2009 for license fees for which we need to meet certain milestones to earn); (2) the extent to which, if any, that revenue level improves operating cash flows; (3) the Company's investments in research and development, facilities, marketing, regulatory approvals, and other investments it may determine to make; and (4) the investment in capital equipment (including production equipment of $323,500 that the Company has contracted for) and the extent to which it improves cash flow through operating efficiencies. There are no assurances that the Company will become profitable or generate positive cash flow by the end of 2009 or, in the alternative, be successful in raising sufficient capital to fund its needs through 2009.

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

Please see section entitled Recent Events above.

2008

During 2008 Chembio increased total revenues by 20% to $11.05MM, increased gross profit by 38% to $3.85MM (based on the presentation in Item 6 Selected Financial Data wherein our reclassification of Royalty Expense and License Fees, reclassified to Cost of Goods Sold in our audited statements for 2008, were also reclassified, for 2004-2007 for comparative purposes), and decreased Selling, General & Administrative Expense by 12% to $3.32MM. Research and Development Expense, net of Research Grant Income, increased 33% to $1.91MM.

2008 revenue growth was attributable to our continued collaboration in Brazil with Oswaldo Cruz Foundation and to strong sales growth to Africa, including but not limited to Nigeria, to and through major programs led by the Global Fund and PEPFAR. Even though our sales to Inverness were less in 2008 than in 2007, this was primarily a result of purchases made by Inverness at the time of the launch in 2007 in excess of the actual demand from their customers in 2007, which in turn was in part a result of delays in our obtaining both the age claim amendment and the CLIA waiver for the barrel product (See Item 1. Business: Regulatory Activities). We believe Inverness' sales of our products increased significantly in 2008 versus 2007, notwithstanding a voluntary component (control kit) recall that occurred during the first half of 2008. With continued sales increases by Inverness to its customers in 2009, which we believe is likely, we would expect to see commensurate increases in our sales to Inverness, as we believe that Inverness' inventories have been substantially reduced as compared to 2008.

Our improved gross margin percentage, even after the fourth quarter 2008 royalty expenses related to prior quarters, occurred as a result of continued cost and efficiency improvements as well as improved product mix, primarily as a result of lower unit production costs for components sold to Brazil. Decreased SG&A costs were achieved through termination of positions within these departments and reduction in other costs throughout this cost area. Our net increase in Research & Development expenses included our costs of completing the lowering of the age limit of our FDA approved rapid HIV tests, as well as the cost of establishing a technical department within R&D that can alternatively support operations, transfer new products to operations, research process improvements, and to the extent there is available capacity within this group, support traditional R&D activities.

2009

Based upon (1) the growing base of business we have in the United States for our two FDA-approved CLIA-waived rapid HIV tests, resulting both from the expansion of the market and from market share gains by our marketing partner Inverness Medical; (2) continued growth opportunities for our rapid HIV test products globally, and; (3) our expectation that 2009 will bring our first significant revenues from our DPP® technology, primarily as a result of the contracts we signed with the Oswaldo Cruz Foundation in 2008, we believe we are positioned for increases in our revenues and improvement in our overall operating results in 2009.

Our base plan for 2009 assumes the following: (1) Growth in our sales to Inverness, as it makes gains in hospital and public health markets and because inventory levels that it brought into 2008 have been normalized, (2) conservative assumptions with regard to our international HIV business, primarily including a significant reduction from Nigeria, partially offset by expected growth from our HIV business through new distribution opportunities in Asia, Africa, South America and, upon receipt of our CE Mark, Europe, and (3) successful execution for approval and sales of our DPP® products pursuant to the contracts we signed with Oswaldo Cruz Foundation in 2008.

We intend to continue improving our manufacturing efficiencies and controlling our SG&A expenses, resulting in continued anticipated improvements in our operating results. Even though we made significant cost reductions during 2008, given the reduced sales from Nigeria, an extremely uncertain economy, and the most challenging financing environment for debt or equity of our time, during the first quarter of 2009 we made additional cost reductions in all departments of the Company, including elimination of a number of salaried positions and implementation of a company-wide pay reduction program for all salaried employees earning at least $30,000, with appropriately larger reductions for those earning higher amounts. During 2008 and 2009 year-to-date we have also eliminated salaries in our sales and marketing and administrative areas, which represented annualized costs in excess of $500,000, exclusive of benefits and other attendant costs. Though this limits some new business development opportunities, many of our new sales opportunities are being developed either through OEM customer relationships, exclusive distribution arrangements, and/or commissioned agents, all of which have enabled us to reduce our sales and marketing costs significantly.

Research & Development expenses in 2009 are budgeted as flat overall when compared with 2008. However, based upon current and pending research and development income from grants, development contracts and feasibility studies (and associated staffing requirements for such commitments), our net R&D cost in 2009 (R&D income less total R&D expense) should decrease substantially as well. Having these external funds for R&D is helping us to increase our experience and capabilities while limiting our cash investment. Should pending contracts not materialize, we will make commensurate adjustments to our Research & Development expenses.

In addition to the DPP® products we anticipate launching in Brazil through Oswaldo Cruz Foundation this year, our contract development work for Bio-Rad Laboratories, and several other research and development programs, our main DPP® products that we are focusing our R&D activities on are our DPP® HIV 1/2 screening test for use with oral fluids and our DPP® Syphilis Screen and Confirm test We are in discussions with a large in vitro diagnostics marketing organization that, if an actual agreement is completed, would fund all external regulatory costs, co-brand this product with our DPP® trademark, and commit to minimum sales of the product in exchange for our granting to it exclusive U.S. marketing rights to this product. We are also actively pursuing opportunities for our oral fluid HIV test in the international markets that we already participate in, as well as others, and we are very encouraged by the interest we have received in this product offering.

Equipment Purchase Commitment:

In January of 2009, the Company entered into an agreement with an equipment manufacturer to design and build equipment that will be used to automate the assembling of our tests and lower our production costs. The estimated cost of $323,500 is being paid in installments.

Critical Accounting Policies and Estimates

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

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

Revenue Recognition –

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

Research & Development Costs –

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

Valuation of Inventories –

Inventories are stated at the lower of cost or market, using the first-in, first-out method (FIFO) to determine cost. Our policy is to periodically evaluate the market value of the inventory and the stage of product life cycle, and record a reserve for any inventory considered slow moving or obsolete. For example, each additional 1% of obsolete inventory would reduce such inventory by approximately $18,000.

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 .83% of accounts receivable. For example each additional 1% of accounts receivable that becomes uncollectible would reduce such balance of accounts receivable by approximately $12,000.

Income Taxes –

Income taxes are accounted for under FAS No. 109, "Accounting for Income Taxes." FAS No. 109 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, if we do not become profitable, we may be unable to utilize our deferred tax asset, which approximates $8,598,000 at December 31, 2008.

FAS 109 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 Company adopted the provisions of FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes ("FIN 48") on January 1, 2007. FIN 48 prescribes a comprehensive model for recognizing, measuring, presenting and disclosing in the consolidated financial statements tax positions taken or expected to be taken on a tax return, including a decision whether to file or not to file in a particular jurisdiction.

The calculation of our tax liabilities involves the inherent uncertainty associated with the application of complex tax laws. We are subject to examination by various taxing authorities. We believe that as a result of our losses sustained to date, any examination would result in a reduction of our net operating losses rather than a tax liability. As such, we have not provided for additional taxes estimated under FIN 48, Accounting for Uncertainty in Income Taxes.

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

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

ITEM 9A. CONTROLS AND PROCEDURES

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

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

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

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

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

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

In evaluating the effectiveness of our internal control over financial reporting, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2008.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this annual report.

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

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors and Executive Officers

Lawrence A. Siebert (52), 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 it's 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.

Richard J. Larkin (52), Chief Financial Officer. Mr. Larkin was appointed as Chief Financial Officer of Chembio Diagnostics, Inc. upon consummation of the merger. Mr. Larkin oversees our financial activities and information systems. Mr. Larkin has been the Chief Financial Officer of Chembio Diagnostic Systems Inc. since September 2003. Prior to joining Chembio Diagnostic Systems Inc., Mr. Larkin served as CFO at Visual Technology Group from May 2000 to September 2003, and also led their consultancy program that provided hands-on expertise in all aspects of financial service, including the initial assessment of client financial reporting requirements within an Enterprise Resource Planning (Manufacturing) environment through training and implementation. Prior to joining VTG, he served as CFO at Protex International Corporation from May 1987 to January 2000. Mr. Larkin holds a BBA in Accounting from Dowling College and is a member of the American Institute of Certified Public Accountants.

Javan Esfandiari (42), 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 (55), 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 (46), 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 (58), Director. Dr. Meller was elected to our Board of Directors on March 15, 2005, and currently serves on the Company's Audit, Compensation and Nominating and Corporate Governance Committees, including as Chairman of the Compensation Committee. Dr. Meller has been the president of CommSense Inc., a healthcare business development company, since 2001. CommSense Inc. works with clients in Europe, Asia, North America, and the Middle East on medical information technology, medical records, pharmaceutical product development and financing, health services operations and strategy, and new product and new market development. From 1999 until 2001 Dr. Meller was the executive vice president, North America, of NextEd Ltd., a leading internet educational services company in the Asia Pacific region. Dr. Meller also is a limited partner and a member of the Advisory Board of Crestview Capital Master LLC, which is 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.

Kathy Davis (52), Director. Ms. Davis was elected to the Company's Board of Directors in May 2007, and currently serves on the Company's Audit, Compensation and Nominating And Corporate Governance Committees, including as Chairman of each of the Audit Committee and the Nominating And Corporate Governance Committee. Ms. Davis is presently the owner of Davis Design Group LLC, a company that provides analytical and visual tools for public policy design. Previously 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, product cost, 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, Indiana Museum of African American History, University of Evansville Institute of Global Enterprise, and Purdue College of Science Dean's Leadership 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.

