

CHEMBIO DIAGNOSTICS, INC.  
Form 10KSB  
March 29, 2007

U.S. Securities and Exchange Commission  
Washington, D.C. 20549

**FORM 10-KSB**

**[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2006

**[ ] TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 [No Fee Required]**

For the transition period from \_ to \_\_\_\_\_.

Commission File No. 0-30379

**CHEMBIO DIAGNOSTICS, INC.**

(Name of small business issuer in its charter)

Nevada 88-0425691

(State or (I.R.S.

jurisdiction of Employer

incorporation Identification

or No.)

organization)

3661 11763

Horseblock

Road,

Medford, NY

(Address of (Zip Code)

principal

executive

offices)

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

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

Title	Name of
of	each
each	exchange
class	on which
	registered
<u>None</u>	<u>None</u>

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

Common  
Stock,  
\$0.01 par  
value  
(Title of  
Class)

Check whether the issuer is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act.

Yes  No

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 past 12 months (or for such shorter period that the registrant was required to file such report), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B (§ 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-KSB or any amendment to this Form 10-KSB. [  ]

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.

Yes  No

State issuer's revenues for its most recent fiscal year: \$6,502,480.

As of March 23, 2007, the registrant had 11,754,015 common shares outstanding, and the aggregate market value of the common shares held by non-affiliates (\*) was approximately \$6,432,947. This calculation is based upon the closing sale price of \$0.68 per share on March 19, 2007.

\* Without asserting that any of the issuer's directors or executive officers, or the entities that own 2,293,800 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. DESCRIPTION OF BUSINESS

#### General

Chembio Diagnostics, Inc. (the "Company", "We", "Our", or "Us") and our subsidiaries develop, manufacture, and market rapid diagnostic tests that detect infectious diseases. Our main products presently commercially available 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 last year. These products employ single path lateral flow technology which we have licensed from Inverness Medical Innovations, Inc. ("Inverness"), who is also our exclusive marketing partner for those two products in the United States 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 are marketed outside the United States through different partners and channels under license from Inverness. We also have a rapid test for Chagas disease (a parasitic disease endemic in Latin America) as well as a line of rapid tests for tuberculosis, including tests for tuberculosis in animals for which USDA approval is pending.

On March 13, 2007, we were issued United States patent #7,189,522 for our Dual Path Platform (DPP™) rapid test system. We believe that as a result of the patent protection we now have with DPP™, we have a significant opportunity to develop and license many new rapid tests in a number of fields including but not limited to infectious diseases. We have already completed initial development on some products in this new platform. We believe the DPP™ provides significant advantages over standard single path lateral flow assays, and are developing most of our new products using this platform.

Our products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments. Our products are sold either under our 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.

#### Rapid HIV Tests

A major component of our revenue growth in 2006 was increased sales of our rapid HIV tests. A large percentage of individuals that are HIV positive worldwide are unaware of their status. Part of the reason for this is that even those that do get tested in public health settings will often not return or call back for their test results when samples have to be sent out to a laboratory that 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.

All three 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 only in the method of sample collection and test procedure, flexibility with different sample types, and cost of manufacture. Our rapid HIV tests have been marketed under our SURE CHECK® and STAT-PAK® trademarks. Pursuant to our agreement with Inverness Medical Innovations, Inc., the SURE CHECK® product is now being marketed globally (with limited exceptions) by Inverness as Clearview® Complete HIV 1/2 and the cassette format of our 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.

#### Regulatory Status:

#### Rapid HIV Tests

The FDA approved our Pre-Market Applications for our SURE CHECK HIV 1/2 (now Inverness' Clearview® Complete HIV 1-2 and HIV 1/2 STAT-PAK (now Inverness' Clearview HIV 1/2 STAT-PAK) 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 is still pending for the Clearview Complete HIV 1-2; accordingly this product is presently only available as a non-waived product. CLIA waiver is required in order to market the products in public health clinics and physicians' offices where the level of training is traditionally less than the training at clinical laboratories and hospitals. Public health clinics and physicians' offices now constitute the largest portion of the available market for our products. We were advised by the FDA in February 2007 that additional user studies will be required in order to obtain CLIA waiver for the Clearview Complete HIV 1/2, and this work is in progress. We believe that we will be able to receive a CLIA waiver for this product during 2007.

Our third rapid HIV test, HIV 1/2 STAT-PAK *Dipstick*, though not FDA approved, qualifies under FDA export regulations to sell, subject to any required approval by the importing country, to customers outside the United States. 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 all three of our HIV tests, Brazil, Mexico, Nigeria and Uganda are the only 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 procurements from programs funded by the United Nations and their partners' programs. All three of our HIV tests have qualified for procurements under the President's Emergency Plan for AIDS Relief.

#### **Partners Involved in the Products:**

On September 29, 2006 we executed marketing and license agreements with Inverness. These agreements not only provide for the marketing of our rapid HIV tests in the United States, but also grant us a license to Inverness' single path lateral flow patents that may be applicable to our other products, including those that we had under development at the time of the grant. As part of these agreements we settled litigation that had been ongoing with another company, StatSure Diagnostics, Inc., relating to the barrel device that is incorporated into our Sure Check® (now Inverness Clearview Complete) HIV 1/2 product.

In 2004 we entered into a thirteen-year supply and technology transfer agreement with FIOCRUZ-Bio-Manguinhos ("FBM"), an affiliate of the Ministry of Health of Brazil relating to our HIV 1/2 STAT-PAK product. FBM will supply this product, which will eventually be produced by FBM completely in Brazil, to the Brazilian public health market and potentially other markets in the region.

In September 2005 we were designated as the confirmatory test in Uganda's national rapid testing protocol, and through the offices we have established in East Africa and Nigeria, each staffed with experienced executives, we hope to be selected in more such national testing protocols. In February 2006 our HIV 1/2 STAT-PAK was designated by the Nigerian Ministry of Health in four out of the eight screening protocols in the Nigerian Interim Rapid Testing Algorithm. We have identified and/or appointed distributors in several countries in Africa (Kenya, Mozambique, South Africa, and others) so that we will be positioned to service those markets if we are selected in their national testing protocols. Our focus is on those African countries that are receiving funding from PEPFAR and other large relief programs.

In January 2006, we became one of four recommended global suppliers to former President Clinton's HIV/AIDS Initiative ("CHAI"), and through that we hope to generate revenues in many of the nearly sixty countries that have agreements with CHAI.

In November 2006, we received an order for 990,000 units of our Sure Check product from our distributor in Mexico, a division of Bio-Rad Laboratories, Inc. This distribution agreement is the one exception to our otherwise global exclusive agreement with Inverness as it relates to this product. Approximately half of this order was shipped during the fourth quarter of 2006 and the balance has been shipped during the first quarter of 2007. Absent other arrangements, this exception to Inverness' global exclusivity will be eliminated on September 29, 2007.

We are establishing distributors in a number of other markets where we believe there is or will be a significant market opportunity for our products.

#### **CHAGAS RAPID TEST**

We have completed development of a rapid test for the detection of antibodies to Chagas disease. This product, Chagas STAT-PAK, was developed in collaboration with a consortium of leading researchers in Latin America that have granted us an exclusive license to their recombinant antigens. Although the Chagas disease is endemic only in regions of Latin America there are an estimated 16-18 million existing Chagas disease cases, resulting in approximately 20,000 deaths annually, and an estimated 300,000 new cases each year. Chagas disease is transmitted by a parasitic bug which lives in cracks and crevices of poor-quality houses usually in rural areas, through blood transfusions or congenitally from infected mother to fetus. There is an effective therapy available to treat the early chronic phase, but this therapy only eliminates the infection if it is administered to children that are diagnosed with the disease. Our Chagas STAT-PAK product is the only rapid test for Chagas disease which has performed well in multi-center studies in endemic regions of Latin America.

In January 2006, we received a \$1.2 million order from the Pan American Health Organization to supply our Chagas disease rapid tests for a screening program in Bolivia. These tests were delivered in the first three quarters of 2006. The Pan American Health Organization, headquartered in Washington D.C., is affiliated with the World Health Organization, and that procurement was used to implement a nationwide Chagas screening program for all children under the age of 10 in endemic regions of Bolivia. We are actively looking at developing additional business opportunities for this product in those regions of Latin America that are impacted by this disease.

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## **Other Products**

Prior to 2005, a majority of our revenues were from the contract manufacture of private label pregnancy tests for regional pharmacies, drug stores and mass merchants in the United States, Europe, Canada and Central America. However, as a result of pricing pressures, regulatory changes and potential patent litigation in this field, and in order to focus our efforts on rapid HIV tests we sold substantially all of the business related to our private label pregnancy tests. We have retained a profit share derived from the sales of these products by the buyer. This has resulted in a substantial reduction of our revenues from these products and this is no longer a material part of our revenues. We also have other commercially available products, such as rapid tests for Lyme disease and other products, whose aggregate revenues are currently not material to us. We also are involved in the development of new products, as described below under “Research and Development”.

## **Lateral Flow Technology**

All our current products employ single path lateral flow technology. Lateral flow, whether single or dual path, generally refers to the process of a sample flowing from the point of application on a test strip to provide a test result on a portion of a strip downstream from either the point of application of the sample or of another reagent. Single path 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.

Our lateral flow technology, whether single or dual path, allows the development of accurate, 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 specimens potentially infected), 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. 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 Pre-Marketing Applications were 99.7% and 99.9%, respectively.

We can develop and produce lateral flow tests that are qualitative (reactive/non-reactive), as in the case of our HIV tests, and we can develop semi-quantitative tests, reflecting different concentrations of the target marker(s) using different colored latex test lines for each concentration. We can also develop tests for multiple conditions, using different colored lines. 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 latex and 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.



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 standard single path lateral flow test systems (See “Intellectual Property”). We believe that this system, which we refer to as DPP™ (for Dual Path Platform), provides us with significant new product development and licensing opportunities.

**Target Market**

**Rapid HIV Tests**

We believe that the prevention and treatment goals that have been established by large programs that are designed to provide greater access to ARVs (Anti-Retroviral Treatments for AIDS) and thwart the spread of HIV will drive the growth and demand for rapid HIV tests in the coming years. We are presently one of only two United States-based manufacturers of rapid HIV tests; and we believe that we are the only one with products that can meet the various demands of the global market.

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Based upon an analysis done by the Global Business Coalition of HIV/AIDS, approximately 500 million people will need to be tested with at least one rapid test over the next three years in order to insure that treatment targets are achieved<sup>1</sup>. In addition, a confirmatory test is needed in the case of a positive result. This is a result of the continuing growth in the epidemic and because anti-retroviral treatments are available, affordable and are being funded, so that people actually have a reason to be tested.

Because HIV medicines have become much less expensive and more widely available, unprecedented multi-billion dollar financial commitments are being allocated in each of the next few years. Some of these commitments are being made by The Global Fund<sup>2</sup> and the United States Presidential Emergency Plan for AIDS Relief (“PEPFAR”). PEPFAR alone has a goal to provide treatment to two million people in order to identify these two million people; rapid testing is being implemented on a very large scale. The United States is the largest donor, by far, to these programs. Each of these programs recognizes that a massive scale-up in the use of rapid HIV tests is the only way their treatment goals can hope to be achieved.

We further believe that the global demand for rapid HIV testing will increase at very high rates well beyond the next few years and for the foreseeable future. According to the UNAIDS 2006 Update Report, as of the end of 2006, there were an estimated nearly 40 million people infected with HIV/AIDS worldwide, of which an estimated 6 million were in need of antiretroviral therapy. There were nearly 4.3 million new infections and 2.9 million AIDS-related deaths in 2006. The number of people in need of treatment will continue to grow as expected infection rates increase significantly worldwide, and there is little expectation for an effective vaccine anytime soon. Even with relatively low prevalence rates in Asia, UNAIDS estimates that 12 million new infections could occur in that region alone between 2005 and 2010.

The marketing of our FDA-approved rapid HIV tests in the United States was just launched by Inverness during the first quarter of 2007. In the United States the need for rapid HIV tests has been developing first in the public health and hospital emergency room segments. However, as a result of recently revised and broadly supported recommendations for routine testing issued by the United States Centers for Disease Control (“CDC”) in September 2006, we expect the United States market to expand as this technology is increasingly employed in physicians’ offices, prisons and other venues. Before the FDA Blood Products Advisory Committee endorsed the FDA’s recommendation to provide rapid HIV tests in the over-the-counter markets, and before the CDC recommendations were published, the United States rapid HIV test market was estimated to become at least a \$50 million market during the next few years. The market may grow much faster and larger however as a result of these two developments.

The non-exclusive licenses we received from Inverness to their lateral flow patents to market our two HIV 1/2 STAT-PAK products outside the United States enable us to further expand our international marketing efforts beyond developing countries. In addition to our efforts in Africa, we have distribution initiatives underway in new markets in Latin America, Europe, and Asia. Registration and regulatory requirements for these markets vary widely.

### **Chagas Rapid Test**

We had developed a Chagas rapid test several years ago, but the market for the product was not meaningful, as most prevention efforts, were minimal and were made using laboratory tests used for blood bank screening of blood. However, there is now a greater interest in our Chagas rapid test because of an important publication that demonstrated the effectiveness of the rapid test in the screening of blood donors (as opposed to the blood in blood banks), and because it can be effectively deployed in rural populations to screen children and pregnant women. Also, studies that have been completed at multiple sites in Central and South America showing sensitivity of between 98.5% and 99.6% and specificity between 94.8% and 99.9%, thus indicating that the test is a good alternative to standard laboratory testing methods. Our Chagas disease test, Chagas STAT-PAK™, was deployed this year to screen every child in Bolivia under the age of 14 in rural areas. Intervention efforts with low cost generic drugs have been shown to cure young children better than those with latent and recurring infections afflicting those beyond early ages.

### **Other Products Under Development**

We are also developing rapid tests for other infectious diseases, particularly rapid tests for human and veterinary tuberculosis.

Tuberculosis (“TB”) is the leading killer of people who have AIDS, yet there is no rapid test for TB as there is for HIV. If successful, our TB product development efforts will leverage the marketing and distribution capability which we have been using for our HIV products. We had our initial human TB product evaluated last year along side several other rapid tests that were evaluated by an organization affiliated with the World Health Organization. Although our test was among the best performing tests, more work is still required. Current efforts on a next generation rapid TB test are focused on incorporating the Dual Path Platform with different and/or additional patented antigens that we have identified and that we would license in order to produce higher sensitivity levels, particularly in HIV-TB co-infected patients. Given the variations both in TB strains and latency presented in different geographic regions, there are questions as to what the performance standards should be and whether certain tests may in fact be appropriate for use only in certain regions.

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<sup>1</sup> [www.businessfightsaids.org/site/pp.asp?c=gwKXJfNVJtF&b=1008825](http://www.businessfightsaids.org/site/pp.asp?c=gwKXJfNVJtF&b=1008825) - Policy Documents/Facilitating Access to Testing

<sup>2</sup> [www.theglobalfund.org/en](http://www.theglobalfund.org/en)

## **Non-Human Primate Tuberculosis Test and other Veterinary Tuberculosis Tests**

Tuberculosis is also a problem in a number of animal species either because of potential transmission to humans or from humans to animals (i.e., zoonotic disease), costs in lost agricultural productivity or because of the potential negative impact on the cost of the animal species themselves. For example, nonhuman primates used in research or in zoos are quite costly, and whole colonies can be lost if transmission is not effectively controlled through routine and accurate diagnosis. Bovine (cattle) TB can be transmitted from livestock or deer to humans and to other animals both domestic and wild. Under rules established by the Animal and Plant Health Inspection Service (“APHIS”), a state can lose the right to move cattle across state lines if TB is detected in two or more herds, and such prohibitions, have recently occurred in Minnesota, Texas, New Mexico and Michigan. TB control of meat at slaughterhouses is dependent upon visual inspection. We believe that a more accurate and rapid test could conceivably complement or supplant these visual inspections.

We have already completed development of a rapid lateral-flow test for the detection of TB in Non-Human Primates (PrimaTB STAT-PAK™), and we have a similar test near completion for multiple host species, including cattle (BovidTB STAT-PAK™), deer both captive and wild species (CervidTB STAT-PAK™), camelids (CamelidTB STAT-PAK™), elephant (ElephantTB STAT-PAK™) and other exotic wildlife. The tests can use serum, plasma, whole blood or “meat juice,” are simple and easy to use, have up to an 18 month shelf life at room temperature (RT) storage, and samples provide definitive results within 20 minutes, permitting easy use of the assay for wild species as a true capture, test and cull assay.

We amended the product license application to the USDA for approval of our PrimaTB STAT-PAK (the detection of active tuberculosis in non-human primates) on July 6, 2006, and the application was accepted by the USDA on August 29, 2006. Clinical trials to validate reproducibility were successfully completed in December of 2006. At the same time, we have been working toward the establishment license with the USDA, which is required along with the first product license requiring an inspection by USDA officials. The inspection of our facility and quality system was completed on February 27, 2007. We anticipate approval of the Prima TB STAT-PAK during the second quarter of 2007.

The next USDA submissions will be for ElephantTB STAT-PAK and CervidTB STAT-PAK.