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, 2008, 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) Form 4 for Former Director James D. Merselis, due on March 24, 2008, was filed on March 25, 2008.

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 filed as Exhibit 14.1 to this Form 10-K.

Identification of Audit Committee; Audit Committee Financial Expert

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

ITEM 11. EXECUTIVE COMPENSATION

The following table summarizes all compensation recorded by the Company in each of the last two completed fiscal years for our principal executive officer, our two most highly compensated executive officers other than our principal executive officer whose annual compensation exceeded $100,000, and two additional individuals for whom disclosure would have been made in this table but for the fact that the individual was not serving as an executive officer of our company at December 31, 2008.

Name / Principal Position	Year	Salary[1] ($)	Bonus[2] ($)	Option Awards[3] ($)	Stock Awards ($)	All Other Compensation[5] ($)	Total ($)
Lawrence A. Siebert[4]	2008	$265,000	$ 26,000	$ 36,695	$ -	$ 8,267	$335,962
CEO	2007	243,135	26,000	-	-	9,314	278,448
Richard J. Larkin	2008	$163,076	$ 15,000	$ 12,193	$ -	$ 1,781	$192,050
CFO	2007	153,654	15,000	-	-	1,304	169,958
Javan Esfandiari	2008	$215,692	$ 16,000	$ 45,297	$ 28,702	$ 5,872	$311,564
VP-R&D	2007	171,192	21,000	99,993	89,850	5,510	387,546
Tom Ippolito	2008	$173,631	$ 12,000	$ 8,129	$ -	$ 1,708	$195,467
VP-Regulatory	2007	152,481	12,000		-	381	164,862
Richard Bruce	2008	$151,923	$ 12,000	$ 8,129	$ -	$ 933	$172,984
VP-Operations	2007	140,654	12,000		-	990	153,644

1 Salary is total base salary.
2 Any bonus earned was paid solely on a discretionary basis, and not pursuant to any bonus plan.
3 The estimated fair value of any option or common stock granted was determined at the date of grant by using the Black-Scholes option pricing model.
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, 2008, 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 one-year term. On June 15, 2006, Mr. Siebert and the Company entered into an Employment Agreement, effective May 10, 2006, which was to terminate on May 10, 2008. 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 also is eligible for a bonus of up to 50% of his salary, consisting of (i) a bonus of up to 25% of his salary that is at the complete discretion and determination of the board of directors, and (ii) a bonus of up to an additional 25% of his salary that will be determined based upon revenue and earnings performance criteria established each year by the board of directors. Mr. Siebert is eligible to participate in any profit sharing, stock option, retirement plan, medical and/or hospitalization plan, and/or other benefit plans except for disability and life insurance that the Company may from time to time place in effect for the Company's executives during the term of Mr. Siebert's employment agreement. If Mr. Siebert's Employment Agreement is terminated by the Company without cause, or if Mr. Siebert terminates his Employment Agreement for a reasonable basis, including within 12 months of a change in control, the Company is required to pay as severance Mr. Siebert's salary for six months. Mr. Siebert has agreed for a period of two years after the termination of his employment with the Company not to induce customers, agents, or other sources of distribution of the Company's business under contract or doing business with the Company to terminate, reduce, alter, or divert business with or from the Company. The terms of the extended May 1, 2008 Employment Agreement are identical to the June 15, 2006 Employment Agreement, except that under the 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 April 23, 2007, and to be effective March 5, 2007 (the "Employment Agreement"), with Mr. Esfandiari to continue as the Company's Senior Vice President of Research and Development for an additional term of three years. Mr. Esfandiari's salary under the Employment Agreement is $185,000 for the first year, $210,000 for the second year, and $235,000 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 37.5% 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, and (ii) a cash bonus of up to 12.5% 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 a stock grant of 200,000 shares of the Company's common stock. 100,000 shares vested when the employment agreement was executed, 50,000 shares vested on the first anniversary date of the Employment Agreement, and 50,000 shares vested on the second anniversary of the Employment Agreement. In addition, although none were granted, the Employment Agreement provided that Mr. Esfandiari could have been granted up to 50,000 shares of the Company's common stock for 2007 and 2008 based upon 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. Pursuant to the Company's 1999 Stock Option Plan, the Company also granted Mr. Esfandiari 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 on April 23, 2007, which is the date on which the Agreement was entered into. 100,000 shares of the stock options vested when the employment agreement was executed, 100,000 shares of the stock options vested on the first anniversary of the Employment Agreement, and 100,000 shares of the stock options vested on the second 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.

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

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END 2008

	Option Awards					Stock Awards		
Name	Number of Securities Underlying Unexcercised Options Excerciseable (#)	Number of Securities Underlying Unexcercised Options Unexcersable (#)	Option Exercise Price ($)	Option Expiration Date	Option Vesting Date	Number of Shares of Stock That Have Not Vest (#)	Market Value of Shares of Stock That Have Not Vested ($)	Foot-note
Lawrence A. Siebert	250,000		0.13	6/3/2013	6/3/2008			**3**
	75,000		0.22	2/15/2013	2/15/2008			**1**
	10,000		0.48	12/31/2008	4/17/2006			**2**
	10,000		0.48	5/4/2011	4/17/2006			**2, 5**
	50,000		0.48	5/28/2011	4/17/2006			**2, 3, 5**
	50,000		0.48	5/28/2011	1/1/2007			**2, 3, 5**
	50,000		0.48	5/4/2011	5/5/2004			**2, 5**
Richard J. Larkin	75,000		0.22	2/15/2013	2/15/2008			**1**
	25,000		0.48	5/17/2010	4/17/2006			**2, 5**
	25,000		0.48	5/17/2010	1/1/2007			**2, 5**
	18,750		0.48	3/24/2011	3/24/2006			**2, 5**
	18,750		0.48	3/24/2011	1/1/2007			**2, 5**
	50,000		0.45	9/15/2010	5/5/2004			**4**
Javan Esfandiari	60,000		0.22	2/15/2013	2/15/2008			**1**
	5,000		0.48	12/31/2008	4/17/2006			**2, 5**
	25,000		0.48	5/17/2010	4/17/2006			**2, 5**
	25,000		0.48	5/17/2010	1/1/2007			**2, 5**
	18,750		0.48	3/24/2011	3/24/2006			**2, 5**
	18,750		0.48	3/24/2011	1/1/2007			**2, 5**
	5,000		0.48	5/4/2011	4/17/2006			**2, 5**
	25,000		0.48	5/28/2011	4/17/2006			**2, 5**
	25,000		0.48	5/28/2011	4/17/2006			**2, 5**
	25,000		0.48	5/28/2011	5/28/2007			**2, 5**
	30,000		0.48	5/4/2011	5/5/2004			**2, 5**
	100,000		0.48	4/23/2012	4/23/2007			**2, 3, 5**
	100,000		0.48	4/23/2012	3/5/2008			**2, 3, 5**
		100,000	0.48	4/23/2012	3/5/2009			**2, 3, 5**
						50,000	5,500	**6**
Tom Ippolito	50,000		0.22	2/15/2013	2/15/2008			**2**
	15,000		0.48	3/24/2011	3/24/2006			**2, 5**
Richard Bruce	50,000		0.22	2/15/2013	2/15/2008			**2**
	5,000		0.48	12/31/2008	4/17/2006			**2, 5**
	12,500		0.48	5/17/2010	4/17/2006			**2, 5**
	12,500		0.48	5/17/2010	1/1/2007			**2, 5**
	12,500		0.48	3/24/2011	3/24/2006			**2, 5**
	12,500		0.48	3/24/2011	1/1/2007			**2, 5**
	5,000		0.48	5/4/2011	4/17/2006			**2, 5**
	10,000		0.48	5/4/2011	5/5/2004			**2, 5**
	20,000		0.48	5/4/2011	5/5/2004			**2, 5**

1 All options issued with a $.62 exercise price were issued during 2006 as part of the Company's 1999 Stock Option Plan. Pursuant to this plan, the Company granted 244,000 options to all employees.
2 All options issued with a $.75 exercise price and an April 17, 2006 vesting date were issued on April 17, 2006 as part of the Company's 1999 Stock Option Plan. Pursuant to this plan, the Company granted 244,000 options to all employees. On April 17, 2006, the Company's Compensation Committee approved the cancellation of each employee stock option award issued under the 1999 Stock Option Plan where the exercise price was greater than $0.75 per share of the Company's common stock, and the issuance of a new stock option award under the 1999 Stock Option Plan, for the same number of shares of the Company's common stock, with an exercise price of $0.75 per share of the Company's common stock for each cancelled stock option award. The market price of the common stock of the Company on April 17, 2006 was $0.72 per share. In total, stock option awards to acquire 795,000 shares of Company common stock were cancelled, and stock option awards to acquire 795,000 shares of Company common stock were issued. Other than the change in the exercise price, all of the terms and conditions in each newly issued stock option award are identical to the cancelled stock option award it replaced, with the following exceptions: (i) Lawrence A. Siebert's stock option award for 50,000 shares of the Company's common stock, exercisable on May 28, 2006 and terminating on May 28, 2011, was replaced with a stock option award for 50,000 shares of the Company's common stock, exercisable on January 1, 2007 and terminating on May 28, 2011;(ii) Avi Pelossof's stock option awards for 72,500 shares of the Company's common stock, exercisable on May 28, 2005 and on May 28, 2006 and both terminating on May 28, 2011 was replaced with a stock option award for 72,500 shares of the Company's common stock, exercisable on January 1, 2007 and terminating on May 28, 2011.
3 Options issued in connection with an employment contract and under the 2008 Stock Incentive Plan.
4 All other options shown were issued prior to 2006 as part of the Company's 1999 Stock Option Plan.
5 On February 15, 2008, the Company's Compensation Committee approved the reduction of the exercise price to $0.48 per share of each employee stock option award issued under the 1999 Stock Option Plan for which the exercise price was greater than $0.48 per share.
6 Stock issued in connection with an employment contract and under the 2008 Stock Incentive Plan.

DIRECTOR COMPENSATION

Name	Fees Earned or Paid in Cash ($) [1]	Option Awards ($) [2]	Total ($)
Katherine L. Davis	$ 25,750	$ 22,987	$ 48,737
Gary Meller	24,250	23,316	47,566
James D. Merselis[3]	20,500	7,816	28,316
Al Carus[4]	14,750	23,635	38,385

[1] Fees earned or paid in cash represents an annual retainer and fees for meeting expenses: (a) Mr. Carus received $9,000 in an annual retainer for the portion of the year that he served as a member of the board of directors, a $1,250 annual retainer as audit committee chairman and $4,500 in meeting fees paid during 2008; (b) Mr. Merselis received an $18,000 annual retainer as a member of the board of directors, and $2,500 in meeting fees paid during 2008; (c) Dr. Meller received an $18,000 annual retainer as a member of the board of directors, and $6,250 in meeting fees; (d) Ms. Davis received an $18,000 annual retainer as a member of the board of directors, a $1,250 retainer as audit committee chairman and $6,500 in meeting fees.
[2] Each outside member of the board of directors is granted an option to purchase 180,000 shares of the company's common stock with an exercise price equal to the market price on the date of the grant as part of their annual compensation. One-fifth of these options are exercisable on the date of grant, one-fifth become exercisable on the first anniversary of the date of grant, and additional one-fifths become exercisable on the second through fourth anniversary of the date of grant. The fair value of options at the date of grant was estimated using the Black-Scholes option pricing model.
[3] Mr. Merselis resigned from our Board of Directors on February 9, 2009.
[4] Mr. Carus resigned from our Board of Directors on July 20, 2008.

Director Compensation

All non-employee directors are paid an $18,000 annual retainer, semi-annually, and once every five years stock options to acquire 180,000 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 36,000 shares become exercisable on the date of grant, and options to acquire an additional 36,000 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.

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 17, 2009.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Owner	Percent of Class
Siebert, Lawrence [1] 3661 Horseblock Road Medford, NY 11763	6,933,615	11.11%
Esfandiari, Javan [2] 3661 Horseblock Road Medford, NY 11763	779,580	1.25%
Larkin, Richard [3] 3661 Horseblock Road Medford, NY 11763	267,672	0.43%
Ippolito, Tom [4] 3661 Horseblock Road Medford, NY 11763	65,000	0.10%
Bruce, Richard [5] 3661 Horseblock Road Medford, NY 11763	135,075	0.22%
Meller, Gary [6] 3661 Horseblock Road Medford, NY 11763	354,300	0.57%
Davis, Katherine L. [7] 3661 Horseblock Road Medford, NY 11763	75,650	0.12%
GROUP [8]	**8,610,892**	**13.53%**
Vicis Capital Master Fund 126 East 56th Street, Tower 56, Suite 700 New York, NY 10022	4,608,707	7.44%
Millenium 3 Opportunity Fund, LLC [9] 4 Becker Farm Road Roseland, NJ 07068	4,006,610	6.31%
Inverness Medical Innovations, Inc. 51 Sawyer Road, Suite 200 Waltham, MA 02453	5,367,840	8.67%
Crestview Capital Master, LLC 95 Revere Drive, Suite A Northbrook, IL 60062	18,907,432	30.52%

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

The beneficial ownership percent in the table is calculated with respect to the number of outstanding shares (61,944,901) of the Company's common stock outstanding as of March 17, 2009. Each stockholder's ownership is calculated as the number of shares of common stock owned plus the number of shares of common stock into which any preferred stock, warrants, options or other convertible securities owned by that stockholder can be converted within 60 days.

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

(1) Includes 495,000 shares issuable upon exercise of options exercisable within 60 days.
(2) Includes 562,500 shares issuable upon exercise of options exercisable within 60 days and 2,007 shares issuable upon exercise of warrants.
(3) Includes 212,500 shares issuable upon exercise of options exercisable within 60 days.
(4) Includes 65,000 shares issuable upon exercise of options exercisable within 60 days.
(5) Includes 140,000 shares issuable upon exercise of options exercisable within 60 days.
(6) Includes 159,000 shares issuable upon exercise of options exercisable within 60 days. Does not include 108,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(7) Includes 75,650 shares issuable upon exercise of options exercisable within 60 days. Does not include 108,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(8) Includes footnotes (1)-(8)
(9) Includes 1,557,376 shares issuable upon exercise of warrants.

Equity Compensation Plan Information

Combined Equity Compensation Plans - Information as of December 31, 2008

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders[1]	2,416,650	$0.366	4,566,350
Equity compensation plans not approved by security holders	--	--	--
Total	2,416,650	$0.366	4,566,350

1 The “Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights” represents 1,983,000 from the 1999 Stock Option Plan and 433,650 under the 2008 Stock Incentive Plan. The “Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans” includes shares issuable under the 2008 Stock Incentive Plan. The Company currently has no intention to issue additional securities under the 1999 Stock Option 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 February 15, 2008, the Compensation Committee approved the reduction of the exercise price to $0.48 per share of each employee stock option award issued under the 1999 Stock Option Plan for which the exercise price was greater than $0.48 per share. As a result of this price reduction, the following number of employee stock options owned by the Company's officers and directors at that time under the 1999 Stock Option Plan qualified for this price reduction: (i) Mr. Siebert: 170,000 options; (ii) Mr. Larkin: 87,500 options; (iii) Mr. Esfandiari: 532,500 options; (iv) Mr. Aromando: 100,000 options; (v) Mr. Ippolito: 15,000 options; (vi) Mr. Bruce: 90,000 options; (vii) Mr. Carus: 252,000 options; (viii) Dr. Meller: 252,000 options; and (ix) Ms. Davis: 180,000 options.

In addition, on February 15, 2008 the Compensation Committee granted, to certain of the Company's existing officers at that time options to purchase the Company's common stock under the 1999 Stock Option Plan as follows: (i) Mr. Siebert, 75,000 options; (ii) Mr. Larkin, 75,000 options; (iii) Mr. Esfandiari, 60,000 options; (iv) Mr. Bruce, 50,000 options; (v) Mr. Ippolito, 50,000 options; and (vi) Mr. Aromando, 25,000 options. The exercise price for each of these options is $0.22 per share, which was the closing market price for the Company's common stock on February 15, 2008. The options vest on the date of the grant, and 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.

Avi Pelossof, the Company's Vice President of Sales and Marketing from May 5, 2004 to January 31, 2007, exercised 100,000 options in December 2006 at $0.60 per share, and another 50,000 options in January 2007 at $0.75 per share.

Robert Aromando, the Company's Executive Vice President of Commercial Operations was hired in May of 2007. In June 2007 in connection with his joining the Company, he was granted options to purchase 100,000 shares of common stock at an exercise price of $0.62 per share. These options will become exercisable one year from the date of grant. As discussed above, on February 15, 2008, the exercise price for these options was reduced to $0.48. Mr. Aromando left the employ of the Company in August 2008 and since then his options have expired.

Dr. Gary Meller, a non-employee director of the Company, currently serves as a limited partner and a member of the Advisory Board of Crestview Capital Master LLC, referred to herein as Crestview, which was the lead investor, investing $3 million, in our Series B Preferred Stock private placement in January 2005, and which subsequently invested an additional $1 million in our Series B Preferred Stock private placement in March 2006. Crestview also invested $2 million in our Series C Preferred Stock private placement in September 2006. Details of these transactions are set forth below. Crestview currently is the largest stockholder of the Company, with beneficial ownership of approximately 30.5 percent of our common stock.

As referred to above, in January 2005, for a purchase price of $3 million, Crestview acquired 60 shares of our Series B Preferred Stock, and warrants to purchase 4,672,130 shares of our common stock at a warrant exercise price of $0.61 per share. As described below, in December 2007, these shares of Preferred Stock and warrants were exchanged for shares of the Company's common stock.

In March 2006, for a purchase price of $1 million, Crestview acquired 20 shares of Series B Preferred Stock with warrants to purchase 1,557,377 shares of common stock at a warrant exercise price of $0.61 per share. These shares were issued in connection with the Company's January 2005 private placement as described herein. In September 2006, for a purchase price of $2 million, we issued 40 shares of Series C Preferred Stock to Crestview together with warrants to purchase 625,000 shares of common stock at an exercise price of $1.00 per share.

In January 2007, because of comments from the staff of the SEC concerning the Company's registration statement No. 333-138266 (the "Prospectus"), Crestview agreed to reduce the number of its shares of common stock covered by the Prospectus to 2,000,000. Crestview also agreed to waive any penalties that the Company would otherwise owe Crestview because of the failure to register all of Crestview's shares in the Prospectus. In consideration for this waiver, the Company agreed that, upon request by Crestview, the Company will file one or more registration statements with the SEC in order to register the resale of other shares beneficially owned by Crestview. The cost of any such registration statements shall be borne by the Company.

In addition to Crestview's $2,000,000 investment in the Company's September 2006 private placement of Series C Preferred Stock, the Company also received an investment of $2,000,000 on that date from Inverness Medical Innovations, Inc. ("Inverness"). At that time, a Certificate of Designation for the Series C Preferred Stock was filed with the Secretary of State of Nevada reflecting the agreed upon conversion price of $0.85 per share of common stock. This private placement of Series C Preferred Stock was completed on October 5, 2006, and it raised an aggregate of $8,150,000 (including the $2,000,000 invested by each of Crestview and Inverness). During the period between September 29, 2006 and October 5, 2006, we requested the assistance of Crestview and others in identifying prospective investors for us.