## **Distribution Channels& 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 and Chembio’s marketing and regulatory teams have been working together since October 2006 after we signed the agreements and we are very encouraged by the commitment they are making to maximize the success of these products in the United States market. We believe that their highly professional cadre of technical field support staff together with the strong distribution partners they support in the hospital, public health and physician office markets will combine to provide a marketing organization that will be a key asset.
- Expand our international sales effort and strategic partnerships in the developed and developing world for our global health rapid test products, particularly our HIV and Chagas disease tests. We are actively engaged in expanding HIV test sales and marketing through our East and West African offices. These offices are headed by seasoned professionals that have extensive marketing and/or public health experience in Africa and are establishing distributor relationships throughout the continent. We also have new collaborations and sales opportunities that we are pursuing in several other markets. These efforts will most likely include obtaining CE Marks for our rapid HIV tests. In order to achieve this we will need to become ISO 13.485 certified, which we expect to complete during the second quarter of 2007.

- Pursue potential over-the-counter marketing opportunities in the United States and internationally for our HIV tests. We will analyze whether to focus our efforts for this market on an oral fluid HIV test product, which we are currently developing with our DPP™ technology.

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- Launch our initial veterinary TB product, PrimaTB STAT PAK™, within our growing line of veterinary TB tests. We anticipate USDA approval of our initial product, a nonhuman primate TB test, in the second quarter of 2007. During 2007 we expect to obtain revenues from certain other veterinary TB products, at very favorable margins.

## Strategic Alliances

Strategic alliances are a key element in our business strategy.

**Inverness Medical Innovations, Inc.** - As described in more detail below in Management's Discussion and Analysis, on September 29, 2006, we executed several agreements by and among the Company, Inverness Medical Innovations, Inc. and StatSure Diagnostic Systems, Inc. Pursuant to these agreements, Inverness became our marketing partner for our two FDA approved rapid HIV tests in the United States and for one of the products in the non-United States markets. We are the exclusive manufacturer of the products. The marketing of the products in the US was begun by Inverness in February 2007. The agreements contain margin sharing formulae that are designed to provide Inverness and Chembio with reasonable profit margins after deduction for certain costs of the products.

**Clinton Foundation HIV/AIDS Initiative** - In January 2006 we entered into an agreement with the William J. Clinton Foundation's HIV/AIDS Initiative ("CHAI") to be recommended by CHAI to receive the procurements from CHAI partner countries (more than 50 countries in the developing world and also including China, Brazil and India) that choose to access CHAI's suppliers products and their preferred pricing in exchange for their sharing information with CHAI and permitting CHAI to fill gaps that will improve and scale up the country's health care delivery systems. We are one of four companies worldwide (and the only United States-based manufacturer) to be recommended by CHAI for sales of rapid HIV tests. While CHAI is not a procurer of the tests per se, it is a major factor in influencing which tests are to be procured. CHAI also has major agreements with generic HIV ARV manufacturers and manufacturers of viral load and CD-4 monitoring diagnostic tests, and those agreements have been very successful models.

**Brazilian Ministry of Health** - We are committed to securing alliances and technology-transfer agreements with government agencies and commercial entities. For example, we signed, in early 2004, a thirteen year technology transfer, supply and license agreement with Bio-Manguinhos, an affiliate of the Brazilian Ministry of Health ("MOH") and the predominant supplier for meeting public health needs in Brazil. Over the initial three-year period which has just now been completed, we were to transfer our proprietary technology related to HIV 1/2 STAT-PAK to Bio-Manguinhos in exchange for commitments to purchase at least one million rapid tests. The purchase commitment has been met, though we expect additional procurements prior to the completion of the technology transfer agreement, currently anticipated to occur in 2007. Thereafter, Bio-Manguinhos will have the right to produce its own rapid tests and we will receive royalties for ten years.

## 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);
  - 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 lateral flow rapid tests, particularly for HIV, Chagas disease and tuberculosis (both human and veterinary), 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 has been instrumental in our obtaining the collaborations we have and that we continue to pursue. Our patent protection that we now have with our Dual Path Platform™ should enhance our ability to develop collaborative relationships and to license out the technology.

Prior to 2005, we had very limited experience with regard to obtaining FDA or other required regulatory approvals, and no experience with obtaining pre-marketing approval of a biologic product such as a rapid test for HIV. (See the “Governmental Regulation” section for definition of pre-marketing approval). For this reason, during 2004 and 2005 we hired employees and consultants that collectively have that experience. We believe this has been critical in our progress toward obtaining these approvals during the last year and in ensuring that we manufacture our products in accordance with FDA, USDA and other regulatory requirements.

Our access to capital is much less than that of several of our competitors, and this is a competitive disadvantage. We believe however that our access to capital may increase since we have obtained FDA approval of our rapid HIV tests and now have our Dual Path Platform (DPP™) patent. This access should continue to improve as we grow our revenues, obtain additional regulatory approvals, and as new development and licensing opportunities ensue for DPP™ (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.

We have been able to obtain patent protection by entering into licensing arrangements for reagents and lateral flow technologies. The very recent issuance, in March 2007, by the United States Patent & Trademark Office of our Dual Path Platform patent gives us our first patent protection on a rapid test platform, which we believe enhances our competitive position.

Competitive factors specifically related to our HIV tests are product quality, price and ease of use as well as distribution. Product quality for a rapid HIV test primarily means accuracy (sensitivity and specificity), early detection of cases, time elapsed between testing and confirmation of results, and product shelf life. We believe that our product offerings and distribution model positions us to compete effectively and win a meaningful share of this expanding market.

The leading products in the international rapid HIV test market are UniGold®, produced by Trinity Biotech in Ireland, and Determine®, produced by Inverness in Tokyo. Until June 2005, the Determine business was owned by Abbot Diagnostics (Abbott) before it was sold to Inverness. In connection with this transaction, Abbott retained the distribution rights to the Determine product for 32 months. The Determine and UniGold products are the market leaders in many of the developing world markets, often as the screening and confirmatory tests, respectively. Inverness’ Organics subsidiary in Israel also has a rapid HIV test, Double Check Gold, and this is one of the three other products recommended by CHAI; the other two companies whose products were selected by CHAI are based in India and China, respectively, and they have not yet established apparent marketing efforts outside their countries, although they are qualified by the World Health Organization. In the developed world, particularly the United States, our competitors are Orasure Technologies with OraQuick®, and Trinity with its UniGold® product, both of which are FDA-approved, CLIA-waived products. Although we do not believe Inverness plans to submit either the Determine or the Organics product to the FDA, our agreements with Inverness provide that in the event one of those submissions are made, (or in any case if Inverness markets 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 can retain a license under the Inverness lateral flow patents to market the products under a Chembio brand and/or through third party distribution partners.



We are targeting the developing world markets that are being funded by PEPFAR and The Global Fund where Determine and UniGold are the established tests. However, neither of those products contains a true IgG control. This means that the control line does not confirm that the test was run properly with the patient sample; it only confirms that the buffer solution was applied. Thus the appearance of the control line in these tests does not necessarily mean that the test was validly performed, so it may not be a true non-reactive or negative result, and this can lead to potential false negative results.

Orasure has been successfully building its brand and market share in the United States market. Its non-United States sales of its rapid HIV test are not significant, and we believe its product is neither suitable nor cost competitive to participate in the international market. Orasure has been successful in bringing attention to the need and availability of rapid HIV testing in the United States. Its main advantage is the fact that its test can be used with oral fluid samples, though its FDA approved sensitivity is 99.3% with these samples. OraQuick is not approved for use with serum samples which may limit its marketability in certain settings.

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The shelf life of our HIV products' is 24 months, which is double that of UniGold and four times that of Orasure's product. Our products have been approved by the FDA for finger-stick whole blood, venous whole blood, serum and plasma. We believe that our products are extremely convenient and easier to use than OraQuick on finger-stick whole blood samples.

We believe that having high level executives in the field in East and West Africa that are engaged with public health officials, NGOs and other organizations provides us with a competitive advantage in those markets. To the best of our knowledge, none of our competitors has actually done a technology transfer such as what we have done in Brazil which we can now replicate in other markets of our choosing.

Even though our rapid tuberculosis test for humans and animals is still under development, we believe we are in a leadership position as it relates to these products. We are not aware of any rapid whole blood test that has the sensitivity and specificity levels necessary to replace or complement the current sputum smear microscopy method being employed in the high incidence tuberculosis countries; and this is what we believe our rapid tuberculosis test, when fully developed and evaluated, will be able to do. We are also not aware of any rapid whole blood test to detect active pulmonary tuberculosis in non-human primates and/or other animals for which we are developing rapid tuberculosis tests.

## **Research and Development**

We are focusing our research and development efforts on new rapid tests that will leverage our expertise and sales channels. Our research and development activities have been in three disease areas: HIV, Human and Veterinary Tuberculosis, and neglected diseases such as Chagas disease (See section entitled General). All of our new product development activities involve employment of our Dual Path Platform technology for which we were recently awarded a patent. We believe that this platform enables us to pursue many new product development and licensing opportunities, and we are currently developing a strategy for doing this. Several studies that we have completed in-house in 2007 further confirm that this platform can provide improved features that include higher sensitivity, earlier detection, use of multiple sample types including oral fluid, and improved ability to detect multiple analytes in one test device. Our studies thus far have primarily been based upon serological, antibody detection tests for infectious diseases. We are beginning to now conduct studies to establish whether these same or other advantages can be realized in the detection of antigens.

### **HIV**

We have completed initial design of an oral fluid HIV antibody detection test on our Dual Path Platform in accordance with our agreement with Inverness, and Inverness has notified us that it would like to enter into negotiations concerning marketing rights to this product as provided in our agreement. In February we commenced the ninety day negotiation period for this marketing opportunity as provided in our agreement. We are considering developing other specialty products for HIV that would incorporate DPP™ and that would be developed in collaboration with contract partners, such as an HIV confirmatory test.

### **Tuberculosis**

Our tuberculosis rapid tests for humans are being designed to significantly increase the accuracy of existing tuberculosis screening methods and technologies. Our initial tuberculosis serology test was developed pursuant to Phase I and II Small Business Innovative Research grants from the National Institute of Health from 1998 until 2002, and our current test, TB STAT-PAK II, was completed in 2003. This test was evaluated by the World Health Organization in 2005 alongside more than fifteen other tests from various manufacturers, and although it was among the best performers, its sensitivity and specificity were not high enough as compared to the benchmarks employed to result in a recommendation by the World Health Organization to switch from the current methodologies (i.e., Acid Fast staining smears) to our test or to any of the other tests in this evaluation. This result was particularly true when

the test was used on co-infected HIV/TB populations in sub-Saharan Africa, where millions are infected with both diseases.

In addition to our research and development efforts for tuberculosis tests for humans, we have developed a test, PrimaTB STAT-PAK, for detecting active pulmonary tuberculosis in non-human primates (monkeys). We hope to obtain a licensure of this product during the first or second quarter of 2007. We are also engaged in collaborations related to the detection of active pulmonary tuberculosis in other animals such as cattle, deer, camels, elephants and other exotic species. We plan on leveraging our current technology for licensure of these additional species TB tests. We do not anticipate any material revenues from these efforts before mid to late 2007.

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## **Syphilis**

In November 2006, we entered into a Cooperative Research & Development agreement with the CDC pursuant to which we hope to complete development of a multi-analyte test on our Dual Path Platform that could be used as a screen and confirmatory test within the same device. The CDC is providing access to its own patented reagents, sera samples and expertise as part of this agreement.

During 2006 and 2005, \$1,401,473 and \$1,364,898, respectively, was spent on research and development activities. A significant portion of these expenditures have been on our HIV and human and non-human primate tuberculosis product development and related regulatory approval efforts.

## **Employees**

At December 31, 2006, we employed 107 people, including 92 full-time employees. Effective May 2004, we entered into an employment agreement with Javan Esfandiari, Director of Research and Development. Effective May 2006, we entered into an employment agreement with Lawrence Siebert, President and Chairman.

## **Governmental Regulation**

Our 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. This regulation governs almost all aspects of development, production and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing and record keeping. Our 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, we must continue to comply with other FDA requirements applicable to marketed products, e.g. CLIA regulations (for medical devices). Failure to comply with the FDA’s requirements can lead to significant penalties, both before and after approval or clearance.

Most of our diagnostic products are regulated as medical devices, and some are regulated as biologics. 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 a pre-market approval (PMA) application before marketing can begin. Pre-market approvals must demonstrate, among other matters, that the medical device provides a reasonable assurance of safety and effectiveness. A pre-market approval is typically a complex submission, including the results of preclinical and clinical studies. Preparing a pre-market approval is a detailed and time-consuming process. Once a pre-market approval has been submitted, the FDA is required to review the submission within a statutory period of time. However, the FDA’s review may, and often is, much longer, often requiring one year or more, and may include requests for additional data.

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.

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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, we consider the applicability of the requirements of CLIA in the design and development of our 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 our products and this is in fact critical to the marketability of a product into the point of care diagnostics market.

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 pre-market approval 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.

We are 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 the Company that might arise from future legislative or administrative action cannot be predicted.

Prior to receiving FDA approval, our rapid HIV tests had been evaluated and approved for marketing in several foreign jurisdictions, including Brazil, Mexico, India and a number of other nations in the developing world. We completed clinical trials for the SURE CHECK HIV (now also known as Inverness/Clearview Complete HIV 1/2) and HIV 1/2 STAT-PAK (now marketed in the United States as Clearview HIV 1/2 STAT-PAK) rapid tests in 2004 and filed the pre-market approval application with the FDA for approval of these products in February 2005. A facility inspection took place in September 2005 and an amendment was made in October 2005 to add an HIV-2 claim to the application. Our pre-market application was approved by the FDA on May 25, 2006, and we filed our CLIA waivers in July, 2006. A CLIA waiver was granted by the FDA for HIV 1/2 STAT-PAK on November 20, 2006. We also have our first veterinary tuberculosis rapid test under review by the USDA, and had our facility inspected by this agency on February 27, 2007.

### **Environmental Laws**

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

### **Intellectual Property**

*Intellectual Property Strategy*

Subject to our available financial resources, 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 (3) develop and acquire proprietary positions to reagents and new hardware platforms for the development and manufacture of rapid diagnostic tests.

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*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 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. We possess know-how to develop tests for multiple conditions using colored latex which is proprietary. 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*

Prior to the issuance of our United States patent covering our Dual Path Platform (DPP™), we owned no issued patents covering lateral flow technology. Therefore we obtained non-exclusive licenses from Inverness Medical Innovations, Inc. and Abbott Laboratories with respect to their portfolios of single path lateral flow patents. Although we believe our DPP™ is outside of the scope of other lateral flow patents that we are aware of, we consult with patent counsel, and seek licenses and/or redesigns of products that we believe to be in our best interests and those of 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 Abbott's and/or Inverness' lateral flow patents will not be challenged or that other patents containing claims relevant to our products will be not be granted and that licenses to such patents if any will be available on reasonable terms, if any.

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 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, which would adversely affect our results of operations, cash flows and business.

The DPP™ technology provides improved sensitivity as compared with conventional platforms in a number of preliminary studies using well characterized HIV, Tuberculosis and other samples. We anticipate signing new development projects based upon these new technologies in the near future that will provide new product applications and marketing opportunities. We have also filed patent applications relating to our veterinary tuberculosis rapid tests and improvements to the sample collection method in our "barrel" (SURE CHECK) device which is one of the formats which Inverness is marketing. On March 20, 2007 we were issued United States Patent #7,192,721 which covers the method and use of a specific combination of antigens on a lateral flow test for the detection of antibodies to tuberculosis in multiple non-primate animal species.

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 our tuberculosis and Chagas disease tests. We have concluded license agreements related to intellectual property rights associated with HIV- 1, and are negotiating the terms of a license agreement for HIV-2, which we hope to close during 2007.

**Our Business Prior to the Merger**

We were incorporated on May 14, 1999 in the state of Nevada under the name "Trading Solutions.com, Inc." We were originally organized to develop a trading school designed to educate people interested in online investing. We offered courses for beginners as well as experienced traders, consisting of theory sessions linked closely with practical hands-on training. We offered individual training, small group sessions and seminars focusing on online trading and various computer-related subjects.

We were not successful with our online trading school, and on August 18, 2001, we entered into an exchange agreement with Springland Beverages, Inc., an Ontario, Canada corporation. Pursuant to the agreement, we exchanged



15,542,500 shares of common stock for all the issued and outstanding shares of Springland Beverages, Inc., making Springland our wholly-owned subsidiary. Concurrent with the agreement, there was a change in control and we changed our business plan to focus on developing and marketing soft drinks. Springland Beverages, Inc. was not able to implement its business plan and failed to achieve profitable operations. On March 28, 2003, we sold the subsidiary back to its president, leaving us with no immediate potential revenue sources.

Since the formation of Chembio Diagnostic Systems Inc. in 1985, it has been involved in developing, manufacturing, selling and distributing tests, including rapid tests beginning in 1995, for a number of diseases and for pregnancy.

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## The Merger

On May 5, 2004, Chembio Diagnostic Systems Inc. completed the merger through which it 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.

## Glossary

AIDS	Acquired Immunodeficiency Syndrome. AIDS is caused by the Human Immunodeficiency Virus, HIV.
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 CD-4	Anti-Retroviral Treatments for AIDS 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
CHAGAS DISEASE	Chagas disease is an infection caused by the parasite <i>Trypanosoma cruzi</i> . Worldwide, it is estimated that 16 to 18 million people are infected with Chagas disease; of those infected, 50,000 will die each year.
CHAI	Clinton HIV/AIDS Initiative
CLIA	Clinical Laboratory Improvement Act
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
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
PROTOCOL	

	<p>A procedure pursuant to which an immunodiagnostic test is performed on a particular specimen in order to obtain the desired reaction.</p>
REAGENT	<p>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.</p>
RETROVIRUS	<p>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.</p>
Ryan White CARE Act	<p>The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act is Federal legislation that addresses the unmet health needs of persons living with HIV disease by funding primary health care and support services. The CARE Act was named after Ryan White, an Indiana teenager whose courageous struggle with HIV/AIDS and against AIDS-related discrimination helped educate the nation.</p>
SAB	<p>Staff Accounting Bulletin</p>
SENSITIVITY	<p>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.</p>
SFAS	<p>Statement of Financial Accounting Standards</p>
SPECIFICITY	<p>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.</p>
SPUTUM	<p>Expectorated matter; saliva mixed with discharges from the respiratory passages</p>
TB	<p>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.</p>
ALGORITHM	<p>For rapid HIV testing this refers both to method or protocol 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.</p>
UNAIDS	<p>Joint United Nations Program on HIV/AIDS</p>
USAID	<p>United States Agency for International Development</p>
USDA	<p>U.S Department of Agriculture</p>
WHO	<p>World Health Organization</p>

**ITEM 2. DESCRIPTION OF PROPERTY**

Our administrative offices and research facilities are located in Medford, New York. We lease approximately 15,600 square feet of industrial space for \$9,671 per month. The space is utilized for R&D (approximately 1,000 square feet), offices (approximately 5,100 square feet) and production (approximately 9,500 square feet). The lease term expires on April 30, 2007, and we have 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.

**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.

*Settlement with StatSure Diagnostic Systems, Inc. (formerly Saliva Diagnostic Systems, Inc.)*

On September 29, 2006, the Company and StatSure Diagnostic Systems, Inc. ("StatSure") entered into a Settlement Agreement pursuant to which all matters in their litigation regarding StatSure's barrel patent and other matters were settled. In addition the parties entered into the Joint HIV Barrel Product Commercialization Agreement, which provides that the parties will equally share in the profits relating to all "HIV Barrel Products" after reimbursement to the Company of our manufacturing and related costs, as defined, and that they will act jointly in the HIV barrel field. The settlement combines each company's HIV barrel intellectual property, including an exclusive manufacturing license from StatSure to the Company of its barrel patent for all HIV applications, thereby ensuring our exclusive right to manufacture.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

NONE.

**PART II****ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS****Market Information**

Our common stock is quoted on the OTC Bulletin Board under the symbol "CEMI." Prior to May 14, 2004, our common stock was traded on the OTC Bulletin Board under the symbol "TSUN." For the periods indicated, the table below sets forth the high and low bid prices per share of our common stock. These prices represent inter-dealer quotations without retail markup, markdown, or commission and may not necessarily represent actual transactions. We completed a 1 for 17 reverse stock split on March 12, 2004, and all of the prices in this table have been adjusted to reflect this split.

<b>Fiscal Year</b>	<b>High Bid</b>	<b>Low Bid</b>
<b>2006</b>		
First Quarter	\$0.75	\$0.33
Second Quarter	\$1.15	\$0.65
Third Quarter	\$0.85	\$0.68
Fourth Quarter	\$0.92	\$0.63
<b>2005</b>		
First Quarter	\$0.90	\$0.50
Second Quarter	\$0.87	\$0.54
Third Quarter	\$0.66	\$0.52
Fourth Quarter	\$0.62	\$0.30

Trades of our common stock are subject to Rule 15g-9 of the Securities and Exchange Commission, known as the Penny Stock Rule. This 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 our common stock. As a result of these rules, investors may find it difficult to sell their shares.

## Holders

As of January 4, 2007, there were approximately 815 record owners of our common stock.

## Dividends

We have never paid cash dividends on our common stock and we have no plans to do so in the foreseeable future. Our future dividend policy will be determined by our board of directors and will depend upon a number of factors, including our financial condition and performance, our cash needs and expansion plans, income tax consequences, and the restrictions that applicable laws, our current preferred stock instruments, and our future credit arrangements may then impose.

Currently under Nevada law, a dividend may not be made by a corporation if, after giving it effect:

- the corporation would not be able to pay its debts as they become due in the usual course of business; or
- except as otherwise specifically allowed by the corporation's articles of incorporation, the corporation's total assets would be less than the sum of its total liabilities plus the amount that would be needed, if the corporation were to be dissolved at the time of distribution, to satisfy the preferential rights upon dissolution of stockholders whose preferential rights are superior to those receiving the distribution.

The certificates of designation authorizing each of our series A, series B and series C preferred stock generally prohibit us from making any distribution with respect to any equity securities that by their terms do not rank senior to the applicable series A, series B or series C preferred stock.

## Recent Sales Of Unregistered Securities; Use Of Proceeds From Registered Securities

On November 30, 2006, pursuant to the terms of a consulting contract with The Investor Relations Group ("IRG"), we issued IRG 8,334 shares of common stock and warrants to purchase 8,334 shares of common stock. The conversion price for these warrants is \$.70 per share and the warrants expire on November 30, 2010. We relied on Section 4(2) of the Securities Act of 1933 as the basis for our exemption from registration of these issuances. The investor in the issuance was an accredited investor of the Company.

On December 1, 2006, we issued to Bio Business Science and Development, LTDA, warrants to purchase 41,417 shares of common stock. The exercise price of these warrants is \$0.81 per share. We relied on Section 4(2) of the Securities Act of 1933 as the basis for our exemption from registration of this issuance. The investor in the issuance was an accredited investor of the Company.

On December 27, 2006, Avi Pelosof exercised warrants to purchase 100,000 shares of common stock. The exercise price was \$0.60 per share and we received \$60,000 in cash for this exercise. We relied on Section 4(2) of the Securities Act of 1933 as the basis for our exemption from registration of this issuance. The investor in this issuance was an accredited investor of the Company.

## ITEM MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS 6. OF OPERATIONS

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 on-going 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 our actual results, performance, or achievements 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,” “will,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimate,” “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.

## **Overview**

The following management discussion and analysis relates to the business of the Company and its subsidiaries, which develop, manufacture, and market rapid diagnostic tests that detect infectious diseases. Our main products presently commercially available 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. These products all employ single path lateral flow technology. We also have a rapid test for Chagas disease (a parasitic disease endemic in Latin America) as well as a line of rapid tests for tuberculosis, including tests for tuberculosis in animals for which USDA approval is pending. Our products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments. Our products are sold either under our STAT PAK® or SURE CHECK® registered trademarks or the private labels of our marketing partners, such as is the case with the Clearview® label owned by Inverness Medical Innovations, Inc., which is our exclusive marketing partner for our rapid HIV test products in the United States.

## **Recent Events**

On March 30, 2006, we 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.

On May 30, 2006, we received approval of our Pre-Market Applications (“PMAs”) from the FDA for our SURE CHECK(R) HIV 1/2 and HIV 1/2 STAT-PAK(TM) rapid tests. The approved PMAs allow us to market our rapid HIV tests to clinical laboratories and hospitals in the United States. FDA approval also allows us to further expand our international marketing efforts into countries that require regulatory approval in the manufacturer’s country of domicile. New labeling for these products to be sold under the Inverness Clearview labels were submitted and approved by the FDA during the first quarter of 2007, thereby allowing Inverness to begin marketing these products in the United States, which has also occurred during the first quarter of 2007.

On June 29, 2006, we borrowed \$1,300,000 from a group of four institutional investors as a bridge financing arrangement. The loan was repaid in part on September 29, 2006 and the balance converted on October 5, 2006 into Series C Preferred Stock. The loan was secured by a lien on our assets.

On September 29, 2006 and October 5, 2006, we completed the Series C Preferred Stock Offering for \$8,150,000. A portion of the proceeds were used to repay the loan borrowed on June 29, 2006.

## **RESULTS OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2006 AS COMPARED WITH THE YEAR ENDED DECEMBER 31, 2005**

### **Revenues:**

Revenues are comprised of \$6.294 million in net product sales and \$.208 million in grants and development income for the year ended December 31, 2006 as compared with \$3.360 million in net product sales, \$.250 million in license revenue and \$.331 million in grants and development income for the year ended December 31, 2005. The increase in net product sales is attributable to increased sales of our HIV product of \$2.034 million and of our Chagas product of \$1.147 million which were partially offset by decreased sales of our pregnancy test kit of \$.116 million and decreases in other product sales aggregating \$.131 million. The decrease in license revenue of \$.250 million was due to a technology transfer agreement that occurred in 2005 and was not recurring. The decrease in grant and development income of \$.123 million was due to grants received in 2005 that weren't continued or awarded in 2006. We are expecting new grants for 2007 that will maintain 2006 levels.

Net product sales for 2006 increased 87% compared to 2005. HIV net product sales increased 85% in 2006 compared to 2005. We believe that sales of our HIV products will continue to increase in 2007 both as a result of the international marketing strategies that were implemented in 2006 and from the sales through our marketing partner Inverness Medical to the United States market as a result of approval from the United States Food and Drug Administration (FDA). We also received our first significant order for our Chagas test (Chagas is a disease which is primarily found in Latin America), in the amount of \$1.2 million which it shipped in 2006, a \$1.1 million dollar increase over 2005. These sales are not expected to continue at this level in 2007.

Net product sales for the three months ended December 31, 2006 increased 93% to \$2.624 million compared to the same period in 2005. HIV product sales increased 101% to \$2.464 million for the three months ended December 31, 2006 compared to the same period in 2005.

**Gross Margin:**

Gross margin on net product sales for the year ended December 31, 2006 was 28.7%, as compared to 22.3% for the year ended December 31, 2005. The increase in gross margin percentage is primarily attributable to the increased sales of HIV products, which were at a higher margin than other product lines.

The gross margin on net product sales for the three months ended December 31, 2006 declined to 32.2% from 38.1% in the comparable 2005 period. This was due in part to the incremental costs of producing a large 990,000 unit order for the HIV barrel product for Mexico, more than half of which was shipped during the fourth quarter of 2006. Incremental costs included increased labor costs due to a second shift and overtime, increased overhead costs for factory supervision, and increased material costs related to acceptance of test components manufactured in-house as well as those purchased from third parties. In addition, product mix also contributed to the decline in gross margin percentage for the fourth quarter of 2006 as compared with the fourth quarter of 2005.

**Research and Development:**

Research and development expenses for the year ended December 31, 2006 were \$1,402,000 compared with \$1,365,000 for the year ended December 31, 2005. This category includes costs incurred for regulatory approvals, product evaluations and registrations. Expenses for Clinical & Regulatory Affairs, totaled \$323,000 for the year ended December 31, 2006, a decrease of \$88,000 compared to the year ended December 31, 2005. This category also includes costs for clinical studies which decreased by \$78,000 and a reduction in outside regulatory consultants of \$28,000 in 2006 compared to 2005, which were partially offset by an increase in salaries of \$14,000. The costs related to the clinical trials and consulting in 2005 were related to the evaluation of our HIV tests in preparation and follow up of our FDA Pre-Marketing Approval (“PMA”) application submitted in February of 2005. Expenses other than Clinical & Regulatory increased \$124,000 in 2006 compared to 2005 and were related to increased salaries and wage-related costs of \$107,000 for new hires and bonuses in the R&D group, and for increases in employee benefits (including stock option expenses per SFAS No. 123R “Share-Based Payment” (“SFAS 123R”) The statement requires a public entity to measure the cost of employee service received in exchange for an award of equity instruments based on the grant-date fair value of the award (with limited exception). That cost will be recognized over the period during which an employee is required to provide service in exchange for the award, usually the vesting period) of \$40,000, increase in temporary labor of \$34,000 offset by a decrease in travel and entertainment of \$14,000, and decreased grant payments to a university of \$54,000.

Subject to cash availability, we currently plan to increase our spending on research and development in 2007 because we believe such spending will result in the development of new and innovative products that are based on the DPP™ technology.

We have several R&D projects underway. Some highlights include:

**Rapid Test for the detection of antibodies to active pulmonary tuberculosis in non-human primate whole blood samples**

We have filed an application with the United States Department of Agriculture (USDA) to license our rapid assay, PrimaTB STAT-PAK™. A final set of clinical reproducibility trials was successfully completed during the fourth quarter of 2006 and the facility inspection, which is the final step to USDA licensure, has been completed. Subject to a satisfactory outcome of the facility inspection, we anticipate that commercialization will begin in the second quarter of 2007, though there is no assurance that this commercialization will successfully occur.

### **Rapid Test for the detection of antibodies to active pulmonary tuberculosis in multiple host species**

We have completed development and are in final validation stage on a series of rapid lateral-flow assays for the detection of veterinary TB in multiple host species including; cattle, cervids, badgers, camels, elephants, and exotic wildlife species. The family name for the technology is VetTB STAT-PAK™. We anticipate commercialization of these products to start in the second quarter of 2007 for at least the ElephantTB STAT-PAK to be followed by veterinary tests for cervids (CervidTB STAT-PAK), cattle (BovidTB STAT-PAK) and camelids (CamelidTB STAT-PAK), although there are no assurances that this commercialization will be successful.

### **Dual Path Platform (DPP™)**

During the fourth quarter of 2006 and 2007 year-to-date, significant additional progress was made in developing prototypes of the Dual Path Platform, including a new HIV test in this format and incorporating an oral fluid collection system that would be used with this DPP HIV product. Generally, we have already seen a great amount of interest in this platform as a result of our initial business development efforts for collaborative and licensing opportunities for this technology; this interest existed prior to the issuance of the DPP™ patent because it represents a way to participate in the lateral flow rapid test market that may not have been otherwise available to certain companies and because of its performance features, which we are increasingly able to demonstrate. Now that the patent has been issued, we intend to more vigorously pursue discussions with several parties and also develop a strategic plan for the long term development of this technology. We believe we can extend this technology to many applications not only within the infectious disease field, but to many other fields as well.

### **Selling, General and Administrative Expense:**

Selling, general and administrative expense increased \$1,930,000 to \$5,195,000 in the year ended December 31, 2006 compared with 2005. This increase was attributable to increased staff and bonuses in the accounting, administration and sales and marketing departments of \$505,000, increase in employee stock option expenses (per SFAS 123R) of \$132,000 and a decrease relating to recruiting expenses of \$104,000. Increased sales resulted in an increase in royalties, advertising and related materials of \$48,000 and commissions of \$159,000 as well as increased consulting costs of \$109,000. In addition there was an increase of \$355,000 in costs regarding investor relations, and \$114,000 increased expenses related to our board of directors (includes option costs per 123R), increases in travel, entertainment and show expenses of \$126,000, increased depreciation expense (related to ERP system and leasehold improvements) of \$89,000, increase in other expenses of \$40,000 and increased legal and accounting expenses of \$363,000 related to patent applications, patent litigation, the filing of a registration statement and other required year-end and quarterly filings. These increases were partially offset by a reduction of \$20,000 related to Sarbanes-Oxley compliance.

As our sales of rapid HIV test products increase, we expect selling, general and administrative expense to also increase. This will be in large measure due to increased costs for commissions and royalties on intellectual property licenses. In September 2006, we entered into agreements with Inverness, which provide a license to the Company to market our lateral flow devices for which we pay a royalty of either 5% or 8.5% of our net sales of the applicable product, depending on the market to which the sales are made.

### **Other Income and Expense:**

Interest expense increased by \$371,000 for the year ended December 31, 2006 compared with the year ended December 31, 2005. This was primarily attributable to the valuation of the bridge warrants (we borrowed \$1.3 million in June of 2006 at a rate of 2% for 90 days plus warrants exercisable at \$.70). Some of this debt was converted into the Series C Offering which allowed for a discount of 12.5%, this resulted in a loss on the extinguishment of \$87,000. Interest income for the year ended December 31, 2006 decreased \$10,000. In addition, during 2006, we received a marketing grant from New York State of \$25,000.



**LIQUIDITY AND CAPITAL RESOURCES**

We had a working capital surplus of \$5,113,000 at December 31, 2006 and a working capital surplus of \$650,000 at December 31, 2005. On September 29, 2006 and October 5, 2006, we completed the Series C Preferred Stock Offering for \$8,150,000. On June 29, 2006, we borrowed \$1,300,000 which was partially repaid in cash (approximately \$700,000) from the Series C Preferred Stock Offering proceeds, and the remainder (approximately \$600,000) was repaid through conversion to the Series C Preferred Stock offering, as described in the Recent Events section above and more fully in Note 1 of the consolidated financial statements. On March 30, 2006, we completed a transaction related to the Series B Preferred Stock Offering under which we raised \$1,000,000 (before costs) in the form of 9% Convertible Series B Preferred Stock and associated warrants (“Series B Offering”). The proceeds from the Series C Offering, the June 29, 2006 bridge loan and the Series B Offering have been and are being used primarily for sales and marketing, research and development, intellectual property, and also for working capital, investor relations and capital expenditures.