On December 19, 2007 (the “Closing Date”), amendments to the governing documents for the Company’s Series A, Series B and Series C Convertible Preferred Stock (collectively, the “Preferred Stock”) and for certain warrants and options (collectively, the “Non-Employee Warrants”), not including options or warrants issued to employees or directors in their capacity as such (these actions collectively, the “Plan”), were approved by the Company and the requisite percentages of the holders of the Preferred Stock and of the Non-Employee Warrants. Subsequent to these amendments, all shares of Preferred Stock were converted to common stock and certain of the Non-Employee Warrants were exercised, including the following: Mr. Siebert’s 38.74442 shares of Series A Preferred Stock were converted into 2,421,526 shares of common stock at $0.48 per share, his 1.08545 shares of Series B Preferred Stock were converted into 113,067 shares of common stock at $0.48 per share, and Mr. Siebert purchased 337,500 shares of common stock through the exercise of warrants at an exercise price of $0.40 per share, for a total of $135,000 in cash; Mr. Larkin on December 19, 2007 pursuant to the Plan converted .50392 shares of his Series A Preferred Stock into 37,794 shares of common stock at $.40 per share, in addition he received 369 shares of common stock as payment of dividends on the series A preferred. He also received 3,050 shares of common stock in the exercise of warrants pursuant to the Plan at $.40 per share, or a total of $1,220 in cash, Inverness’ 40 shares of Series C Preferred Stock were converted into 4,166,666 shares of common stock, and Inverness exercised all of its Series C Warrants to purchase a total of 625,000 shares of common stock for an aggregate purchase price of $250,000 and Crestview’s 82.32274 shares of Series B Preferred Stock were converted into 10,290,342 shares of the Company’s common stock, Crestview’s 40 shares of Series C Preferred Stock were converted into 4,166,666 shares of common stock, Crestview exercised a portion of its Series B Warrants to purchase a total of 60,451 shares of common stock for an aggregate purchase price of $24,180.40, and Crestview exercised all of its Series C Warrants to purchase a total of 625,000 shares of common stock for an aggregate purchase price of $250,000.

In June 2008, pursuant to the Plan (see above), Mr. Siebert, exercised 2,205,731 warrants, on a cashless basis, into 332,940 shares of common stock, Mr. Larkin exercised 27,436 warrants, on a cashless basis, into 4,141 shares of common stock, and Crestview exercised 6,169,055 warrants, on a cashless basis, into 931,177 shares of common stock.

During the quarter ended December 31, 2008, Inverness notified the Company that Inverness had entered into a contract with Bio-Rad Laboratories, Inc. (“Bio-Rad”) for royalties on Bio-Rad’s patent for the detection of HIV-2 antibodies. The agreement also provided for Inverness to pay past royalties. The agreements between the Company and Inverness provide that the Company is to share in this expense and as such Inverness requested it be reimbursed for the Company’s share of past royalties. The Company negotiated with Inverness that this liability is to be paid from future revenues over approximately the next 18 months. In addition Inverness agreed to allow Chembio to pay its royalty obligation to Inverness on Chembio’s sales to third parties in the same way and over the same period.

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 (NASDAQ Marketplace Rule 4200). Under this definition, we have determined that Katherine L. Davis currently qualifies as independent director. We do not list the “independent” definition we use on our Internet website.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

All fees discussed below were paid to Lazar Levine & Felix LLP. Remaining fees for the December 31, 2008 audit will be paid in 2009 to Parente Randolph, LLC. In February 2009, Lazar Levine & Felix LLP merged its practice into Parente Randolph, LLC.

Audit Fees

For the years ended December 31, 2008 and 2007, the Company's independent accounting firm, billed the Company $136,000 and $119,000, 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, 2008 and 2007, 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, 2008 and 2007, the independent accounting firm billed the Company $13,500 and $10,000, respectively, for professional services for tax compliance, tax advice and tax planning.

All Other Fees

For the years ended December 31, 2008 and 2007, the independent accounting firm billed the Company $2,500 and $8,500 for fees associated with the preparation and filing of the Company's registration statements, responses to SEC comment letters and other related matters.

Audit Committee Pre-Approval Policies

The Audit Committee (and prior to the adoption of the Audit Committee, the Board of Directors) 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.

As disclosed in the Company's Amendment No. 2 to Form 8-K/A filed with the SEC on March 3, 2009, on February 15, 2009, the practice of Lazar Levine & Felix LLP was acquired by Parente Randolph, LLC ("Parente") in a transaction pursuant to which Lazar merged its operations into Parente and certain of the professional staff and principals of Lazar joined Parente either as employees or partners of Parente. On February 19, 2009, as a result of this transaction, Lazar resigned from its role as principal auditor of the Company's financial statements. The Company, through and with the approval of the Audit Committee of the Company's Board of Directors, engaged Parente as its independent registered public accounting firm.

Lazar's reports regarding the Company's financial statements for the fiscal years ended December 31, 2007 and 2006 did not contain any adverse opinion or disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principles. During the years ended December 31, 2008 and 2007, and during the interim period from the end of the most recently completed fiscal year through February 19, 2009, the date of resignation, there were no disagreements with Lazar on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedures, which disagreements, if not resolved to the satisfaction of Lazar would have caused it to make reference to such disagreement in its reports.

During the years ended December 31, 2008 and 2007, and during the interim period from the end of the most recently completed fiscal year through February 19, 2009, the date of engagement, the Company did not consult with Parente regarding the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinions that might be rendered by Parente on the Company's financial statements. Parente did not provide the Company a written report or any oral advice that was an important factor considered by the Company in reaching a decision as to any accounting, auditing or financial reporting issue.

In addition, during the years ended December 31, 2008 and 2007, and during the interim period from the end of the most recently completed fiscal year through February 19, 2009, the date of engagement, the Company did not consult with Parente on any matter that was either the subject of a disagreement (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions to this item) or a reportable event (as described in Item304(a)(1)(v) of Regulation S-K). As such none of the required disclosures under Item 304(a)(2)(ii) apply.

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Number	Description & #160;
3.1	Articles of Incorporation, as amended. (3)
3.2	Amended and Restated Bylaws. (1)
4.2	Registration Rights Agreement, dated as of May 5, 2004, by and among the Registrant and the Purchasers listed therein. (2)
4.4	Amended Form of Common Stock Warrant issued pursuant to the May 4, 2004 Stock and Warrant Purchase Agreement. (16)
4.5	Form of $0.90 Warrant issued to Mark L. Baum pursuant to the Consulting Agreement dated as of May 5, 2004 between the Registrant and Mark L. Baum. (2)
4.6	Form of $0.60 Warrant issued to Mark L. Baum pursuant to the Consulting Agreement dated as of May 5, 2004 between the Registrant and Mark L. Baum. (2)
4.8	Form of Common Stock Warrant issued pursuant to the January 26, 2005 Securities Purchase Agreement. (9)
4.9	Amended Form of Common Stock Warrant issued pursuant to the January 26, 2005 Securities Purchase Agreement. (16)
4.10	Registration Rights Agreement, dated as of January 26, 2005, by and among the Registrant and the purchasers listed therein. (9)
4.11	Form of Warrant, dated June 29, 2006, issued pursuant to Company and purchasers of the Company's Secured Debentures. (4)
4.12	Registration Rights Agreement, dated June 29, 2006. (4)
4.14	Registration Rights Agreement, dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (6)
4.15	Form of Common Stock Warrant issued pursuant to the Securities Purchase Agreements dated September 29, 2006 (6).
4.16	Amended Form of Common Stock Warrant issued pursuant to the Securities Purchase Agreements dated October 5, 2006. (16)
4.17	Amended Form of Common Stock Warrant issued to Placement Agents pursuant to the October 5, 2005 Securities Purchase Agreement. (16)
4.18*	Form of Employee Option Agreement. (16)
4.19	Amended Form of Warrant used for Consultant Services, and in connection with the Company's 2004 merger. (16)
4.20	1999 Equity Incentive Plan. (14)
4.20	2008 Stock Incentive Plan. (15)
10.1*	Employment Agreement dated June 15, 2006 with Lawrence A. Siebert. (5)
10.2*	Employment Agreement dated April 23, 2007 with Javan Esfandiari. (13)
10.3	Series A Convertible Preferred Stock and Warrant Purchase Agreement (the "Stock and Warrant Purchase Agreement"), dated as of May 5, 2004, by and among the Registrant and the purchasers listed therein. (2)
10.4	Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of January 26, 2005, by and among the Registrant and the purchasers listed therein. (9)
10.5	Amendment No. 1 to Securities Purchase Agreement, dated as of January 28, 2005 by and among the Registrant and the purchasers listed therein. (10)
10.7	Security Purchase Agreement, dated June 29, 2006, among the Company and purchasers of the Company's Secured Debentures. (4)
10.11	Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (6)
10.12	Letter of Amendment to Securities Purchase Agreements dated as of September 29, 2006 by and among the Registrant and the Purchasers listed therein. (6)
10.13	HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Inverness and StatSure. (6)
10.14	HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Inverness. (6)
10.15	Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Inverness. (6)
10.16	Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (6)
10.19	License and Supply Agreement dated as of August 30, 2002 by and between Chembio Diagnostic Systems Inc. and Adaltis Inc. (8)
14.1	Ethics Policy (11)
21	List of Subsidiaries.
23.1	Consent of Parente Randolph LLC, Independent Accountants.
23.2	Consent of Lazar Levine & Felix LLP, Independent Accountants.
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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

SIGNATURES

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

CHEMBIO DIAGNOSTICS, INC.

Date: March 18, 2009

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 18, 2009
/s/ Richard J. Larkin Richard J. Larkin	Chief Financial Officer (Principal Financial & Accounting Officer)	March 18, 2009
/s/ Gary Meller Dr. Gary Meller	Director	March 18, 2009
/s/ Katherine L. Davis Katherine L. Davis	Director	March 18, 2009

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES

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REPORT OF REGISTERED INDEPENDENT PUBLIC ACCOUNTING FIRM

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

We have audited the consolidated balance sheet of Chembio Diagnostics, Inc. and Subsidiaries (the "Company") as of December 31, 2008 and the consolidated statements of operations, stockholders' equity and cash flows for the year ended December 31, 2008. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

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

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

PARENTE RANDOLPH, LLC

/s/ PARENTE RANDOLPH, LLC

New York, New York
March 18, 2009

REPORT OF REGISTERED INDEPENDENT PUBLIC ACCOUNTING FIRM

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

We have audited the consolidated balance sheet of Chembio Diagnostics, Inc. and Subsidiaries (the "Company") as of December 31, 2007 and the consolidated statements of operations, stockholders' equity and cash flows for the year ended December 31, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Chembio Diagnostics, Inc. and Subsidiaries as of December 31, 2007, and the consolidated results of its operations and its cash flows for the year ended December 31, 2007 in conformity with accounting principles generally accepted in the United States of America.

LAZAR LEVINE & FELIX LLP

/s/ LAZAR LEVINE & FELIX LLP

New York, New York
March 7, 2008

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

	December 31, 2008	December 31, 2007
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	**$ 1,212,222**	$ 2,827,369
Accounts receivable, net of allowance for doubtful accounts of $10,000 for 2008 and 2007	**809,303**	946,340
Inventories	**1,819,037**	1,453,850
Prepaid expenses and other current assets	**225,153**	243,748
TOTAL CURRENT ASSETS	**4,065,715**	5,471,307
FIXED ASSETS, net of accumulated depreciation	**881,406**	829,332
OTHER ASSETS:		
License agreements, net of current portion	**940,000**	255,948
Deposits and other assets	**27,820**	28,410
	$ 5,914,941	$ 6,584,997
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	**$ 2,383,021**	$ 2,175,791
Deferred research and development revenue	**-**	43,334
Current portion of obligations under capital leases	**18,780**	23,458
TOTAL CURRENT LIABILITIES	**2,401,801**	2,242,583
OTHER LIABILITIES:		
Obligations under capital leases - net of current portion	**60,808**	79,588
License fee payable - net of current portion	**875,000**	-
TOTAL LIABILITIES	**3,337,609**	2,322,171
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Preferred stock – 10,000,000 shares authorized, none outstanding	**-**	-
Common stock - $.01 par value; 100,000,000 shares authorized 61,944,901 and 60,537,534 shares issued and outstanding as of 2008 and 2007, respectively	**619,449**	605,375
Additional paid-in capital	**39,252,350**	39,003,148
Accumulated deficit	**(37,294,467)**	(35,345,697)
TOTAL STOCKHOLDERS' EQUITY	**2,577,332**	4,262,826
	$ 5,914,941	$ 6,584,997

See accompanying notes

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

	December 31, 2008	December 31, 2007
REVENUES:		
Net sales	**$ 10,355,768**	$ 8,764,877
Research grant income	**693,803**	466,071
TOTAL REVENUES	**11,049,571**	9,230,948
Cost of sales	**7,197,850**	6,435,238
GROSS PROFIT	**3,851,721**	2,795,710
OPERATING EXPENSES:		
Research and development expenses	**2,605,343**	1,906,653
Selling, general and administrative expenses	**3,317,046**	3,765,221
TOTAL OPERATING EXPENSES	**5,922,389**	5,671,874
LOSS FROM OPERATIONS	**(2,070,668)**	(2,876,164)
OTHER INCOME (EXPENSES):		
Other income - net	**95,812**	120,862
Interest income	**34,403**	145,289
Interest expense	**(8,317)**	(16,879)
	121,898	249,272
LOSS BEFORE INCOME TAXES	**(1,948,770)**	(2,626,892)
Provision for income taxes	**-**	-
NET LOSS	**(1,948,770)**	(2,626,892)
Dividends payable in stock to preferred stockholders	**-**	5,645,310
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	**$ (1,948,770)**	$ (8,272,202)
Basic and diluted loss per share	**$ (0.03)**	$ (0.57)
Weighted average number of shares outstanding, basic and diluted	**61,266,954**	14,608,478

See accompanying notes

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2008 AND 2007

	Series A Preferred Stock		Series B Preferred Stock		Common Stock		Additional paid in capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Amount	Amount	Amount
Balance at December 31, 2006	**149.92119**	**$ 2,504,313**	**113.93591**	**$ 3,555,786**	**11,296,961**	**$ 112,970**	**$19,960,618**	**$ (27,073,494)**	**$ (939,807)**
Preferred Stock related:									
Accretion of preferred dividend	-	**331,375**	-	**491,302**	-	-	-	**(1,385,594)**	**(562,917)**
Payment of dividends	-	**(391,343)**	-	**(758,087)**	**3,442,467**	**34,425**	**1,705,505**	-	**590,500**
Common Stock Issued:									
Common converted from preferred (including Series C)	**(149.92119)**	**(2,444,345)**	**(113.93591)**	**(3,289,001)**	**41,861,540**	**418,615**	**16,425,733**	**(4,259,717)**	**6,851,285**
For services	-	-	-	-	**200,000**	**2,000**	**117,800**	-	**119,800**
Warrants and options:									
Consultants/Advisory Board	-	-	-	-	-	-	**20,000**	-	**20,000**
Exercised	-	-	-	-	**3,736,566**	**37,365**	**1,082,996**	-	**1,120,361**
Fee for plan	-	-	-	-	-	-	**(561,816)**	-	**(561,816)**
Stock option compensation	-	-	-	-	-	-	**252,312**	-	**252,312**
Net loss for 2007	-	-	-	-	-	-	-	**(2,626,892)**	**(2,626,892)**
Balance at December 31, 2007	-	-	-	-	**60,537,534**	**605,375**	**39,003,148**	**(35,345,697)**	**4,262,826**
Warrants and options:									
Excercised	-	-	-	-	**1,407,367**	**14,074**	**(14,074)**	-	-
Stock option compensation	-	-	-	-	-	-	**263,276**	-	**263,276**
Net loss for 2008	-	-	-	-	-	-	-	**(1,948,770)**	**(1,948,770)**
Balance at December 31, 2008	-	**$** -	-	**$** -	**61,944,901**	**$ 619,449**	**$39,252,350**	**$ (37,294,467)**	**$ 2,577,332**

See accompanying notes

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

		December 31, 2008		December 31, 2007
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS:				
CASH FLOWS FROM OPERATING ACTIVITIES:				
Cash received from customers	**$**	**11,186,608**	$	9,802,348
Cash paid to suppliers and employees		**(12,406,921)**		(11,276,554)
Interest received		**34,403**		145,289
Interest paid		**(8,317)**		(16,879)
Net cash used in operating activities		**(1,194,227)**		(1,345,796)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Acquisition of fixed assets		**(397,462)**		(410,425)
Net cash used in investing activities		**(397,462)**		(410,425)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from exercise of options and warrants, net of cash cost of financing of $561,816 in 2007		-		558,545
Payment of accrued interest		-		(93,160)
Payment of dividends		-		(120,000)
Payment of capital lease obligation		**(23,458)**		(52,181)
Net cash used in financing activities		**(23,458)**		293,204
NET (DECREASE) IN CASH AND CASH EQUIVALENTS		**(1,615,147)**		(1,463,017)
Cash and cash equivalents - beginning of the period		**2,827,369**		4,290,386
Cash and cash equivalents - end of the period	**$**	**1,212,222**	$	2,827,369
RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:				
Net Loss	**$**	**(1,948,770)**	$	(2,626,892)
Adjustments:				
Depreciation and amortization		**345,388**		283,359
Loss on retirement of fixed assets		-		12,146
Provision for doubtful accounts		-		(32,922)
Common stock, options and warrants issued as compensation		**291,979**		342,163
Changes in assets and liabilities:				
Accounts receivable		**137,037**		436,822
Inventories		**(365,187)**		(344,900)
Prepaid expenses and other assets		**(10,108)**		(9,706)
Other assets and deposits		**(683,462)**		64,948
Deferred revenue		**(43,334)**		-
Accounts payable and accrued expenses		**207,230**		529,186
Licenses fee payable		**875,000**		-
Net cash used in operating activities	**$**	**(1,194,227)**	$	(1,345,796)
Supplemental disclosures for non-cash investing and financing activities:				
Value of common stock issued upon cashless warrant exercise	**$**	**14,074**	$	-
Value of warrants/options/stock issued allocated to additional paid-in capital		-		61,181
Accreted dividend to preferred stock		-		1,385,594
Value of Common stock issued as payment of dividend		-		1,739,930
Value of Preferred stock converted to common stock		-		5,733,346
Assets acquired under capital leases		-		110,810

See accompanying notes

NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. (the "Company" or "Chembio") and its subsidiaries 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 2008. The Company also has other rapid tests that together represented approximately 10% of sales in 2008. The Company's products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments. Chembio's products are sold under the Company's STAT PAK® or SURE CHECK ® registered trademarks or under the private labels of its marketing partners, for example the Clearview® label owned by Inverness Medical Innovations, Inc., which is the Company's exclusive marketing partner for its rapid HIV lateral flow test products in the United States. These products employ lateral flow technologies that are proprietary and/or licensed to the Company. All of the Company's products that are currently being developed are based on its patented Dual Path Platform (DPP®), which is a unique diagnostic point-of-care platform that has certain advantages over lateral flow technology. In 2008, the Company completed development of its first two products that employ the DPP® and has a number of additional products under development that employ the DPP®.