We believe our resources are sufficient to fund our needs through the end of 2007 and into early 2008. Our liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenue growth; (2) the extent to which, if any, that revenue growth improves operating cash flows; (3) our investments in research and development, facilities, marketing, regulatory approvals, and other investments it may determine to make; and (4) the investment in capital equipment and the extent to which it improves cash flow through operating efficiencies. There are no assurances that it will be successful in raising additional capital.

The following table lists the future payments required on our debt and any other contractual obligations as of December 31, 2006:

<b>OBLIGATIONS</b>	<b>Total</b>	<b>Less than 1</b>			<b>Greater than 5</b>
		<b>Year</b>	<b>1-3 Years</b>	<b>4-5 Years</b>	
Long Term Debt(1)	\$ 93,160	\$ 93,160	\$ -	\$ -	\$ -
Capital Leases (2)	51,498	44,417	7,081	-	-
Operating Leases	38,683	38,683	-	-	-
Other Long Term Obligations(3)	707,500	442,500	177,500	25,000	62,500
<b>Total Obligations</b>	<b>\$ 890,841</b>	<b>\$ 618,760</b>	<b>\$ 184,581</b>	<b>\$ 25,000</b>	<b>\$ 62,500</b>

(1) This includes the balance of accrued interest.

(2) This represents capital leases used to purchase capital equipment.

(3) This represents contractual obligations for fixed cost licenses and employment contracts.

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

Please see section entitled Recent Events above.

On September 29, 2006, we executed several agreements by and among the Company, Inverness Medical Innovations, Inc. (“Inverness”) and StatSure Diagnostic Systems, Inc. (“StatSure”). Pursuant to these agreements, Inverness is marketing our FDA approved rapid HIV tests, we have a nonexclusive license to Inverness’ lateral flow patents, and the Company and StatSure settled their patent litigation. The distribution agreements contain gross margin sharing formulae among Inverness, the Company and StatSure. In addition, we have the exclusive right and duty to manufacture the products marketed by Inverness under all the agreements, and we have the right to subcontract

manufacturing, but not sublicense or subcontract our rights or obligations.

First, we executed an HIV Barrel License, Marketing and Distribution Agreement among the Company, Inverness and StatSure. This agreement covers our FDA-approved SURE CHECK® HIV 1/2 (“SURE CHECK”), a lateral flow rapid HIV test employing a proprietary barrel system that is an integrated single-use rapid HIV antibody detection screening test. Some terms of the agreement are:

- Inverness will market the SURE CHECK product under Inverness brands globally [subject only to certain existing international agreements that each of the Company and StatSure may keep in place for up to one year];

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- Inverness will exclusively market SURE CHECK as well as any new HIV products in the “barrel field” that are developed, and may not compete with any products in the “barrel field” as defined in the agreement worldwide ;
- The Company and StatSure have each granted Inverness exclusive rights to their intellectual property in the HIV barrel field;
- Inverness has a first right to negotiate agreements to market and distribute any of our new HIV antibody detection tests, including products that may incorporate our patent-pending Dual Path Platform (DPP(TM)); and
- As described above, the SURE CHECK HIV 1/2 product has been re-labeled Clearview Complete HIV 1/2 and Inverness has commenced marketing of this product. CLIA waiver for this product is still pending.

In addition, we executed an HIV Cassette License, Marketing and Distribution Agreement with Inverness. This agreement covers our FDA-approved HIV 1/2 STAT-PAK(TM) lateral flow rapid HIV test employing a cassette system that is a single-use rapid HIV antibody detection screening test. Some of the terms of the agreement are:

- Inverness will market this product in the United States market only, and we have a non-exclusive license under the Inverness lateral flow patents to continue to market the product under our brand in the rest of the world;
- Inverness may bring a competitive HIV cassette product to the United States market, but in that event we can expand our lateral flow license for this product to the United States and have other options under the agreement;
- We received a non-exclusive license under the Inverness lateral flow patents for our HIV 1/2 STAT-PAK cassette for marketing outside the United States; and
  - As described above, the HIV 1/2 STAT-PAK product has been re-labeled Clearview HIV 1/2 STAT-PAK and Inverness has commenced marketing of this product. CLIA waiver for this product has been granted.

The Company and Inverness also executed a Non-Exclusive License, Marketing and Distribution Agreement, which covers our other lateral flow rapid tests, including but not limited to our HIV 1/2 STAT-PAK(TM) Dipstick Some of the terms of this agreement are:

- We received a non-exclusive license under the Inverness lateral flow patents for our HIV 1/2 STAT-PAK Dipstick for marketing outside the United States;
  - We received a worldwide non-exclusive license to manufacture and market a number of other Company-branded products under the Inverness lateral flow patents, including all of our rapid tests for human and veterinary and tuberculosis, Chagas disease, and tests for other defined emerging and neglected diseases;
- Inverness has the right to market each of these products (except the HIV 1/2 STAT PAK Dipstick) under an Inverness brand pursuant to an agreed-upon pricing and margin sharing formula similar to the other agreements; and
- The Company and StatSure also entered into a Settlement Agreement pursuant to which all matters in their litigation regarding StatSure’s barrel patent and other matters were settled. Under the terms of this agreement, the parties will equally share in the profits relating to HIV barrel products after reimbursement to the Company of our manufacturing and related costs, as defined, and the parties will act jointly in the HIV barrel field. The settlement combines each company’s HIV barrel intellectual property, including an exclusive manufacturing license from StatSure to the Company of its barrel patent for all HIV applications, thereby ensuring our exclusive right to manufacture, as well as Inverness’ right to market though the marketing license that StatSure granted Inverness under the three way agreement. In addition, pursuant to this Agreement, StatSure and the Company will share

equally the net sales to Inverness of HIV barrel products after these deductions.

In July 2006, we submitted to the FDA CLIA (“Clinical Laboratory Improvement Act”) waiver applications for our HIV 1/2 STAT-PAK® and SURE CHECK® HIV 1/2 products. These waivers are essential in order to market FDA approved products to the physician office laboratory and public health segments of the United States market. A CLIA waiver was granted by the FDA for HIV 1/2 STAT PAK (now Clearview HIV 1/2 STAT-PAK) in November of 2006. The CLIA waiver application concerning the HIV barrel product formerly submitted to the FDA as SURE CHECK HIV 1/2 and now approved as Clearview Complete HIV 1/2 is still pending at the FDA.

There have been many developments recently regarding the market for HIV testing in the United States. For example, the United States Centers for Disease Control recently issued final revised recommendations advocating routine HIV testing for all Americans between the ages of 13 and 64, a White House 2007 budget request for \$90 million to test an additional three million Americans using rapid HIV tests is being negotiated by Senate and House conference committees, and the FDA adopted guidelines recommended by its Blood Products Advisory Committee that set forth the conditions under which rapid HIV tests could be approved for direct over-the-counter sales to United States consumers. All of these developments bode well for the expansion of the United States rapid HIV test market. However, there are still many obstacles and uncertainties which must be overcome before these developments become a reality that will result in realizable opportunities for the Company, and there is no assurance that any of these developments will be realized.

During 2005, we established offices in Nigeria and Tanzania, and we believe these offices will be significant in our continuing efforts to become part of the national testing protocols in many countries in Africa. Our STAT-PAK is designated as the confirmatory test in all of the national rapid HIV testing protocols in the Republic of Uganda, and in February of 2006 STAT-PAK was designated in four of the eight parallel testing algorithms (two tests used on each patient) adopted by the Nigerian Ministry of Health in its Interim National Testing Algorithm. We have made some progress towards having our HIV products designated in other countries where we have focused our efforts, though this progress is more uncertain and slower than we anticipated it would be. We have registered our products and have arrangements with distribution partners in certain of these countries and we are in negotiations for similar arrangements in other countries. We believe that our strategy of establishing offices in these challenging markets is a very effective way to obtain sustainable and supportable business.

In 2006, we were one of four companies selected by the Clinton Foundation HIV/AIDS Initiative (“CHAI”) to make available low-cost rapid HIV tests in order to more quickly and cost effectively achieve treatment objectives. Under the CHAI agreement, we have agreed to offer our HIV STAT-PAK Dipstick, our lowest cost rapid HIV test product, at a reduced price in the expectation that we will receive significant order volume not otherwise obtainable. If these order volumes are not realized, we have the right to terminate the agreement or renegotiate pricing. We are the only United States-based manufacturer of the four companies in this agreement. The CHAI Procurement Consortium is currently comprised of more than 50 countries in Africa, Asia, Eastern Europe, Latin America and the Caribbean that have Memoranda of Understanding (MOUs) with CHAI. Consequently, we are now actively engaged with CHAI in developing sales opportunities in many of these countries. Although in some of these countries we have already made substantive sales efforts, there are many more where this is not the case. To date we have not derived any tangible results from our being selected by the Clinton HIV/AIDS Initiative, though these efforts continue. There is no commitment or assurance that either our direct efforts to establish additional distributors and/or local assembly, or our activities through CHAI will materialize into meaningful sales.

Our technology transfer and supply agreement in Brazil is moving forward. We shipped \$1,515,000 of rapid HIV test components to this customer in the year ended December 31, 2006, a 28% increase over the same period in 2005.

In November 2006, we received an order for 990,000 units of our Sure Check product from our distributor in Mexico, a division of Bio-Rad Laboratories, Inc. This distribution agreement is the one exception to our otherwise global exclusive agreement with Inverness as it relates to this product. Approximately half of this order was shipped during the fourth quarter of 2006, and the balance was shipped during the first quarter of 2007. Absent other arrangements,

this exception to Inverness' global exclusivity will be eliminated on September 29, 2007.

We also received an order for \$1.2 million, which we shipped in 2006, to supply our Chagas disease rapid test. We have shipped this order in full. This procurement was made by the Pan American Health Organization, headquartered in Washington D.C., which is affiliated with the World Health Organization. The procurement was used to implement a nationwide Chagas screening program for all children under the age of 10 in endemic regions of Bolivia. We are actively looking at developing additional business opportunities for this product in Bolivia, and other markets in Latin America that are impacted by this disease.

We have hired a senior diagnostics marketing executive to focus on our Tuberculosis products, both for veterinary and human TB. Our non-human primate Tuberculosis product is currently under review by the United States Department of Agriculture (USDA), and we hope to receive USDA approval during the second quarter of 2007 for our first product, PrimaTB STAT-PAK™ subject only now to a satisfactory facility inspection by the USDA which has been scheduled. We plan to submit additional veterinary Tuberculosis products to the USDA, including a cattle Tuberculosis test, subject to having the necessary performance data.

### **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 is recognized upon shipment to the customer. Income from research grants are recognized when earned. 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 \$11,000.

#### *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 3.09% of accounts receivable. For example, each additional 1% of accounts receivable that becomes uncollectible would reduce such balance of accounts receivable by approximately \$13,500.

#### *Income Taxes -*

Income taxes are accounted for under SFAS No. 109, "Accounting for Income Taxes." SFAS 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 \$7,183,000 and \$6,128,000 at December 31, 2006 and 2005, respectively.

SFAS 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.

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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 7. FINANCIAL STATEMENTS**

The Consolidated Financial Statements and schedules that constitute Item 7 are attached at the end of this Annual Report on Form 10-KSB. An index to these Financial Statements and schedules is also included on page F-1 of this Annual Report on Form 10-KSB.

**ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.**

Not applicable.

**ITEM 8A. CONTROLS AND PROCEDURES**

As of the end of the period covered by this report, we conducted an evaluation under the supervision and with the participation of the principal executive officer and principal financial officer, of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")). Based on this evaluation, the principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms. There was no change in our internal controls over financial reporting during our most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 8B. OTHER INFORMATION**

Not applicable.

**PART III**

**ITEM 9. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(A) OF THE EXCHANGE ACT**

**Directors and Executive Officers**

**Lawrence A. Siebert (50)**, 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 12 years and its President since May 2002. Mr. Siebert's background is in private equity and venture capital investing. From 1982 to 1991, Mr. Siebert was associated with Stanwich Partners, Inc, which during that period invested in middle market manufacturing and distribution companies. From 1992 to 1999, Mr. Siebert was an investment consultant and business broker with Siebert Capital Corp. and Siebert Associates LLC, and was a principal investor in a privately held test and measurement company which was sold in 2002. Mr. Siebert received a JD from Case Western Reserve University

School of Law in 1981 and a BA with Distinction in Economics from the University of Connecticut in 1978.



**Richard J. Larkin (50)**, 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 (40)**, Director 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 (52)**, 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 bioMérieux Inc. From 1998 to 2000, he held a management position at V.I. Technologies. Mr. Bruce has over 25 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.

**Les Stutzman (55)**, VP of Marketing. In 2005, Mr. Stutzman joined Chembio as Vice President of Marketing to lead the development and launch of rapid tests for veterinary and human TB and other veterinary products. Mr. Stutzman has spent over twenty years in marketing leadership positions within various diagnostics companies. He has held Global Director and Business Development Director positions in Marketing for diagnostic companies including bioMérieux Inc., (formerly Organon Teknika Corp.), Durham, North Carolina from 1997 to 2002 and TREK Diagnostic Systems, Cleveland, Ohio from 2002 to 2005. Mr. Stutzman received his MBA in Marketing from Duke University Fuqua School of Business in 1988 and his Masters in Microbiology from Wagner College in 1982. Mr. Stutzman is MT (ASCP) SM certified.

**Tom Ippolito (44)**, 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.

**Alan Carus, CPA (68)**, Director, Audit Committee chair. Mr. Carus was elected to Chembio’s Board of Directors on April 15, 2005. He is a co-founder of LARC Strategic Concepts LLC, a consulting firm dedicated to guiding emerging companies to next stage development. Prior to co-founding LARC Strategic Concepts LLC, Mr. Carus was Senior Vice President of Maritime Overseas Corporation (“MOC”) and a senior executive of Overseas Ship holding Group, Inc. (“OSG”) from 1981 to 1998 when he retired. MOC was managing agent for OSG, one of the world’s largest ship-owners. He was a member of OSG’s senior management committee and had senior responsibility in areas relating to

administration, accounting, tax, finance, budgets, long-range projections, and human resources. Mr. Carus was involved in numerous acquisitions, debt and equity offerings, complex transaction structuring, and was active in the management of OSG's major investments in the cruise industry and other development stage companies. From 1964 to 1981, he was with Ernst & Young (including predecessors), the last seven years as a partner. Mr. Carus has a B.B.A. from the Baruch School of Business of the City College of New York.

**Dr. Gary Meller (55)**, Director. Dr. Meller was elected to our Board of Directors on March 15, 2005. 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 was the lead investor in our series B preferred stock private placement. Dr. Meller is a graduate of the University of New Mexico School of Medicine and has an MBA from the Harvard Business School.

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**Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), requires our directors, executive officers and beneficial owners of more than 10% of our 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. We believe that during the year ended December 31, 2006, each person who was an officer, director and beneficial owner of more than 10% of our common stock complied with all Section 16(a) filing requirements, except the following filings were filed late: (i) Form 4 for Lawrence A. Siebert filed on January 10, 2006; (ii) Form 4 for Gary Meller filed on April 6, 2006; (iii) Form 4 for Gerald A. Eppner filed on April 8, 2006; (iv) Form 4 filed for Avi Pelossof on April 26, 2006; (v) Form 4 for Lawrence A. Siebert filed on July 20, 2006; (vi) Form 4 for Avi Pelossof filed on July 20, 2006; (vii) Form 4 for Richard Larkin filed on July 20, 2006; and (viii) Form 4 for Lawrence A. Siebert filed on August 24, 2006.

**Code of Ethics**

We adopted a code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer, controller, and persons performing similar functions. A copy of our code of ethics is filed as Exhibit 14.1 to this Form 10-KSB.

**Identification of Audit Committee; Audit Committee Financial Expert**

Our board of directors has established an audit committee. Alan Carus, and Dr. Gary Meller each serve on the audit committee, with Mr. Carus serving as chairman. Our board of directors has determined that Alan Carus is an audit committee financial expert.

**ITEM 10.****EXECUTIVE COMPENSATION**

The following table summarizes all compensation recorded by the Company in the latest completed fiscal year 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 up to 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, 2006.

<b>Name and Principal Position</b>	<b>Year</b>	<b>Salary (\$)<sup>1</sup></b>	<b>Bonus (\$)<sup>2</sup></b>	<b>Option Awards (\$)<sup>3</sup></b>	<b>All Other Compensation</b>	<b>Total (\$)</b>
Lawrence A. Siebert, CEO and Director <sup>4</sup>	2006	\$ 207,115	\$ 20,000	\$ 21,017	\$ 7,200	\$ 255,332
Richard J. Larkin, CFO	2006	\$ 140,385	\$ 15,000	\$ 27,300	\$ -	\$ 182,685
Avi Pelossof, Vice President of Sales and Marketing <sup>5</sup>	2006	\$ 156,538	\$ 12,000	\$ 51,081	\$ 6,120	\$ 225,739
Javan Esfandiari, Director of Research and Development	2006	\$ 150,385	\$ 12,000	\$ 41,390	\$ 4,800	\$ 208,575
Les Stutzman - Vice President of Marketing	2006	\$ 116,539	\$ 11,500	\$ 12,009	\$ 20,075 <sup>6</sup>	\$ 160,123

<sup>1</sup> Salary is total base salary.