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern. Although revenues and gross margins increased in the year ended December 31, 2008 as compared to the same period in 2007, the Company continues to generate significant operating losses. At December 31, 2008, the Company had a positive stockholders' equity of $2,577,000 and working capital of $1,664,000. The Company estimates that its resources are sufficient to fund its needs through the end of 2009 and beyond or that, in the alternative, it could raise additional capital although the terms under which that capital could be raised would likely be very dilutive to current shareholders**.** The Company's liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenues (the Company received $340,000 in 2009 for license fees for which we need to meet certain milestones to earn); (2) the extent to which, if any, that revenue level improves operating cash flows; (3) the Company's investments in research and development, facilities, marketing, regulatory approvals, and other investments it may determine to make; and (4) the investment in capital equipment (including production equipment of $323,500 that the Company has contracted for) and the extent to which it improves cash flow through operating efficiencies. There are no assurances that the Company will become profitable or generate positive cash flow by the end of 2009 or, in the alternative, be successful in raising sufficient capital to fund its needs through 2009.

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 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 reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

(c) Fair Value of Financial Instruments:

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

(d) Statements of Cash Flows:

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

(e) Concentrations of Credit Risk:

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of temporary cash investments and trade receivables. The Company places its temporary cash instruments with well-known financial institutions and, at times, may maintain balances in excess of the $250,000 FDIC Insurance limit. The Company monitors the credit ratings of the financial institutions to mitigate this risk. The Company maintains three accounts with a well established multi-national bank and as of December 31, 2008 had approximately $1.1 million above these limits. Concentration of credit risk with respect to trade receivables is principally mitigated by the Company's obtaining of letters of credit from certain foreign customers, and its diverse customer base both in number of customers and geographic locations. We currently do not require collateral.

(f) Inventories:

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

(g) Fixed Assets:

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

(h) License Agreement:

In February 2008, the Company entered into a sublicense agreement (see Note 6) for which it has recorded an asset of $1,000,000. This asset is being expensed over an estimated economic life of ten years. The current portion of this asset is $100,000 and is reported in prepaid expenses and other current assets. The long-term portion as of December 31, 2008 is $800,000 and is reflected in other assets along with other unexpensed long-term license fees of $140,000.

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

In accordance with FAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets", long-lived assets to be held and used are analyzed for impairment whenever events or changes in circumstances indicate that the related carrying amounts may not be recoverable. The Company evaluates at each balance sheet date whether events and circumstances have occurred that indicate possible impairment. If there are indications of impairment, the Company uses future undiscounted cash flows of the related asset or asset grouping over the remaining life in measuring whether the assets are recoverable. In the event such cash flows are not expected to be sufficient to recover the recorded asset values, the assets are written down to their estimated fair value. We believe that the carrying values of our long-lived tangible and intangible assets were realizable at December 31, 2008.

(j) Revenue Recognition:

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

The Company recognizes income from research projects and grants when earned. Grants are invoiced after expenses are incurred. Any projects or grants funded in advance are deferred until earned.

(k) Shipping and Handling Costs:

We incur shipping and handling costs associated with the shipment of goods to customer and independent distributors. All shipping and handling amounts billed to customers are included in net sales. All shipping and handling costs associated with the shipment of goods to customers are netted against the amounts billed and are reflected in net sales. All other shipping and handling costs are included in selling, general and administrative expenses.

(l) Research and Development:

Research and development costs are charged to expense as incurred.

(m) Stock Based Compensation:

The Company's 2008 Stock Incentive Plan and 1999 Stock Option Plan ("Plans") are accounted for in accordance with the recognition and measurement provisions of Statement of Financial Accounting Standards ("FAS") No. 123 (revised 2004), Share-Based Payment ("FAS 123(R)"). FAS 123(R) 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 FAS No. 123(R) 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.

(n) Income Taxes:

The Company accounts for income taxes under the provisions of Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes" (FAS 109). Under FAS 109, 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.

Effective January 1, 2007, we adopted the Financial Accounting Standards Board ("FASB") Interpretation No. 48, Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109 ("FIN 48"). FIN 48 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. FIN 48 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. The adoption of FIN 48 had no impact on the Company's financial statements for the year ended December 31, 2007.

(o) 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, 2008	December 31, 2007
Basic	**61,266,954**	14,608,478
Diluted	**61,266,954**	14,608,478

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 loss per share reflects the potential dilution from the exercise or conversion of other securities into common stock, but only if dilutive. Diluted loss per share for the years ended December 31, 2008 and 2007 is the same as basic loss per share, since the effects of the calculation were anti-dilutive due to the fact that the Company incurred losses for all periods presented. The following securities, presented on a common share equivalent basis, have been excluded from the per share computations:

	For the years ended	
	December 31, 2008	December 31, 2007
1999 & 2008 Plan Stock Options	**2,555,837**	2,015,352
Other Stock Options	**124,625**	124,625
Warrants	**14,657,050**	25,972,223
Convertible Preferred Stock	**-**	25,872,315
	17,337,512	53,984,515

(p) Recent Accounting Pronouncements Affecting the Company:

In September 2006, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("FAS") No. 157, Fair Value Measurements, which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. This statement does not require any new fair value measurements, but provides guidance on how to measure fair value by providing a fair value hierarchy used to classify the source of the information. FAS No. 157 is effective for fiscal years beginning after November 15, 2007, and all interim periods within those fiscal years. In February 2008, the FASB released FASB Staff Position (FSP FAS 157-2 – Effective Date of FASB Statement No. 157) which delays the effective date of FAS No. 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), to fiscal years beginning after November 15, 2008 and interim periods within those fiscal years. The implementation of FAS No. 157 for financial assets and liabilities, effective January 1, 2008, did not have an impact on the Company's financial position and results of operations. The Company is currently evaluating the impact of adoption of this statement on its nonfinancial assets and liabilities which is expected to be determined by the first quarter of fiscal 2009.

In February 2007, the FASB issued FAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities" ("FAS No. 159"). FAS No. 159 permits entities to choose to measure, on an item-by-item basis, specified financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected are required to be reported in earnings at each reporting date. FAS No. 159 is effective for fiscal years beginning after November 15, 2007, the provisions of which are required to be applied prospectively. The Company adopted this statement as of January 1, 2008 and has elected not to apply the fair value option to any of its financial instruments.

In December 2007, the FASB issued FAS No. 141 (revised 2007), Business Combinations, which replaces FAS No 141. The statement retains the purchase method of accounting for acquisitions, but requires a number of changes, including changes in the way assets and liabilities are recognized in the purchase accounting. It also changes the recognition of assets acquired and liabilities assumed arising from contingencies, requires the capitalization of in-process research and development at fair value, and requires the expensing of acquisition-related costs as incurred. FAS No. 141R is effective for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. The adoption of FAS 141R is not expected to have an impact on the Company's financial statements.

In December 2007, the FASB issued FAS No. 160, "Noncontrolling Interests in Consolidated Financial Statements – an Amendment of ARB No. 51." FAS 160 establishes accounting and reporting standards pertaining to ownership interests in subsidiaries held by parties other than the parent, the amount of net income attributable to the parent and to the noncontrolling interest, changes in a parent's ownership interest, and the valuation of any retained noncontrolling equity investment when a subsidiary is deconsolidated. This statement also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. FAS 160 is effective for fiscal years beginning on or after December 15, 2008. The adoption of FAS 160 is not currently expected to have a material effect on the Company's consolidated financial position, results of operations, or cash flows.

In March 2008, the FASB issued FAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities – an Amendment of FASB Statement No. 133." The new standard is intended to improve financial reporting about derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity's financial position, financial performance, and cash flows. It is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. The Company is currently evaluating the impact of adopting FAS No. 161 on its financial statements.

In December 2007, the Emerging Issues Task Force ("EITF") reached a consensus with respect to Issue No. 07-1 "Accounting for Collaborative Arrangements". This EITF applies to participants in a collaborative arrangement. A collaborative arrangement is a contractual arrangement that involves a joint operating activity. These arrangements involve two (or more) parties who are both (a) active participants in the activity and (b) exposed to significant risks and rewards dependent on the commercial success of the activity. Many collaborative arrangements involve licenses of intellectual property, and the participants may exchange consideration related to the license at the inception of the arrangement. Participants in a collaborative arrangement shall report costs incurred and revenue generated from transactions with third parties (that is, parties that do not participate in the arrangement) in each entity's respective income statement pursuant to the guidance in EITF No. 99-19. An entity should not apply the equity method of accounting under APB 18 to activities of collaborative arrangements. This EITF, which can be applied retrospectively, is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. The guidance in this EITF is not expected to have an impact on the Company's financial statements.

In June 2007, EITF reached a consensus with respect to Issue No. 07-3 "Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities". EITF 07-3 confirms that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the related services are performed. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. This EITF is effective for financial statements issued for fiscal years beginning after December 15, 2007. The guidance in this EITF had no impact on the Company's financial statements in 2008.

(q) Reclassifications

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.

NOTE 3 — INVENTORIES:

Inventories consist of the following at December 31:

	2008	2007
Raw materials	**$ 836,446**	$ 705,873
Work in process	**300,986**	234,077
Finished goods	**681,605**	513,900
	$ 1,819,037	$ 1,453,850

NOTE 4 — FIXED ASSETS:

Fixed assets consist of at December 31:

	2008	2007
Machinery and equipment	**$ 1,195,975**	$982,440
Furniture and fixtures	**195,611**	156,313
Computer and telephone equipment	**329,865**	308,591
Leasehold improvements	**400,589**	306,676
Automobiles	**29,442**	-
	2,151,482	1,754,020
Less accumulated depreciation and amortization	**(1,270,076)**	(924,688)
	$ 881,406	$829,332

Included in the above fixed assets is $70,500 and $121,000, net of accumulated depreciation of $40,000 and $69,000 of assets held under capital leases as of December 31, 2008 and 2007, respectively. Depreciation expense for the 2008 and 2007 years aggregated $345,388 and $283,359, respectively.

NOTE 5 — ACCOUNTS PAYABLE AND ACCRUED LIABILITIES:

Accounts payable and accrued liabilities as of December 31:

	2008	2007
Accounts payable – suppliers	**$ 634,083**	$ 726,174
Accrued commissions	**67,857**	14,251
Accrued royalties / license fees (see Note 8)	**1,400,941**	852,119
Accrued payroll	**95,135**	279,598
Accrued vacation	**91,895**	155,480
Accrued legal and accounting	**18,000**	10,000
Accrued expenses – other	**75,110**	138,169
TOTAL	**$ 2,383,021**	$ 2,175,791

NOTE 6 — LICENSE FEE PAYABLE:

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

NOTE 7 — 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, 2008 were as follows:

Year ending December 31,

2009	$28,572
2010	28,572
2011	28,572
2012	15,204
	100,920
Less: imputed interest	(21,332)
Present value of future minimum lease payments	79,588
Less: current maturities	(18,780)
	$ 60,808

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

NOTE 8 — RELATED PARTIES:

In September 2006, the Company received an investment of $2,000,000 from Inverness Medical Innovations, Inc. ("Inverness"). Inverness markets the Company's FDA-approved rapid HIV tests under Inverness' Clearview® brand, Chembio received a nonexclusive license to Inverness' lateral flow patents. The distribution agreements with Inverness contain gross margin sharing formulae among Inverness, the Company and, in the case of the HIV barrel product, StatSure Diagnostic Systems, Inc.

During the quarter ended December 31, 2008, Inverness Medical Innovations, Inc. ("Inverness") notified the Company that Inverness had entered into a contract with Bio-Rad Laboratories, Inc. ("Bio-Rad") for royalties on Bio-Rad's patent for the detection of HIV-2 antibodies. The agreement also provided for Inverness to pay past royalties. The agreements between the Company and Inverness provide that the Company is to share in these past royalties and Inverness requested it be reimbursed for the Company's share of these past royalties. The Company and Inverness have agreed that this liability, which is approximately $500,000 as of December 31, 2008 (included in accounts payable and accrued expenses – see Note 5), is to be paid from future revenues over approximately the next 18 months.

NOTE 9 — RESEARCH GRANTS AND DEVELOPMENT CONTRACTS:

In 2008 and 2007, the Company earned $694,000 and $466,000, respectively from research grants, feasibility and development contracts. The Company is now involved in additional feasibility and development contracts related to its DPP® technology.

NOTE 10 — INCOME TAXES:

No provision for Federal income taxes was required for the years ended December 31, 2008 or 2007, due to the Company's operating losses. At December 31, 2008 and 2007, the Company has unused net operating loss carry-forwards of approximately $22,200,000 and $21,000,000 which expire at various dates through 2028. Most of this amount is 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 $505,000 and $460,000 for the years ended December 31, 2008 and 2007, respectively which expire at various dates through 2028.

As of December 31, 2008 and 2007, the deferred tax assets related to the aforementioned carry-forwards have been fully offset by valuation allowances, since significant utilization of such amounts is not presently expected in the foreseeable future.

Deferred tax assets and valuation allowances consist of:

	2008	2007
Net operating loss carry-forwards	**$7,750,000**	$7,300,000
Research and development credit	**505,000**	551,000
Other	**343,000**	137,000
Gross deferred tax assets	**8,598,000**	7,988,000
Valuation allowances	**(8,598,000)**	(7,988,000)
Net deferred tax assets	**$ —**	**$ —**

We file income tax returns in the U.S. federal and New York state jurisdictions. Tax years for fiscal 2005 through 2007 are open and potentially subject to examination by the federal and New York state taxing authorities.

NOTE 11 — STOCKHOLDERS' EQUITY:

(a) **Common Stock**

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

On December 19, 2007 the Company issued pursuant to the Plan:

i) 99,086, 599,331, and 574,818 shares of common stock for the payment of dividends for the Series A, B and C preferred stock, respectively. These shares were valued, in the aggregate at $558,000, using the respective conversion price at the time of the conversion of the preferred stock;

ii) 10,134,954, 13,938,118, and 17,187,496 shares of common stock for the conversion of the Series A, B and C preferred stock, respectively. These shares were valued, in the aggregate at $16,504,000, using the market price on December 19, 2007;

iii) 963,163 shares of common stock for the cashless exercise of 6,381,052 warrants, and

iv) 2,723,403 shares of common stock for the cash exercise of warrants where the Company received $1,089,000 less $562,000 paid in fees.

During the year ended December 31, 2007, the Company issued 200,000 shares of its Common Stock upon the execution of an employment agreement, of which 100,000 shares vested immediately, 50,000 shares will vest on March 5, 2008 and 50,000 shares will vest on March 5, 2009. These shares were valued at the market price on the date of grant and aggregated $119,800 and are being expensed over the vesting periods.

During year ended December 31, 2007 the Company issued 50,000 shares of its Common Stock upon the exercise of options and received cash of $31,000.

During the year ended December 31, 2007 Series A Preferred shareholders, other than in the Plan, converted 8.33092 shares of Series A Preferred Stock into 416,546 shares of Common Stock.

During the year ended December 31, 2007 Series B Preferred shareholders, other than in the Plan, converted 2.25 shares of Series B Preferred Stock into 184,426 shares of Common Stock.

In the year ended December 31, 2007, other than in the Plan, the Company issued 897,896, 835,577 and 435,759 shares of its Common Stock as payment of dividends on its Series C Preferred Stock, Series B Preferred Stock and Series A Preferred Stock, respectively. These shares were valued, in the aggregate at $1,182,000, using a volume weighted average price (VWAP) for the ten trading days immediately preceding the issue date.

(b) ***Warrants***

On December 19, 2007, in connection with the Plan certain holders of the Non-Employee Warrants did not consent to the Plan transactions. Pursuant to the anti-dilution terms existing in certain of the Non-Employee Warrants held by these non-consenting holders, the number of warrants that these non-consenting holders are permitted to exercise has been increased by 2,395,466. In addition, the exercise prices of certain of the Non-Employee Warrants held by non-consenting holders was reduced to $0.40 pursuant to the terms of these warrants, and these non-consenting holders are permitted to exercise their warrants for cash only at $0.40 per share until the expiration of the warrants. The increased warrants expire as follows: a) 1,303,928 on January 29, 2010; b) 149,350 on June 29, 2011; and c) 942,188 on October 5, 2011.

During the year ended December 31, 2007, the Company issued warrants to purchase 33,381 shares of Common Stock at an exercise price of $0.81 per share to a sales agent as payment for commissions accrued at year end 2006 (value $20,000). These warrants have a five-year life.

The above warrants were valued using a Black-Scholes option pricing model based on assumptions for expected volatility of 104.8%, expected life of 5 years and expected risk-free interest rate of 4.54%.

(c) ***Series A 8% Convertible Preferred Stock***:

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

On December 19, 2007, according to the Plan, all of the Series A preferred stock was converted into common stock. The common stock issued was valued at the market price on December 19, 2007 of $.40 per share. This value was adjusted against the carrying value of the Series A Preferred Stock and the difference of $1,726,000 was charged to deemed dividends.

The Series A Preferred Stock was issued in 2004 at a face value of $30,000 per share with detachable warrants. The recorded amount of the preferred shares was calculated using a fair value allocation between the preferred shares and detachable warrants.

(d) ***Series B 9% Convertible Preferred Stock***:

On December 19, 2007, according to the Plan, all of the Series B preferred stock was converted into common stock. The common stock issued was valued at the market price on December 19, 2007 of $.40 per share. This value was adjusted against the carrying value of the Series B Preferred Stock and the difference of $2,349,000 was charged to deemed dividends.

The Series B Preferred Stock was issued in January 2005 at a face value of $50,000 per share with detachable warrants. The recorded amount of the preferred shares was calculated using a fair value allocation between the preferred shares and detachable warrants. On March 30, 2006, the Company sold $1 million of additional Series B Preferred Stock to a Series B Preferred shareholder pursuant to provisions of the January 2005 Series B 9% Preferred Stock financing agreements. Such provisions were exclusive to said shareholder. Approximately $140,000 of these proceeds was used to pay cash dividends which were accrued as of December 31, 2005. The recorded amount of the preferred shares was calculated using a fair value allocation between the preferred shares and detachable warrants.

(e) ***Series C 7% Convertible Preferred Stock***:

On December 19, 2007, according to the Plan, all of the Series C preferred stock was converted into common stock. The common stock issued was valued at the market price on December 19, 2007 of $.40 per share. This value was adjusted against the carrying value of the Series C Preferred Stock and the difference of $185,102 was charged to deemed dividends.

On September 29, 2006 and October 5, 2006, the Company sold $8.25 million of Series C Preferred Stock (see Note 1) pursuant to provisions of the September 29, 2006 as amended on October 5, 2006 Series C 7% Preferred Stock financing agreements. In addition the Company issued 2,578,125 warrants to the investors.

NOTE 12 — EMPLOYEE STOCK OPTION PLAN:

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

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

As a result of the adoption of FAS 123(R), the Company's results for the years ended December 31, 2008 and 2007 include share-based compensation expense totaling $263,000 and $252,000, respectively. Such amounts have been included in the Consolidated Statements of Operations within cost of goods sold ($19,000 and none, respectively), research and development ($56,000 and $100,000, respectively) and selling, general and administrative expenses ($188,000 and $152,000, 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, 2008 and 2007 represent the estimated fair value of options outstanding which are 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, 2008 and 2007 was $.37 and $.46 per share, respectively. The fair value of options at the date of grant was estimated using the Black-Scholes option pricing model. The expected volatility is based upon historical volatility of our stock and other contributing factors. The expected term is determined using the simplified method as permitted by SAB 107, as the Company has no history of employee exercise of options to-date.

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

	For the years ended	
	December 31, 2008	December 31, 2007
Expected term (in years)	**1 to 4**	5
Expected volatility	**109.33-112.33%**	102.84-104.80%
Expected dividend yield	**n/a**	n/a
Risk-free interest rate	**1.91 to 2.98%**	4.50-5.06%

The Company granted 967,650 new options under the Plans during the year ended December 31, 2008 at prices ranging from $.13 to $0.22 per share (534,000 were issued under the SOP and 433,650 were issued under the SIP). As of February 15, 2008, the board of directors voted to re-price any SOP options in excess of $.48 to $.48, the estimated expense related to this re-price is $20,000.