<sup>2</sup> Any bonus earned was paid solely on a discretionary basis, and not pursuant to any bonus plan.

<sup>3</sup> The valuations of these options reflect the compensation costs of each option award over the requisite service period in accordance with FAS123R.

<sup>4</sup> 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.

<sup>5</sup> Mr. Pelossof voluntarily resigned from the Company on December 6, 2006, effective January 31, 2007.

<sup>6</sup> This amount represents the rental payments the Company makes for the apartment Mr. Stutzman rents when he visits the Company.

## Employment Agreements

**Mr. Siebert.** On June 15, 2006, Mr. Siebert and the Company entered into an employment agreement, effective May 10, 2006, which terminates on May 10, 2008. Pursuant to the employment agreement, Mr. Siebert serves as the President and Chief Executive Officer of the Company and is entitled to receive a base compensation of \$240,000 per year, subject to review by the board of directors of the Company at the end of the first twelve months. Mr. Siebert also shall be 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.

**Mr. Pelossof.** On May 5, 2004, Mr. Pelossof and the Company entered into an employment agreement, effective May 10, 2004, which terminates on May 10, 2007. Pursuant to the employment agreement, Mr. Pelossof serves as the Vice President of Sales, Marketing and Business Development of the Company. On June 15, 2006, the board of directors amended this agreement, and increased Mr. Pelossof's salary from a base compensation of \$120,000 per year, to a base salary of \$170,000 per year. Mr. Pelossof is also eligible for a bonus of up to 25% of his salary, consisting of (i) a bonus of up to 12.5% 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 12.5% of his salary that will be determined based upon revenue and earnings performance criteria established each year by the board of directors. Mr. Pelossof 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. Pelossof's employment agreement. If Mr. Pelossof's employment agreement is terminated by the Company without cause, or if Mr. Pelossof 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. Pelossof's salary for six months. Mr. Pelossof 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. Mr. Pelossof voluntarily resigned from the effective January 31, 2007.

**Mr. Esfandiari.** On May 5, 2004, Mr. Esfandiari and the Company entered into an employment agreement, effective May 10, 2004, which terminates on May 10, 2007. Pursuant to the employment agreement, Mr. Esfandiari serves as the Director of Research & Development for the Company. On June 15, 2006, the board of directors amended this agreement, and increased Mr. Esfandiari's salary from a base compensation of \$115,000 per year, subject to periodic review by the board of directors of the Company, to a base salary of \$160,000 per year. Mr. Esfandiari is also eligible for a bonus of up to 25% of his salary, consisting of (i) a bonus of up to 12.5% 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 12.5% of his salary that will be determined based upon revenue and earnings performance criteria established each year by the board of directors. 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, including within 12 months of a change in control, the Company is

required to pay as severance Mr. Esfandiari's salary for six months. Mr. Esfandiari 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.

Neither Mr. Larkin nor Mr. Stutzman has an employment contract with the Company.

**OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END 2006**

Name	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price (\$)	Option Expiration Date	Option Vesting Date
<b>Lawrence A. Siebert</b>	50,000 <sup>2</sup>		0.75	11/19/2007	4/17/2006
	10,000 <sup>2</sup>		0.75	12/31/2008	4/17/2006
	10,000 <sup>2</sup>		0.75	5/4/2011	4/17/2006
	50,000 <sup>2</sup>		0.75	5/28/2011	4/17/2006
		50,000 <sup>2</sup>	0.75	5/28/2011	1/1/2007
	50,000 <sup>3</sup>		0.75	5/4/2011	5/5/2004
<b>Richard J. Larkin</b>	25,000 <sup>2</sup>		0.75	5/17/2010	4/17/2006
		25,000 <sup>2</sup>	0.75	5/17/2010	4/17/2006
	18,750 <sup>1</sup>		0.62	3/24/2011	3/24/2006
		18,750 <sup>1</sup>	0.62	3/24/2011	1/1/2007
	50,000 <sup>3</sup>		0.45	9/15/2010	5/5/2004
<b>Avi Pelossof</b>	40,000 <sup>2</sup>		0.75	11/19/2007	4/17/2006
	10,000 <sup>2</sup>		0.75	12/31/2008	4/17/2006
	25,000 <sup>2</sup>		0.75	5/17/2010	4/17/2006
		25,000 <sup>2</sup>	0.75	5/17/2010	1/1/2007
	25,000 <sup>1</sup>		0.62	3/24/2011	3/24/2006
		25,000 <sup>1</sup>	0.62	3/24/2011	1/1/2007
	10,000 <sup>2</sup>		0.75	5/4/2011	4/17/2006
	27,500 <sup>2</sup>		0.75	5/27/2011	4/17/2006
		50,000 <sup>2</sup>	0.75	5/27/2011	1/1/2007
		22,500 <sup>2</sup>	0.75	5/27/2011	1/1/2007
	40,000 <sup>3</sup>		0.75	5/4/2011	5/5/2004
<b>Javan Esfandiari</b>	30,000 <sup>2</sup>		0.75	3/31/2008	4/17/2006
	5,000 <sup>2</sup>		0.75	12/31/2008	4/17/2006
	25,000 <sup>2</sup>		0.75	5/17/2010	4/17/2006
		25,000 <sup>2</sup>	0.75	5/17/2010	1/1/2007
	18,750 <sup>1</sup>		0.62	3/24/2011	3/24/2006
		18,750 <sup>1</sup>	0.62	3/24/2011	1/1/2007
	5,000 <sup>2</sup>		0.75	5/4/2011	4/17/2006
	25,000 <sup>2</sup>		0.75	5/28/2011	4/17/2006
	25,000 <sup>2</sup>		0.75	5/28/2011	4/17/2006
		25,000 <sup>2</sup>	0.75	5/28/2011	5/28/2007
	30,000 <sup>3</sup>		0.75	5/4/2011	5/5/2004
<b>Les Stutzman</b>	15,000 <sup>1</sup>		0.62	3/24/2011	3/24/2006
	10,000 <sup>3</sup>		0.57	9/19/2010	9/19/2006
		10,000 <sup>3</sup>	0.57	9/19/2010	9/19/2007

<sup>1</sup> All options issued with a \$.62 exercise price were issued during 2006 as part of the Company's 1999 Option Plan. Pursuant to this plan, the Company granted 244,000 options to all employees.

<sup>2</sup> 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 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 Equity Incentive 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 Equity Incentive 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 replaces, 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 Pelosof'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.

<sup>3</sup> All other options shown were issued prior to 2006 as part of the Company's 1999 Option Plan.



**DIRECTOR COMPENSATION**

<b>Name</b>	<b>Fees Earned or Paid in Cash (\$)<sup>1</sup></b>	<b>Stock Awards (\$)<sup>2</sup></b>	<b>Option Awards (\$)<sup>3</sup></b>	<b>Total (\$)</b>
Alan Carus	\$ 40,000	\$ 10,650	\$ 14,663	\$ 65,313
Gerald Eppner <sup>4</sup>	37,500	-	16,504	54,004
Gary Meller	34,750	-	16,504	51,254

<sup>1</sup> Fees earned or paid in cash represents a yearly fee and fees for meeting expenses: (a) Mr. Carus received an \$18,000 annual fee as a member of the board of directors, a \$2,500 annual fee as audit committee chairman and \$19,500 in meeting fees paid during 2006; (b) Mr. Eppner received an \$18,000 annual fee as a member of the board of directors, and \$19,500 in meeting fees paid during 2006; (c) Mr. Meller received an \$18,000 annual fee as a member of the board of directors, and \$16,750 in meeting fees.

<sup>2</sup> Alan Carus was awarded 15,000 shares of common stock as compensation for services as the audit committee chairman. The shares were awarded on July 18, 2006 and 5,000 of these shares vested immediately, 5000 vest on July 1, 2007, and 5,000 vest on July 1, 2008. This stock was valued based on the market closing price on the date of the grant at \$10,650.

<sup>3</sup> Each outside member of the board of directors is issued options granting the holder the right to purchase 36,000 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 the director's annual compensation. One-third of these options are exercisable on the date of grant, one-third become exercisable on the first anniversary of the date of grant, and one-third become exercisable on the second 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.

<sup>4</sup> Mr. Eppner resigned from our Board of Directors on January 30, 2007.

**Director Compensation**

All non-employee directors are paid an \$18,000 annual retainer, semi-annually, and 36,000 stock options, with an exercise price equal to the market price on the date of the grant. One-third of each non-employee director's stock options are exercisable on the date of grant, one-third become exercisable on the first anniversary of the date of grant, and one-third become exercisable on the second anniversary of the date of grant. 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. In addition, in December 2005, each of the three non-employee directors was granted options to purchase 15,000 shares of our common stock at an exercise price equal to the market price of the underlying common stock on the date of grant.

**ITEM 11. 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 19, 2007.

<b>Name and Address of Beneficial Owner</b>	<b>Number of Shares Beneficially Owned</b>	<b>Percent of Class</b>
Lawrence Siebert <sup>(2)</sup> 3661 Horseblock Road Medford, NY 11763	2,141,919	17.68%
Javan Esfandiari <sup>(3)</sup> 3661 Horseblock Road Medford, NY 11763	229,580	1.92%
Richard J. Larkin <sup>(4)</sup> 3661 Horseblock Road Medford, NY 11763	145,261	1.22%
Alan Carus <sup>(5)</sup> 3661 Horseblock Road Medford, NY 11763	90,000	0.76%
Les Stutzman <sup>(1)</sup> 3661 Horseblock Road Medford, NY 11763	25,000	0.21%
Gary Meller <sup>(6)</sup> 3661 Horseblock Road	87,000	0.73%

Medford, NY  
11763

**All officers  
and directors  
as a group<sup>(7)</sup> 2,718,760 21.49%**

Mark Baum<sup>(8)</sup>

580 Second  
Street, Suite  
102

Encinitas, CA  
92024 1,408,597 11.18%

Avi Pelosof<sup>(9)</sup>

3661  
Horseblock 5.41%

Road  
Medford, NY  
11763 650,113

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 (11,642,540) of our common stock outstanding as of January 12, 2007. 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. In addition to the 11,642,540 shares of common stock outstanding, our outstanding series A, B and C preferred stock is convertible into a total of approximately 17.9 million shares of preferred stock, and there are warrants to purchase approximately 16.7 million shares of common stock outstanding. This table does not include convertible securities which, due to contractual restrictions, are not exercisable within 60 days of the date of this prospectus. Specifically, at no time may a holder of shares of series A, series B or series C preferred stock convert shares of the series A, series B or series C preferred stock if the number of shares of common stock to be issued pursuant to such conversion would exceed, when aggregated with all other shares of common stock owned by such holder at such time, the number of shares of common stock which would result in such holder beneficially owning (as determined in accordance with Section 13(d) of the Securities Exchange Act) in excess of either 4.999% or 9.999% of the then issued and outstanding shares of common stock outstanding at such time, unless the holder has provided us with sixty-one (61) days notice that the holder has elected to waive this restriction. As a result of this provision, holders of preferred stock that is convertible into common stock and holders of warrants to purchase common stock who, with 61 days' advance notice, can convert those securities into more than 5% of our outstanding stock are not required to be listed in this table.

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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 2006, 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 2006.

None of the preferred shares can be converted into common stock and none of the warrants can be exercised if the conversion or exercise would result in the holder owning more than 4.99% of our outstanding common stock unless the holder provides the Company with 61 days advance written notice.

- (1) Includes 25,000 shares issuable upon exercise of options exercisable within 60 days.
- (2) Includes 220,000 shares issuable upon exercise of options exercisable within 60 days and 140,697 warrants. Does not include 1,937,220 shares issuable upon conversion of series A preferred stock, 2,324,666 shares issuable upon exercise of warrants, 88,971 shares issuable upon conversion of series B preferred stock and 77,868 shares issuable upon exercise of warrants because they can be exercised only upon 61 days prior notice and therefore are not exercisable within 60 days.
- (3) Includes 207,500 shares issuable upon exercise of options exercisable within 60 days and 2,007 shares issuable upon exercise of warrants. Does not include 25,000 shares issuable upon exercise of options that are not exercisable within the next 60 days
- (4) Includes 137,500 shares issuable upon exercise of options exercisable within 60 days and 260 shares issuable upon exercise of warrants. Does not include 30,236 shares issuable upon conversion of series A preferred stock and 25,196 shares issuable upon exercise of warrants because they can be exercised only upon 61 days prior notice and therefore are not exercisable within 60 days.
- (5) Includes 51,000 shares issuable upon exercise of options exercisable within 60 days. Does not include 36,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
- (6) Includes 51,000 shares issuable upon exercise of options exercisable within 60 days. Does not include 36,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
- (7) Includes footnotes (1)-(6)
- (8) Includes 850,000 shares issuable upon exercise of warrants. Does not include 108,333 shares issuable upon conversion of series A preferred stock and 130,000 shares issuable upon exercise of warrants because they can be exercised only upon 61 days prior notice and therefore are not exercisable within 60 days.
- (9) Includes 300,000 shares issuable upon exercise of options exercisable within 60 days and 22,555 shares issuable upon exercise of warrants. Does not include 10,078 shares issuable upon conversion of series A preferred stock and 12,095 shares issuable upon exercise of warrants because they can be exercised only upon 61 days prior notice and therefore are not exercisable within 60 days. Mr. Pelossof voluntarily resigned from the Company on December 6, 2006, effective January 31, 2007.

## Equity Compensation Plan Information

Equity Compensation Plan Information			
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

	(a)	(b)	Column (a) (c)
Equity compensation plans approved by security holders	1,529,750	\$0.696	1,355,250
Equity compensation plans not approved by security holders	--	--	--
Total	1,529,750	\$0.696	1,355,250

**ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

Mark L. Baum, our former president prior to the merger and a former director of the Company, entered into a nine-month employment agreement with the Company, effective upon the closing of the merger, pursuant to which Mr. Baum received 400,000 shares of our common stock as well as a warrant to acquire 425,000 shares of common stock at \$.60 per share and a warrant to acquire an additional 425,000 shares of common stock at \$.90 per share. The warrants expire five years after the date of grant. Pursuant to the employment agreement, Mr. Baum was to advise the Company concerning management, marketing, strategic planning, corporate structure, business operations, expansion of services, acquisitions and business opportunities, matters related to our public reporting obligations, and our overall needs through February 5, 2005. Mr. Baum also invested \$65,000 in the private placement of series A preferred stock, pursuant to which he received 2.167 shares of series A preferred stock convertible into 108,350 shares of common stock, and a warrant to purchase 130,020 shares of common stock. Mr. Baum also owns 300,000 shares of our common stock in addition to the stock and warrants described above. In November of 2004 as payment of dividends on the series A preferred he received 4,333 shares of common stock. Prior to the merger, Mr. Baum was the sole director and officer of the Company. On March 18, 2005, as compensation for Mr. Baum's service on the board of directors of Chembio the Company, the exercise price of Mr. Baum's warrant to acquire 425,000 shares of common stock at \$.90 per share was reduced to \$.75 per share. Mr. Baum received no other compensation for his services on the board of directors.

Lawrence A. Siebert, the president and chairman of the board of directors of the Company beginning at the time of and after the merger, and the president and chairman of Chembio Diagnostic Systems Inc. since May 2002, held two promissory notes issued by Chembio Diagnostic Systems Inc. One note was issued on August 1, 1999 in the original principal amount of \$338,125, bearing interest at a rate of 11% per annum. The other was issued on April 25, 2001 in the original principal amount of \$795,937, bearing interest at a rate of 12% per annum. Mr. Siebert converted the entire outstanding principal amount of the 11% note and \$561,875 principal amount of the 12% note into 30 shares of the Company series A preferred stock, together with warrants to acquire 1,800,000 shares of common stock at \$.90 per share, pursuant to the Company private placement of our series A preferred stock on May 5, 2004. The shares of series A preferred stock held by Mr. Siebert are convertible into 1,547,100 shares of the Company's common stock. The remaining debt of \$234,062 held by Mr. Siebert was exchanged on December 29, 2004 into 7.80208 shares of the Company's series A preferred stock, together with warrants to acquire 468,125 shares of common stock at \$.90 per share, pursuant to the terms of the Company's private placement of our series A preferred stock on May 5, 2004. As of December 31, 2006, \$65,287.39 of accrued interest on the debt is also due to Mr. Siebert, but is not accruing interest. The accrued interest will be paid out according to the terms of the Company's private placement of its series B preferred stock on January 28, 2005. Mr. Siebert also invested \$50,000 in our series B preferred stock private placement pursuant to which he received 1 share of series B preferred stock convertible into 81,967 shares of common stock and a warrant to purchase 77,868 shares of common stock.

Mr. Siebert also invested \$18,700 in Chembio Diagnostic Systems Inc. pursuant to a private placement of convertible notes on March 22, 2004. Mr. Siebert converted the entire principal amount of the note that he received, together with accrued interest thereon, into .942 shares of the Company's series A preferred stock, together with warrants to acquire 56,520 shares of common stock at \$.90 per share, pursuant to the Company's private placement of our series A preferred stock on May 5, 2004. In November of 2004 as payment of dividends on the series A preferred he received 61,884 shares of common stock. Mr. Siebert exercised a warrant to purchase 66,869 shares of common stock on December 30, 2004 at a price of \$0.45 per share. These shares were gifted by Mr. Siebert to a third party. In May of 2005 as payment of dividends on the series A preferred he received 72,234 shares of common stock. In July of 2005 as payment of dividends on the series B preferred he received .03871 shares of series B preferred stock. In November of 2005 as payment of dividends on the series A preferred he received 77,488 shares of common stock. In January of 2006 as payment of dividends on the series B preferred he received .04674 shares of series B preferred stock. In June of 2006 as payment of dividends on the series A preferred and series B preferred, Mr. Siebert received 22,714 shares of common stock. In July and August of 2006 as payment of dividends on the series B preferred, Mr. Siebert received

3,295 shares of common stock. In November of 2006 as payment of dividends on the series A preferred he received 55,860 shares of common stock. In January 2007 as payment of dividends on the series B preferred, Mr. Siebert received 3,292 shares of common stock.

Mr. Siebert prior to March 22, 2004 had either advanced funds to Chembio Diagnostic Systems, Inc. or paid vendors directly on Chembio Diagnostic Systems, Inc.'s behalf. The total amount so paid or advanced totaled \$182,181 and was repaid in the fourth quarter of 2006.

Richard J. Larkin, the Chief Financial Officer of the Company, invested \$10,000 in Chembio Diagnostic Systems Inc. pursuant to the March 22, 2004 private placement of convertible notes. Mr. Larkin converted the entire principal amount of the note that he received, together with accrued interest thereon, into .504 shares of the Company's series A preferred stock, together with warrants to acquire 30,240 shares of common stock at \$.90 per share, pursuant to the Company's private placement of our series A preferred stock on May 5, 2004. In November of 2004 as payment of dividends on the series A preferred he received 1,007 shares of common stock. In May of 2005 as payment of dividends on the series A preferred he received 999 shares of common stock. In November of 2005 as payment of dividends on the series A preferred he received 1,007 shares of common stock. In May of 2006 as payment of dividends on the series A preferred he received 1007 shares of common stock. In June of 2006 as payment of dividends on the series A preferred Mr. Larkin received 265 shares of common stock. In November of 2006 as payment of dividends on the series A preferred he received 726 shares of common stock.

Avi Pelossof, vice president of sales and marketing of the Company, from May 5, 2004 to January 31, 2007, invested \$4,000 in the Company pursuant to the March 22, 2004 private placement of convertible notes. Mr. Pelossof converted the entire principal amount of the note that he received, together with accrued interest thereon, into .202 shares of the Company's series A preferred stock, together with warrants to acquire 22,555 shares of common stock at \$.90 per share, pursuant to the Company's private placement of our series A preferred stock on May 5, 2004. In November of 2004 as payment of dividends on the series A preferred he received 403 shares of common stock. In May of 2005 as payment of dividends on the series A preferred he received 399 shares of common stock. In November of 2005 as payment of dividends on the series A preferred he received 403 shares of common stock. In May of 2006 as payment of dividends on the series A preferred he received 403 shares of common stock. In June of 2006 as payment of dividends on the series A preferred Mr. Pelossof received 106 shares of common stock. In November of 2006 as payment of dividends on the series A preferred he received 290 shares of common stock.

In addition Mr. Pelossof exercised 100,000 options in December 2006 at \$.60 per share and another 50,000 options in January 2006 at \$.75 per share.

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 in March 2006. Crestview also invested \$2 million in our series C preferred stock private placement. in September 2006.

As referred to above, in January 2005, for a purchase price of \$3 million, we issued Crestview 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 \$.61 per share. In July 2005, we issued Crestview dividends on these series B preferred shares in the form of 2.32274 additional series B preferred shares.

In March 2006, for a purchase price of \$1 million, we issued Crestview 20 shares of series B preferred shares with warrants to purchase 1,557,377 shares of common stock at a warrant exercise price of \$.61 per share. These shares were issued in connection with the our January 2005 private placement as described herein. Subsequently, in July 2006, we issued dividends on all of Crestview's shares in the form of 220,301 shares of common stock. In September 2006, for a purchase price of \$2 million, we issued 40 shares of series C preferred shares 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 registration statement of which this prospectus is a part, Crestview agreed to reduce the number of its shares of common stock covered by this prospectus to 2,000,000. Crestview also agreed to waive any penalties that we would otherwise owe Crestview because of the failure to register all of Crestview's shares in the current registration statement. In return, we have agreed that, upon request by Crestview, we 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 us.

The series B preferred shares owned by Crestview are convertible into a total of 6,747,748 shares of common stock, and the series C preferred shares owned by Crestview are convertible into a total of 2,500,000 shares of common stock.

Crestview invested \$2,000,000 in our series C preferred stock private placement on September 29, 2006. We also received an investment of \$2,000,000 on that date from Inverness. A certificate of designation for the series C preferred was filed with the Secretary of State of Nevada reflecting the agreed upon conversion price of \$.85. The series C preferred stock private placement for an aggregate of \$8,150,000 (including the \$2,000,000 invested by each of Crestview and Inverness) was completed on October 5, 2006. During the period between September 29, 2006 and October 5, 2006, we requested the assistance of Crestview and others in identifying to us prospective investors. A representative of Crestview informed Mr. Siebert on October 3, 2006 of a conversation he had earlier that day with a fund manager that the fund would be interested in investing a substantial amount in the offering, but only at a conversion price of no more than \$.80.

At a board of directors meeting on October 4, 2006, Mr. Siebert expressed his recommendation that the board approve lowering the conversion price to \$.80 in order to be able to obtain the additional funds. The board discussed the bridge financing of \$1,300,000 in promissory notes which had been completed in June 2006, the noteholders who expected to convert their notes into the series C preferred stock, and the restrictions on future equity sales by us in the bridge financing purchase agreement that necessitated finalizing promptly the series C preferred stock offering. After discussion to approve the funding, the motion was approved unanimously, with the exception of Gerald Eppner<sup>1</sup> who abstained. Mr. Eppner stated that he understood the benefits of the economics of the transaction and our need to proceed so quickly, but that he did not wish to vote in favor.

At a board meeting held on October 11, 2006, the board members discussed the series C preferred stock private placement. Mr. Eppner stated in his view that it would be desirable to review the sequence of events in this transaction to assure proper guidelines for corporate governance and to determine if disclosure or other issues needed to be considered. At a board meeting held on October 26, 2006, it was discussed that a subcommittee of the audit committee, whose members would be Mr. Eppner and Alan Carus, would review certain issues related to the series C preferred stock private placement.

The first meeting of the audit committee to review the series C preferred stock offering was held on October 27, 2006. The audit committee decided it would review the role of Crestview in the series C preferred stock offering, Crestview's status as a possible control person, the role of Gary Meller in the offering and his relationship with Crestview, and whether the audit committee should recommend new corporate governance procedures to be implemented or any action to be taken by the board of directors. The audit committee utilized legal counsel to assist in its review. The audit committee held seven meetings during the period from October 27, 2006 to January 10, 2007. Messrs. Carus and Eppner attended all of the meetings. Mr. Carus concluded that: (i) he was satisfied with the review, and (ii) although with fewer time constraints, there could have been more deliberation regarding the change in the conversion price, he believed there was no inappropriate conduct, that the Company had not suffered any damage and that the matter should be closed. Mr. Eppner stated his concerns that: (i) Crestview is an affiliate of the Company, (ii) there was no participation by the Company in the reduction in the conversion price from \$.85 to \$.80, (iii) although he agreed with Mr. Carus that the \$.80 price may have been acceptable to the Company, it was not as good as a higher price, (iv) Mr. Siebert should not have allowed this to happen, and that because he did, it was evidence of control by Crestview, and (v) disclosure of the review of the audit committee should be made in a registration statement that was to be filed shortly thereafter.

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<sup>1</sup> Mr. Eppner resigned from the board of directors on January 30, 2007.

## **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.

Since we are not currently subject to corporate governance standards relating to the independence of our directors, we choose to define an “independent” director in accordance with the NASDAQ Global Market's requirements for independent directors (NASDAQ Marketplace Rule 4200). We do not currently have an independent director under the above definition. We do not list that definition on our Internet website.

**ITEM 13.**

**EXHIBITS**

Number Description

- 3.1 Articles of Incorporation, as amended. (3)
- 3.2 Bylaws. (1)
- 3.3 Amendment No. 1 to Bylaws dated May 3, 2004. (2)
- 4.1 Certificate of Designation of the Relative Rights and Preferences of the series A convertible preferred stock of the Registrant. (2)
- 4.2 Registration Rights Agreement, dated as of May 5, 2004, by and among the Registrant and the Purchasers listed therein. (2)
- 4.3 Lock-Up Agreement, dated as of May 5, 2004, by and among the Registrant and the shareholders of the Registrant listed therein. (2)
- 4.4 Form of Common Stock Warrant issued pursuant to the Stock and Warrant Purchase Agreement. (2)
- 4.5 Form of \$.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 \$.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)
- 4.7 Form of Warrant issued to Placement Agents pursuant to the Series A Convertible Stock Private Placement. (7)
- 4.8 Certificate of Designation of Preferences, Rights, and Limitations of Series B 9% Convertible Preferred Stock of the Registrant. (9)
- 4.9 Form of Common Stock Warrant issued to Midtown Partners & Co., LLC. (9)
- 4.10 Form of Common Stock Warrant issued pursuant to the Securities Purchase Agreement. (9)
- 4.11 Registration Rights Agreement, dated as of January 26, 2005, by and among the Registrant and the purchasers listed therein. (9)
- 4.12 Form of Warrant, dated June 29, 2006, issued pursuant to Company and purchasers of the Company's Secured Debentures. (4)
- 4.13 Registration Rights Agreement, dated June 29, 2006. (4)
- 4.14 Certificate of Designation of Preferences, Rights and Limitations of Series C 7% Convertible Preferred Stock of the Registrant. (6)
- 4.15 Registration Rights Agreement, dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (6)
- 4.16 Form of Common Stock Warrant issued pursuant to the Securities Purchase Agreements dated September 29, 2006 (6)
- 10.1 Employment Agreement dated June 15, 2006 w/ Lawrence A. Siebert. (5)
- 10.2 Employment Agreement dated May 5, 2004 w/ Avi Pelosof. (8)
- 10.3 Employment Agreement dated May 5, 2004 w/ Javan Esfandiari. (8)
- 10.4 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)
- 10.5 Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of January 26, 2005, by and among the Registrant and the purchasers listed therein. (9)
- 10.6 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 Equity Exchange Agreement, dated as of January 28, 2005, by and between the Registrant and Kurzman Partners, LP. (10)
- 10.8 Security Purchase Agreement, dated June 29, 2006, among the Company and purchasers of the Company's Secured Debentures. (4)
- 10.9 Form of Secured Debenture, dated June 29, 2006. (4)



- 10.10 Security Agreement, dated June 29, 2006, among the Company, Chembio Diagnostic Systems, Inc., and purchasers of the Company's Secured Debentures. (4)
- 10.11 Subsidiary Guarantee, dated June 29, 2006, made by Chembio Diagnostic Systems, Inc., in favor of Purchasers of the Company's Secured Debentures. (4)
- 10.12 Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (6)
- 10.13 Letter of Amendment to Securities Purchase Agreements dated as of September 29, 2006 by and among the Registrant and the Purchasers listed therein. (6)
- 10.14 HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Inverness and StatSure. (6)
- 10.15 HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Inverness. (6)
- 10.16 Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Inverness. (6)
- 10.17 Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (6)
- 10.18 Settlement Agreement, dated September 29, 2006, between the Registrant and StatSure. (6)
- 10.19 Contract for Transfer of Technology and Materials with Bio-Manguinhos. (7)
- 10.20 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 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

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- (1) Incorporated by reference to the Registrant's registration statement on Form SB-2 filed with the Commission on August 23, 1999.
  - (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 Report on Form 8-K filed with the Commission on June 21, 2006.
  - (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. Avi Pelosof's and Javan Esfandiari's Employment Agreements were amended by board consent on June 15, 2006.
  - (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.

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**ITEM 14.**

**PRINCIPAL ACCOUNTANT FEES AND SERVICES**

**Audit Fees**

For the years ended December 31, 2006 and December 31, 2005, Lazar Levine & Felix LLP, our principal accountants, billed the Company \$72,000 and \$99,000, respectively, for fees for the audit of our annual financial statements and review of financial statements included in our Forms 10-QSB and 10-KSB.

**Audit-Related Fees**

For the years ended December 31, 2006 and December 31, 2005, Lazar Levine & Felix LLP, did not provide us with any assurances or related services reasonably related to the performance of the audit or review of our financial statements that are not reported above under "Audit Fees."

**Tax Fees**

For the years ended December 31, 2006 and December 31, 2005, Lazar Levine & Felix LLP billed the Company \$3,130 and \$9,100, respectively, for professional services for tax compliance, tax advice, and tax planning.

**All Other Fees**

For the years ended December 31, 2006 and December 31, 2005, Lazar Levine & Felix LLP billed the Company \$30,200 and \$17,700 for fees associated with the preparation and filing of our 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 Lazar Levine & Felix LLP. There are no other specific policies or procedures relating to the pre-approval of services performed by Lazar Levine & Felix LLP.



**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 28, 2007            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.

<u>Signatures</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Lawrence A. Siebert</u> Lawrence A. Siebert	Chief Executive Officer, President and Chairman of the Board (Principal Executive Officer)	March 28, 2007
<u>/s/ Richard J. Larkin</u> Richard J. Larkin	Chief Financial Officer (Principal Financial & Accounting Officer)	March 28, 2007
<u>/s/ Alan Carus</u> Alan Carus	Director	March 28, 2007
<u>/s/ Gary Meller</u> Dr. Gary Meller	Director	March 28, 2007

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**

**Index to Consolidated Financial Statements**

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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 sheets of Chembio Diagnostics, Inc. and Subsidiaries (the "Company") as of December 31, 2006 and 2005 and the consolidated statements of operations, stockholders' equity (deficit) and cash flows for the two years in the period ended December 31, 2006. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits 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 audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Chembio Diagnostics, Inc. and Subsidiaries as of December 31, 2006 and 2005, and the consolidated results of its operations and its cash flows for the two years in the period ended December 31, 2006 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 28, 2007

**CHEMBIO DIAGNOSTIC SYSTEMS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**  
**AS OF DECEMBER 31,**

- ASSETS -

	2006	2005
<b>CURRENT ASSETS:</b>		
Cash	\$ 4,290,386	\$ 232,148
Accounts receivable, net of allowance for doubtful accounts of \$42,967 and \$20,488 for 2006 and 2005, respectively	1,350,240	1,255,073
Inventories	1,108,950	687,983
Prepaid expenses and other current assets	204,092	292,989
<b>TOTAL CURRENT ASSETS</b>	<b>6,953,668</b>	<b>2,468,193</b>
<b>FIXED ASSETS, net of accumulated depreciation</b>	<b>603,603</b>	<b>438,632</b>
<b>OTHER ASSETS</b>	<b>349,306</b>	<b>109,581</b>
	\$ 7,906,577	\$ 3,016,406

- LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT) -

<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$ 1,709,939	\$ 1,477,925
Current portion of accrued interest payable	93,160	120,000
Current portion of obligations under capital leases	37,336	38,368
Payable to related party	-	182,181
<b>TOTAL CURRENT LIABILITIES</b>	<b>1,840,435</b>	<b>1,818,474</b>
<b>OTHER LIABILITIES:</b>		
Obligations under capital leases, net of current portion	7,081	44,417
Accrued interest, net of current portion	-	100,812
Series C redemption put	449,677	-
<b>TOTAL LIABILITIES</b>	<b>2,297,193</b>	<b>1,963,703</b>
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>PREFERRED STOCK</b>		
Series C 7% Convertible - \$.01 par value: 165 shares issued and outstanding. Liquidation preference-\$8,397,583	6,549,191	-

**STOCKHOLDERS' EQUITY (DEFICIT)**

Preferred Stock - 10,000,000 shares authorized:

Series A 8% Convertible - \$.01 par value: 149,921,119 and 158,680,999 shares issued and outstanding for 2006 and 2005, respectively. Liquidation preference \$4,557,604 and \$4,822,957 for 2006 and 2005, respectively.	<b>2,504,313</b>	2,628,879
Series B 9% Convertible - \$.01 par value: 113,935,911 and 102,197,600 shares issued and outstanding for 2006 and 2005, respectively. Liquidation preference-\$5,958,848 and \$5,341,896 for 2006 and 2005, respectively	<b>3,555,786</b>	3,173,239
Common stock - \$.01 par value; 100,000,000 shares authorized 11,296,961 and 8,491,429 shares issued and outstanding for 2006 and 2005, respectively.	<b>112,970</b>	84,914
Additional paid-in capital	<b>19,960,618</b>	14,034,099
Accumulated deficit	<b>(27,073,494)</b>	(18,868,428)
<b>TOTAL STOCKHOLDERS' EQUITY (DEFICIT)</b>	<b>(939,807)</b>	1,052,703
	<b>\$ 7,906,577</b>	<b>\$ 3,016,406</b>

The accompanying notes are an integral part of these consolidated financial statements.