The following table provides stock options activity for the years ended December 31, 2008 and 2007:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2007	1,529,750	$0.65		
Granted	960,000	$0.57		
Exercised	(50,000)	$0.62		
Forfeited/expired /cancelled	(238,250)	$0.67		
Outstanding at December 31, 2007	**2,201,500**	**$0.64**	**3.52 years**	**$ -**
Impact of re-price (for accounting purposes treated as a cancelation and re-issue):				
effect as if cancelled	(1,846,500)	$0.64		
effect as if re-issiued	1,846,500	$0.48		
Granted	967,650	$0.18		
Exercised	-	-		
Forfeited/expired	(752,500)	$0.58		
Outstanding at December 31, 2008	**2,416,650**	**$0.36**	**3.23 years**	**$ -**
Exercisable at December 31, 2008	**1,956,650**	**$0.36**	**3.11 years**	**$ -**

The following table summarizes information about stock options outstanding as of December 31, 2008:

	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 - 0.21	442,650	4.42	0.130	$ -	298,650	0.131	$ -
$ 0.22 - 0.34	465,000	4.13	0.220	-	465,000	0.220	-
$ 0.35 - 0.45	65,000	1.77	0.427	-	15,000	0.350	-
$ 0.46 - 0.88	1,444,000	2.65	0.483	-	1,178,000	0.482	-
Total	2,416,650		0.366	$ -	1,956,650	0.365	$ -

As of December 31, 2008, there was $74,000 of net unrecognized compensation cost related to stock options that are not vested, which is expected to be recognized over a weighted average period of approximately 1.25 years. The total fair value of shares vested during the years ended December 31, 2008 and 2007, was $273,000 and $276,000, respectively.

NOTE 13 — GEOGRAPHIC INFORMATION:

FAS No. 131, “Disclosures about Segments of an Enterprise and Related Information” establishes standards for the way that business enterprises report information about operating segments in financial statements and requires that those enterprises report selected information. It also establishes standards for related disclosures about product and services, geographic areas, and major customers.

The Company produces only one group of similar products known collectively as “rapid medical tests”. As per the provisions of FAS 131, management believes that it operates in a single business segment. Net sales by geographic area are as follows:

	For the years ended	
	December 31, 2008	December 31, 2007
Africa	**$ 4,740,858**	$ 3,784,791
Asia	**227,049**	158,577
Europe	**160,824**	153,808
Middle East	**308,053**	239,838
North America	**2,415,344**	4,226,442
South America	**2,503,640**	201,421
	$ 10,355,768	$ 8,764,877

Sales to Africa in 2008 were primarily from Nigeria of approximately $2.86 million. We have been advised recently that our designation in Nigeria as one of the screening tests has changed to that of the confirmatory test as this country moves from a parallel to a serial testing algorithm, which we expect will significantly reduce our sales to Nigeria in 2009, In addition sales to North America and South America in 2008 were primarily from sales into the U.S. and Brazil, respectively.

NOTE 14 — COMMITMENTS AND CONTINGENCIES:

Employment Contracts:

The Company has contracts with two key employees. The contracts call for salaries presently aggregating $500,000 per year. One contract expires in May of 2009 and one contract expires in March of 2010. The following table is a schedule of future minimum salary commitments:

2009	$ 319,166
2010	39,167
	$ 358,333

***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 $23,850 and $20,500 for the years ended December 31, 2008 and 2007, respectively.

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

Obligations Under Operating Leases:

The Company leases office, R&D and manufacturing facilities, currently with a monthly rent of $11,987. The current lease expires on April 30, 2009. The following is a schedule of future minimum rental commitments:

Year ending December 31,2009	$ 47,948

As of the filing date of this Annual Report, the Company is in discussion for a lease extension for its administrative offices and research facilities. The principle terms being discussed are as follows: (a) a lease term of five years; (b) an initial rent of $11,350 per month; (c) the monthly rent for year two of the lease will increase by the lower of (i) the change in the consumer price index, or (ii) five percent; and (d) the monthly rent for years three through five of the lease will increase each year by the lower of (i) the change in the consumer price index, or (ii) two and one half percent. Although the Company believes that the extension will be entered into on terms that are substantially similar to the terms being discussed, there is no assurance that this will occur. After this lease is executed the following would be the schedule of future minimum rental commitments (assuming 5% increase the first year and 2.5% thereafter):

Year ending December 31,

2009	$ 138,748
2010	140,740
2011	145,394
2012	149,029
2013	152,754
2014	51,473
	$ 778,138

Rent expense aggregated $130,300 and $123,500 for the years ended December 31, 2008 and 2007, 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, 2008		December 31, 2007		As of	
	Sales	% of Sales	Sales	% of Sales	Dec 31, 2008	Dec 31, 2007
Customer 1	$ 2,434,420	24	*	*	$ 265,276	*
Customer 2	$ 3,502,737	34	$ 2,248,992	26	-	-
Customer 3	$ 2,183,510	21	$ 2,456,071	28	$ 283,722	$ 222,396
Customer 4	*	*	$ 1,398,125	16	*	-

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 to vendors in excess of 10% of total purchases for the periods indicated:

	For the years ended				Accounts Payable	
	December 31, 2008		December 31, 2007		As of	
	Purchases	% of Purc.	Purchases	% of Purc.	Dec. 31, 2008	Dec. 31, 2007
Vendor 1	$ 627,637	21	$ 356,136	15	$ 17,460	$ 19,469
Vendor 2	$ 303,750	10	*	*	$ 87,840	*

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

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

Governmental Regulation:

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

Voluntary Component Recall:

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

Nigeria:

During the first quarter of 2008, the Nigerian Ministry of Health published a report indicating that our designation in Nigeria as one of the screening tests would be changed to that of a confirmatory and/or tie-breaker test (Many countries use a serial algorithm with tests from different manufacturers. A serial algorithm uses a screening test from one manufacturer, a second confirmatory test, from another manufacturer, 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, from a third manufacturer, resolves discrepancies between the screen and the confirmatory test) which change has become effective in the first quarter of 2009. Consequently we expect our sales to Nigeria to decrease significantly in 2009 as compared to 2008.

Equipment Purchase Commitment:

In January of 2009, the Company entered into an agreement with an equipment manufacturer to design and build equipment that will be used to automate the assembling of our tests and lower our production costs. The estimated cost of $323,500 is being paid in installments over a five month period.

DPP® Agreements:

a. Brazil:

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

On October 2, 2008 the Company announced a fourth technology transfer supply and license agreement with FIOCRUZ for it's DPP® HIV 1/2 rapid test (for use with oral fluid or whole blood samples). Based upon the four agreements we signed with FIOCRUZ in 2008, together with revenues that are anticipated under the original agreement we signed with FIOCRUZ in 2004 for our STAT PAK® rapid test, and subject to required regulatory approval and Ministry of Health funding of the screening programs these tests are designated for.

b. Bio-Rad:

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

Exhibit 21

List of Subsidiaries

Chembio Diagnostics Systems, Inc. (Delaware)

Exhibit 23.1

CONSENT OF REGISTERED INDEPENDENT PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in Registration Statement No. 333-69460 and Registration Statement No. 333-141555 on Form S-8 of our report dated March 18, 2009 relating to the consolidated balance sheet of Chembio Diagnostics Inc. and Subsidiaries as of December 31, 2008 and the consolidated statement of operations, stockholders' equity and cash flow for the year ended December 31, 2008 appearing in this Annual Report on Form 10-K of Chembio Diagnostics, Inc. for the year ended December 31, 2008.

Parente Randolph, LLC

/s/ Parente Randolph, LLC

New York, New York
March 18, 2009

Exhibit 23.2

CONSENT OF REGISTERED INDEPENDENT PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in Registration Statement No. 333-69460 and Registration Statement No. 333-141555 on Form S-8 of our report dated March 7, 2008 relating to the consolidated balance sheet of Chembio Diagnostics Inc. and Subsidiaries as of December 31, 2007 and the consolidated statement of operations, stockholders' equity and cash flow for the year ended December 31, 2007 appearing in this Annual Report on Form 10-K of Chembio Diagnostics, Inc. for the year ended December 31, 2008.

Lazar Levine & Felix LLP

/s/ Lazar Levine & Felix LLP

New York, New York
March 18, 2009

EXHIBIT 31.1

CERTIFICATION

I, Lawrence A. Siebert, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 18, 2009

/s / Lawrence A. Siebert
Lawrence A. Siebert
Chief Executive Officer, President, and Chairman
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Richard J. Larkin, certify that:

1. I have reviewed this annual report on Form 10-Kof Chembio Diagnostics, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: March 18, 2009

/s / Richard J. Larkin
Richard J. Larkin
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32

CHEMBIO DIAGNOSTICS, INC.
SARBANES-OXLEY ACT SECTION 906 CERTIFICATION

In connection with this annual report on Form 10-K of Chembio Diagnostics, Inc. (the "Company") for the fiscal year ended December 31, 2008, each of the undersigned, Lawrence A. Siebert, the Chief Executive Officer, President and Chairman of the Company, and Richard J. Larkin, the Chief Financial Officer of the Company, hereby certify pursuant to 18 U.S.C. section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002, that:

1. This Form 10-KSB for the fiscal year ended December 31, 2008 fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in this Form 10-KSB for the fiscal year ended December 31, 2008 fairly presents, in all material respects, the financial condition and results of operations of Chembio Diagnostics, Inc. for the periods presented therein.

Date: March 18, 2009

/s / Lawrence A. Siebert
Lawrence A. Siebert
Chief Executive Officer, President and Chairman
(Principle Executive Officer)

/s./ Richard J. Larkin
Richard J. Larkin
Chief Financial Officer
(Principle Financial Officer)