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	FOR THE YEARS ENDED	
	December 31, 2006	December 31, 2005
<b>REVENUES:</b>		
Net sales	\$ 6,294,012	\$ 3,359,532
License revenue	-	250,000
Research grants and development income	208,468	331,198
<b>TOTAL REVENUES</b>	<b>6,502,480</b>	<b>3,940,730</b>
Cost of sales	4,485,912	2,608,584
<b>GROSS PROFIT</b>	<b>2,016,568</b>	<b>1,332,146</b>
<b>OVERHEAD COSTS:</b>		
Selling, general and administrative expenses	5,195,289	3,265,235
Research and development expenses	1,401,472	1,364,898
	<b>6,596,761</b>	<b>4,630,133</b>
<b>LOSS FROM OPERATIONS</b>	<b>(4,580,193)</b>	<b>(3,297,987)</b>
<b>OTHER INCOME (EXPENSES):</b>		
Settlement of accounts payable	-	21,867
Other income	25,000	-
Interest income	29,532	39,803
Interest expense	(386,895)	(15,683)
Loss on extinguishment of debt	(87,464)	-
Gain on disposal of fixed assets	5,000	-
<b>LOSS BEFORE INCOME TAXES</b>	<b>(4,995,020)</b>	<b>(3,252,000)</b>
Income taxes	-	-
<b>NET LOSS</b>	<b>(4,995,020)</b>	<b>(3,252,000)</b>
Dividends payable in stock to preferred stockholders	1,022,897	818,321
Dividend accreted to preferred stock for associated costs and a beneficial conversion feature	2,187,149	2,698,701
<b>NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS</b>	<b>\$ (8,205,066)</b>	<b>\$ (6,769,022)</b>
<b>Basic and diluted loss per share</b>	<b>\$ (0.80)</b>	<b>\$ (0.88)</b>

<i>Weighted number of shares outstanding, basic and diluted</i>	<b>10,293,168</b>	7,705,782
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The accompanying notes are an integral part of these consolidated financial statements.

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)**  
**FOR THE YEAR ENDED DECEMBER 31, 2005**

	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
<b>Balance at December 31, 2004</b>	-	\$ -	-	\$ -	6,907,143	\$ 69,071	\$ 9,079,341	\$ (12,099,406)	\$ (2,950,994)
Adjustment to reflect reclassification of Series A Preferred to permanent equity	162.37241	2,427,030	-	-	-	-	-	-	2,427,030
<b>Preferred Stock Issued:</b>									
For cash	-	-	100.95000	5,047,500	-	-	(321,639)	-	4,725,861
For fees	-	-	4.98000	249,000	-	-	(249,000)	-	-
Exchanged from Series A Preferred to Series B Preferred	(0.66666)	(11,600)	0.40000	20,000	-	-	(8,400)	-	-
Allocation of Fair value to warrants	-	-	-	(2,349,893)	-	-	2,349,893	-	-
Allocation of value of beneficial conversion Series B Preferred	-	-	-	(2,437,035)	-	-	2,437,035	-	-
Dividend	-	-	4.06988	435,509	-	-	-	(435,509)	-
Accretion of beneficial conversion	-	261,666	-	2,437,035	-	-	-	(2,698,701)	-
<b>Common Stock Issued:</b>									
Upon conversion of Preferred Series A Preferred	(3.02476)	(52,631)	(8.20228)	(228,877)	823,654	8,237	273,271	-	-
Dividend		4,414			630,632	6,306	372,092	(382,812)	-



For services	-	-	-	-	95,000	950	52,300	-	53,250
<b>Warrants and options:</b>									
Issued for services	-	-	-	-	-	-	90,288	-	90,288
Exercised	-	-	-	-	35,000	350	24,850	-	25,200
Cancelled	-	-	-	-	-	-	(65,932)	-	(65,932)
<b>Net loss for 2005</b>	-	-	-	-	-	-	-	(3,252,000)	(3,252,000)

**Balance at December 31, 2005**      **158.68099**   **\$2,628,879**   **102.19760**   **\$ 3,173,239**   **8,491,429**   **\$ 84,914**   **\$14,034,099**   **\$ (18,868,428)**   **\$ 1,052,703**

The accompanying notes are an integral part of these consolidated financial statements.

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)**  
**FOR THE YEAR ENDED DECEMBER 31, 2006**

	Series A Preferred Stock		Series B Preferred Stock		Common Stock		Additional paid in capital Amount	Accumulated Deficit Amount	Total Amount
	Shares	Amount	Shares	Amount	Shares	Amount			
<b>Balance at December 31, 2005</b>	<b>158.68099</b>	<b>\$2,628,879</b>	<b>102.19760</b>	<b>\$3,173,239</b>	<b>8,491,429</b>	<b>\$ 84,914</b>	<b>\$14,034,099</b>	<b>\$ (18,868,428)</b>	<b>\$ 1,052,7</b>
<b>Preferred Stock</b>									
<b>Issued:</b>									
cash	-	-	20.0000	1,000,000	-	-	(112,750)	-	887,2
fees	-	-	2.0000	100,000	-	-	(100,000)	-	
dividends	-	-	1.79797	89,899	-	-	(89,899)	-	
location of fair value to warrants	-	-	-	(481,470)	-	-	1,880,185	-	1,398,7
location of value beneficial conversion	-	-	-	(463,434)	-	-	2,187,149	-	1,723,7
creation of Preferred dividend	-	366,563	-	508,751	-	-	-	(1,022,897)	(147,5
creation of beneficial conversion	-	-	-	463,434	-	-	-	(2,187,149)	(1,723,7
payment of dividends	-	(369,123)	-	(473,982)	959,608	9,596	633,284	-	(200,2
<b>Common Stock</b>									
<b>Issued:</b>									
Common converted from preferred	(8.75980)	(122,006)	(12.05966)	(360,651)	1,426,483	14,265	468,392	-	
services	-	-	-	-	178,750	1,788	137,890	-	139,6
<b>Warrants and Options:</b>									
consultants/Advisory board	-	-	-	-	-	-	137,022	-	137,0
for CEO warrant	-	-	-	-	-	-	34,000	-	34,0
exercised	-	-	-	-	240,691	2,407	143,914	-	146,3
issued for bridge	-	-	-	-	-	-	328,341	-	328,3
option valuation per RSU	-	-	-	-	-	-	278,991	-	278,9
<b>Loss for 2006</b>	-	-	-	-	-	-	-	(4,995,020)	(4,995,0
<b>Balance at December 31, 2006</b>	<b>149.92119</b>	<b>\$2,504,313</b>	<b>113.93591</b>	<b>\$3,555,786</b>	<b>11,296,961</b>	<b>\$ 112,970</b>	<b>\$19,960,618</b>	<b>\$ (27,073,494)</b>	<b>\$ (939,8</b>

The accompanying notes are an integral part of these consolidated financial statements.

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**FOR THE YEARS ENDED:**

	<b>December 31, 2006</b>	<b>December 31, 2005</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (4,995,020)	\$ (3,252,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	209,541	98,508
Provision for doubtful accounts	22,479	4,120
Expenses related to shares, options and warrants issued for services	565,668	77,606
Expenses related to warrants issued with bridge financing	328,341	-
Expenses related to conversion of bridge into Series C Preferred Stock	99,469	-
Changes in:		
Accounts receivable	(117,645)	(1,094,137)
Restricted cash	-	250,000
Inventory	(420,967)	(149,336)
Accounts payable and accrued expenses	256,039	212,939
Other	(150,828)	(153,060)
<b>Net cash used in operating activities</b>	<b>(4,202,923)</b>	<b>(4,005,360)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Acquisition of fixed assets	(374,513)	(348,741)
<b>Net cash used in investing activities</b>	<b>(374,513)</b>	<b>(348,741)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Sale of Series C Preferred Stock and associated warrants, net of cash cost of financing of \$110,000	7,440,285	-
Sale of Series B Preferred Stock and associated warrants, net of cash cost of financing for the periods ended 2006 and 2005 of \$2,750 and \$321,639, respectively	997,250	4,725,861
Payment of obligations to related party	(182,181)	-
Payment of capital lease obligation	(38,368)	(42,511)

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Payment of accrued interest	(127,652)	(112,138)
Proceeds from bridge/working capital loan	1,300,000	161,917
Payment of bridge/working capital loan	(699,755)	(206,917)
Payment of dividends	(200,226)	-
Proceeds from exercise of warrants	146,321	25,200
<b>Net cash provided by financing activities</b>	<b>8,635,674</b>	<b>4,551,412</b>
<b>NET INCREASE IN CASH</b>	<b>4,058,238</b>	<b>197,311</b>
Cash - beginning of the period	232,148	34,837
<b>CASH - end of the period</b>	<b>\$ 4,290,386</b>	<b>\$ 232,148</b>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid during the period for interest	\$ 173,438	\$ 124,805
Cash paid during the period for corporate taxes	2,269	3,763
<b>Supplemental disclosures for non-cash investing and financing activities:</b>		
Warrants issued as payment for fees	\$ -	\$ 388,631
Value of warrants issued allocated to additional paid in capital	1,880,185	
Accreted beneficial conversion to preferred stock	2,187,149	2,698,701
Bridge debt and associated interest converted to Series C Preferred Stock	699,714	-
Series B Preferred issued as payment for financing fees	100,000	249,000
Preferred stock converted to common stock	482,657	
Series A Preferred and associated warrants exchanged for Series B Preferred and associated warrants	-	20,000
Accreted Dividend to Preferred Stock	1,022,897	818,321
Preferred B issued as payment of dividend	89,899	203,493
Common Stock issued as payment of dividend	642,879	378,398

The accompanying notes are an integral part of these consolidated financial statements.

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2006 AND 2005**

<b>NOTE</b>	<b>1</b>	—	<b>Description of Business:</b>
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Chembio Diagnostics, Inc. (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, two of which were approved by the FDA in 2006; the third is sold for export only. These products all employ single path lateral flow technology. The Company also has a rapid test for Chagas disease (a parasitic disease endemic in Latin America) as well as a line of rapid tests for tuberculosis, including tests for tuberculosis in animals for which USDA approval is pending. 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 either under its STAT PAK® or SURE CHECK® registered trademarks or the private labels of our marketing partners, such as is the case with the Clearview® label owned by Inverness Medical Innovations, Inc., which is the Company's exclusive marketing partner for its rapid HIV test products in the United States.

Chembio Diagnostics, Inc. (the Company) was formerly known as Trading Solutions.com, Inc. On May 5, 2004, the Company issued 4,000,000 shares of its Common Stock to acquire all the outstanding Common Stock of Chembio Diagnostic Systems, Inc. (CDS) and assumed all outstanding options and warrants of CDS. On May 5, 2004, New Trading Solutions, Inc., a wholly owned subsidiary of the Company merged with and into CDS with CDS remaining as the surviving corporation (the "Merger"). For financial reporting purposes, the acquisition was treated as a recapitalization of Chembio Diagnostics, Inc. with CDS, as the acquiror. Trading Solutions.com, Inc. had no assets, liabilities or transactions (other than a 1:17 reverse split of its Common Stock) in the fiscal year preceding the merger. Prior to the merger, Trading Solutions.com, Inc.'s fiscal year ended September 30. After the merger, Chembio Diagnostics, Inc. adopted a fiscal year ending on December 31, the fiscal year-end of CDS.

***Series C Financing***

On September 29, 2006 and October 5, 2006, the Company completed a private placement of 7% Series C Convertible Preferred Stock and associated warrants for \$8,250,000. The purchase price per unit (one share plus associated warrants) was \$50,000 and a total of 165 shares and warrants to purchase 2,578,125 shares of Common Stock were issued in the transaction.

In connection with this private placement, we employed Midtown Partners & Co., LLC to serve as the placement agent with respect to investors who invested \$1,000,000 in this offering. As compensation for services rendered to the Company, we agreed to (i) pay Midtown a cash fee equal to 5% of the amount of cash proceeds the Company received from the investors Midtown solicited, and (ii) issue to Midtown warrants to purchase 62,500 shares of our common stock. The warrants issued to Midtown are exercisable for a period of five years from their issuance and have an exercise price of \$1.00 per share.

<b>NOTE</b>	<b>2</b>	—	<b>SIGNIFICANT ACCOUNTING POLICIES:</b>
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***(a) Principles of Consolidation:***

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

***(b) Inventories:***

Inventories are stated at the lower of cost or market. Cost is determined on the first-in, first-out method.

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2006 AND 2005**

**(c) 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.

**(d) 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.

**(e) Income Taxes:**

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

**(f) Research and Development:**

Research and development costs are charged to expense as incurred.

**(g) Stock Based Compensation:**

Effective January 1, 2006, the Company's Plan is 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)", which replaces FAS No. 123, Accounting for Stock-Based Compensation, and supersedes Accounting Principles Board Opinion ("APB") No. 25, Accounting for Stock Issued to Employees, and related interpretations. 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 SFAS 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 footnote 5 for further details.

**(h) 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.

**(i) 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



collectibility 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 grants when earned. Grants are invoiced after expenses are incurred. Any grants funded in advance are deferred until earned.

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2006 AND 2005**

*(j) 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 \$100,000 FDIC Insurance limit. The Company monitors the credit ratings of the financial institutions to mitigate this risk. Concentration of credit risk with respect to trade receivables is principally mitigated by the Company's obtaining of letters of credit from certain foreign customers, and its diverse customer base both in number of customers and geographic locations.

*(k) Fair Value of Financial Instruments:*

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

*(l) Recent Accounting Pronouncements Affecting the Company:*

**SEC Staff Accounting Bulletin 108 ("SAB 108"), Considering the Effects of Prior Year Misstatements when Qualifying Misstatements in Current Year Financial Statements**

In September 2006, the SEC staff issued Staff Accounting Bulletin No. 108, "Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements." SAB 108 was issued in order to eliminate the diversity of practice surrounding how public companies quantify financial statement misstatements.

In SAB 108, the SEC staff established an approach that requires quantification of financial statement misstatements based on the effects of the misstatements on each of the company's financial statements and the related financial statement disclosures. This model is commonly referred to as a "dual approach" because it requires quantification of errors under both the iron curtain and the roll-over methods.

SAB 108 permits existing public companies to initially apply its provisions either by (i) restating prior financial statements as if the "dual approach" had always been used or (ii) recording the cumulative effect of initially applying the "dual approach" as adjustments to the carrying values of assets and liabilities as of January 1, 2006 with an offsetting adjustment recorded to the opening balance of retained earnings.

**Statement of Financial Accounting Standard 155, Accounting for Certain Hybrid Financial Instruments ("SFAS No. 155")**

In February 2006, the FASB amended SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities", and SFAS No. 140, "Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities", with the issuance of SFAS No. 155, "Accounting for Certain Hybrid Financial Instruments". SFAS No. 155 resolves issues addressed in the earlier standards and is effective for all financial instruments acquired or issued after the beginning of an entity's first fiscal year that begins after September 15, 2006.

**Statement of Financial Accounting Standard 157, Fair Value Measurements ("SFAS 157")**

In September 2006, the Financial Accounting Standard Board issued a standard that provides enhanced guidance for using fair value to measure assets and liabilities. The standard applies whenever other standards require (or permit) assets or liabilities to be measured at fair value. The standard does not expand the use of fair value in any new

circumstances.

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2006 AND 2005**

This Statement is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. Earlier application is encouraged, provided that the reporting entity has not yet issued financial statements for that fiscal year, including financial statements for an interim period within that fiscal year.

**Financial Accounting Standards Board (FASB) No. 48, Accounting for Uncertainty in Income Taxes (“FIN 48”)**

In June 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109 (FIN 48), which provides clarification related to the process associated with accounting for uncertain tax positions recognized in consolidated financial statements. 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. We are required to adopt FIN 48 on January 1, 2007, although early adoption is permitted. We are currently evaluating the impact of adopting FIN 48 on our consolidated financial statements.

**FSP FAS 123(R)-5, Amendment of FASB Staff Position FAS 123(R)-1**

FSP FAS 123(R)-5 was issued in October 2006. The FSP provides that instruments that were originally issued as employee compensation and then modified, and that modification is made to the terms of the instrument solely to reflect an equity restructuring that occurs when the holders are no longer employees, no change in the recognition or the measurement (due to a change in classification) of those instruments will result if both of the following conditions are met: (a). There is no increase in fair value of the award (or the ratio of intrinsic value to the exercise price of the award is preserved, that is, the holder is made whole), or the antidilution provision is not added to the terms of the award in contemplation of an equity restructuring; and (b). All holders of the same class of equity instruments (for example, stock options) are treated in the same manner. The provisions in this FSP shall be applied in the first reporting period beginning after the date the FSP is posted to the FASB website. We will adopt this FSP from its effective date. We currently do not believe that its adoption will have any impact on our financial statements.

***(m) Preferred Stock:***

The Company’s Series A and Series B Preferred Stock both contained provisions whereby, under certain conditions outside of the control of management, the holders could have required redemption; accordingly, they were initially classified outside of permanent equity. At December 31, 2005, such conditions no longer applied; accordingly, the Series A and Series B Preferred were reclassified to permanent equity at December 31, 2005.

The Company’s Series C Preferred Stock contains provisions whereby, under certain conditions outside of the control of management, the holders could require redemption; accordingly, it is currently classified outside of permanent equity.

***(n) Earnings Per Share***

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

	<b><u>For the years ended</u></b>	
	<b><u>December</u></b>	<b><u>December</u></b>
	<b><u>31, 2006</u></b>	<b><u>31, 2005</u></b>
<b>Basic</b>	<b>10,293,168</b>	<b>7,705,782</b>

<b>Diluted</b>	<b>10,293,168</b>	7,705,782
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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2006 AND 2005**

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, 2006 and 2005 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:

	<b><u>For the years ended</u></b>	
	<b><u>December</u></b>	<b><u>December</u></b>
	<b><u>31, 2006</u></b>	<b><u>31, 2005</u></b>
<b>Stock</b>		
<b>Options</b>	<b>1,674,375</b>	1,430,375
<b>Warrants</b>	<b>26,162,704</b>	21,327,972
<b>Preferred</b>		
<b>Stock</b>	<b>27,147,535</b>	16,311,602

**NOTE 3 — Geographic Information:**

SFAS 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 SFAS 131, management believes that it operates in a single business segment. Net sales by geographic area are as follows:

	<b><u>For the years ended</u></b>	
	<b><u>December</u></b>	<b><u>December 31,</u></b>
	<b><u>31, 2006</u></b>	<b><u>2005</u></b>
Africa	<b>\$ 1,552,043</b>	\$ 802,925
Asia	<b>245,838</b>	124,467
Australia	<b>4,405</b>	10,585
Europe	<b>92,248</b>	125,135
Middle East	<b>194,767</b>	55,652
North America	<b>1,384,933</b>	503,456
South America	<b>2,819,778</b>	1,737,312
	<b>\$ 6,294,012</b>	\$ 3,359,532

**NOTE 4 — Accounts payable and accrued liabilities:**

Accounts payable and accrued liabilities as of December 31:

	<b>2006</b>	<b>2005</b>
	<b>\$ 679,990</b>	\$ 550,247

Accounts payable - suppliers		
Accrued commissions	<b>91,920</b>	171,587
Accrued royalties	<b>461,048</b>	381,510
Accrued payroll and other taxes	<b>87,637</b>	63,146
Accrued vacation	<b>214,858</b>	145,566
Accrued legal and accounting	<b>7,000</b>	50,024
Accrued expenses - other	<b>167,486</b>	115,845
<b>TOTAL</b>	<b>\$ 1,709,939</b>	<b>\$ 1,477,925</b>

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2006 AND 2005**

**NOTE                    5                    —                    EMPLOYEE STOCK OPTION PLAN:**

As part of the merger, the Company adopted the 1999 Stock Option Plan (the "Plan") of CDS covering 1,500,000 shares of Common Stock. Under the terms of the Plan, 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 Plan was amended at the Company's 2005 stockholders' meeting. The number of options under the Plan 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 Plan concerning non-qualified options.

Effective January 1, 2006, the Company's Plan is 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)"), which replaces FAS No. 123, Accounting for Stock-Based Compensation, and supersedes Accounting Principles Board Opinion ("APB") No. 25, Accounting for Stock Issued to Employees, and related interpretations. 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 SFAS No. 123(R) and certain SEC rules and regulations and provides interpretations with respect to the valuation of share-based payments for public companies.

Prior to January 1, 2006, the Company accounted for similar transactions in accordance with APB No. 25 which employed the intrinsic value method of measuring compensation cost. Accordingly, compensation expense was not recognized for fixed stock options if the exercise price of the option equaled or exceeded the fair value of the underlying stock at the grant date.

While FAS No. 123 encouraged recognition of the fair value of all stock-based awards on the date of grant as expense over the vesting period, companies were permitted to continue to apply the intrinsic value-based method of accounting prescribed by APB No. 25 and disclose certain pro-forma amounts as if the fair value approach of SFAS No. 123 had been applied. In December 2002, FAS No. 148, Accounting for Stock-Based Compensation-Transition and Disclosure, an amendment of SFAS No. 123, was issued, which, in addition to providing alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based employee compensation, required more prominent pro-forma disclosures in both the annual and interim financial statements. The Company complied with these disclosure requirements for all applicable periods prior to January 1, 2006.

In adopting FAS 123(R), the Company applied the modified prospective approach to transition. Under the modified prospective approach, the provisions of FAS 123(R) are to be applied to new awards and to awards modified, repurchased, or cancelled after the required effective date. Additionally, compensation cost for the portion of awards for which the requisite service has not been rendered that are outstanding as of the required effective date shall be recognized as the requisite service is rendered on or after the required effective date. The compensation cost for that portion of awards shall be based on the grant-date fair value of those awards as calculated for either recognition or pro-forma disclosures under FAS 123.

As a result of the adoption of FAS 123(R), the Company's results for the year ended December 31, 2006 include share-based compensation expense totaling approximately \$279,000. Such amounts have been included in the Consolidated Statements of Operations within cost of goods sold (\$28,000), research and development (\$68,000) and



selling, general and administrative expenses (\$183,000). No income tax benefit has been recognized in the income statement for share-based compensation arrangements due to the history of operating losses.

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
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Stock option compensation expense in the year ended December 31, 2006 represents 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, 2006 and 2005 was \$.53 and \$.50, respectively. The fair value of options at the date of grant was estimated using the Black-Scholes option pricing model. During 2006, the Company took into consideration guidance under SFAS 123(R) and SAB 107 when reviewing and updating assumptions. 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:

	Years Ended	
	December 31, 2006	December 31, 2005
Expected term (in years)	4 to 5	5
	116.20%	
Expected volatility	to 118.16%	95.56% to 114.94%
Expected dividend yield	0%	0%
Risk-free interest rate	4.39% to 4.92%	3.72% to 4.36%

The following table addresses the additional disclosure requirements of 123(R) in the period of adoption. The table illustrates the effect on net income and earnings per share as if the fair value recognition provisions of FAS No. 123 had been applied to all outstanding and unvested awards in the prior year comparable period.

	<b>For the year ended December 31, 2005</b>
Net loss attributable to common stockholders, as reported	\$ (6,769,022)
Add: Stock-based compensation included in reported net loss	-
Deduct: Total stock based compensation expense determined under the fair value based method	(180,195)

for all awards (no tax effect)	
Pro forma net loss attributable to common stockholders	\$ (6,949,217)
Net loss per share:	
Basic and diluted loss per share - as reported	\$ (0.88)
Basic and diluted loss per share - pro forma	\$ (0.90)

The Company granted 831,250 new options under the Plan during the year ended December 31, 2006 at an exercise price of \$0.75 per share. The Company granted 316,000 new options under the Plan during year ended December 31, 2006 at exercise prices ranging from \$0.55 per share to \$0.62 per share.

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
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The following table provides stock options activity for the years ended December 31, 2005 and 2006:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2005	1,105,000	\$ 1.55		
Granted	481,500	\$ 0.74		
Cancelled	(300,750)	\$ 1.75		
<b>Outstanding at December 31, 2005</b>	<b>1,285,750</b>	<b>\$ 1.20</b>	<b>4.49 years</b>	<b>-</b>
Granted	1,147,250	\$ 0.71		
Cancelled	(795,250)	\$ 1.56		
Exercised	(100,000)	\$ 0.60		
Forfeited/expired	(8,000)	\$ 0.75		
<b>Outstanding at December 31, 2006</b>	<b>1,529,750</b>	<b>\$ 0.70</b>	<b>3.60 years</b>	<b>204,866</b>
<b>Exercisable at December 31, 2006</b>	<b>1,099,250</b>	<b>\$ 0.64</b>	<b>3.44 years</b>	<b>150,956</b>

As of December 31, 2006, there was \$18,859 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 0.15 years. The total fair value of shares vested during the years ended December 31, 2006 and 2005, was \$420,881 and \$78,933, respectively.

On April 17, 2006 the Compensation Committee of the Company's Board of Directors approved the cancellation of all employee options where the exercise price was greater than \$.75 per share (an aggregate of 795,250 options) and issued new options at an exercise price of \$.75 per share with the same vesting schedule and expiration dates (except for 122,500 new options that were issued with a vesting date of January 1, 2007 which is later than the vesting date of the options they replaced). The expense related to this modification in the second quarter of 2006 was \$58,000.

**NOTE****6****—****RELATED PARTIES:**

The Company's former president, also a former director, received in March 2005, as compensation for his service on the Board of Directors, a reduction from \$.90 per share to \$.75 per share in the exercise price of a warrant to acquire 425,000 shares of Common Stock. The Company is accounting for these warrants as variable from the date of the modification to the date the award is exercised, forfeited, or expires unexercised. At December 31, 2006 the stock price was higher than the revised exercise price; therefore there was an adjustment to compensation as required of \$34,000. Such warrants remain unexercised as of December 31, 2006.

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
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The Company has a liability to its President on December 31, 2006 for \$65,000 of accrued interest on prior debt that is not accruing additional interest. The accrued interest is being repaid according to the terms related to the Series B offering, \$91,822 was repaid in 2006. In addition, the Company had a liability to its President for funds advanced by him to it or paid directly by him to vendors on its behalf of \$182,000 (non-interest bearing and payable on demand) which was repaid in October of 2006.

**NOTE**                                **7**                                **—**                                **INVENTORIES:**

Inventories consist of at December 31:

	<b>2006</b>	2005
Raw Materials	<b>\$ 629,967</b>	\$ 425,758
Work in Process	<b>257,208</b>	86,001
Finished Goods	<b>221,775</b>	176,224
	<b>\$ 1,108,950</b>	\$ 687,983

**NOTE**                                **8**                                **—**                                **FIXED ASSETS:**

Fixed assets consist of at December 31:

	<b>2006</b>	2005
Machinery and equipment	<b>\$ 604,668</b>	\$ 604,243
Furniture and fixtures	<b>139,624</b>	126,277
Computer and telephone equipment	<b>259,078</b>	94,283
Leasehold improvements	<b>226,415</b>	131,157
Tooling	<b>41,900</b>	41,900
	<b>1,271,685</b>	997,860
Less accumulated depreciation and amortization	<b>(668,082)</b>	(559,228)
	<b>\$ 603,603</b>	\$ 438,632

Included in the above fixed assets is \$52,631, net of accumulated depreciation of \$105,610, of assets held under capital leases as of December 31, 2006. Depreciation for the 2006 and 2005 years aggregated \$209,541 and \$98,508, respectively.

**NOTE**                                **9**                                **—**                                **LONG-TERM DEBT:**

In connection with the Series B offering interest payable on certain debt was agreed to be paid over 33 months in installments of \$10,000 per month and a final payment of \$3,160 in the 34<sup>th</sup> month. These payments are subordinate to the redemption rights of the Series B preferred stockholders. No additional interest accrues on this payable. The accrued interest repaid was \$127,652 and \$112,348 in the year ended 2006 and 2005, respectively. The balance remaining unpaid was \$93,160 and \$220,812 as of December 31, 2006 and 2005, respectively.

On June 29, 2006, the Company borrowed \$1,300,000 from a group of four institutional investors as a bridge financing arrangement. The loan was repaid in part on September 29, 2006 and the balance converted on October 5, 2006 into Series C Preferred Stock. The loan was secured by a lien on the assets of the Company.

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
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**DECEMBER 31, 2006 AND 2005**

**NOTE 10 — OBLIGATIONS UNDER CAPITAL LEASES:**

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

Future minimum lease payments under these capitalized lease obligations, including interest as of December 31, 2006 were as follows:

Year ending December 31,

2007	\$ 40,113
2008	7,260
	47,373
Less: imputed interest	(2,956)
Present value of future minimum lease payments	44,417
Less: current maturities	(37,336)
	<u>\$ 7,081</u>

These leases have interest rates ranging from 8% - 15%.

**NOTE 11 — RESEARCH GRANTS AND DEVELOPMENT CONTRACTS:**

In 2006 and 2005, the Company received research grants and development contracts in the amounts of \$208,468 and \$331,198, respectively. The decrease in grant and development income was due to grants received in 2005 that weren't continued or awarded in 2006.

**NOTE 12 — INCOME TAXES:**

No provision for Federal income taxes was required for the years ended December 31, 2006 or 2005, due to the Company's operating losses. At December 31, 2006 and 2005, the Company has unused net operating loss carry-forwards of approximately \$16,900,000 and \$12,000,000, respectively which expire at various dates through 2026. 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 \$350,000 and \$294,000 for the years ended December 31, 2006 and 2005, respectively which expire at various dates through 2026.

As of December 31, 2006 and 2005, 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:

<b>December 31,</b>	
<b>2006</b>	December 31, 2005



Net operating loss				
carry-forwards	\$	6,800,000	\$	5,800,000
Research and development				
credit		350,000		288,000
Other		33,000		40,000
Gross deferred tax assets		7,183,000		6,128,000
Valuation allowances		(7,183,000)		(6,128,000)
Net deferred tax assets	\$	—	\$	—

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
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**NOTE 13—STOCKHOLDERS' EQUITY:**

**(a) Common Stock**

During the year ended December 31, 2006 the Company issued 163,750 shares, respectively of its' Common Stock to a consultant as compensation. The number of shares issued was a fixed number set forth in the consultant's contract, with specific issue dates and without regard to the market price of the stock on the date of issuance. For accounting purposes, the shares were valued based on the closing market price on dates of issuance from \$0.55 to \$0.91 per share and the related compensation expense for the year ended December 31, 2006 was \$129,029.

In July 2006, the Company issued to a member of the Board of Directors 15,000 shares of common stock as additional compensation for services as the audit committee chair. This stock was valued based on the market closing price on the date of the grant and \$10,650 was charged to expense.

During the year ended December 31, 2006 Series A Preferred shareholders converted 8.75980 shares into 437,989 shares of Common Stock and Series B Preferred shareholders converted 12.05966 shares into 988,494 shares of Common Stock.

During the year ended December 31, 2006 the Company issued 140,691 shares of its Common Stock upon the exercise of warrants and received cash of \$86,321.

During the year ended December 31, 2006 the Company issued 100,000 shares of its Common Stock upon the exercise of options and received cash of \$60,000.

In the year ended December 31, 2006 the Company issued 543,168 shares of its Common Stock as payment of dividends on its Series A Preferred Stock and 416,440 shares of its Common Stock as payment of dividends on its Series B Preferred Stock, These shares were valued using a 10 day volume weighted average price for the ten trading days immediately preceding the issue date.

During 2005 the Company issued 95,000 shares of its Common Stock to consultants as compensation. The shares were valued from \$0.43 to \$0.75 per share and were expensed over the lives of the related contracts.

In 2005 Series A Preferred shareholders converted 3.02476 shares into 151,237 shares of Common Stock. Series B Preferred shareholders converted 8.20228 shares into 672,417 shares of Common Stock and warrants were exercised to purchase 35,000 shares of Common Stock at an exercise price of \$0.72 per share.

On May 14, 2005 and November 15, 2005 the Company issued 312,773 and 317,859 shares, respectively, of its Common Stock as payment of dividends on its series A preferred stock.

**(b) Warrants**

The warrants to purchase 1,713,114 shares of Common Stock issued in connection with the March 2006 Series B offering were assigned a value of \$481,470. These warrants have an exercise price of \$0.61 per share and a five year life.

Warrants to purchase 520,000 shares of Common Stock were issued in connection with the bridge loan and were assigned a value of \$328,341. These warrants have an exercise price of \$0.75 per share and a five year life.

Warrants to purchase 2,578,125 shares of Common Stock were issued in connection with the completed Series C Offering and were assigned a value of \$1,398,715. These warrants have an exercise price of \$1.00 per share and a five year life.

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
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During the year ended December 31, 2006, the Company issued warrants to purchase 241,684 shares of Common Stock at exercise prices from \$0.55 to \$0.883 per share to a sales agent as payment for commissions (value \$61,700) and commissions accrued at year end 2005 (value \$24,000) and to consultants as compensation for 2006 (\$51,324). These warrants have a five year life.

All of the above warrants were valued using a Black-Scholes option pricing model based on assumptions for expected volatilities from 116.2% to 118.16%, expected lives of 5 years and expected risk free interest rates from 4.39% to 5.13%.

The warrants to purchase 8,280,550 shares of Common Stock issued in connection with the Series B offering were assigned a value of \$2,349,893.

Warrants were issued in January 2005 to placement agents in connection with the Series B Preferred Stock financing to purchase a total of 737,712 shares of Common Stock at an exercise price of \$0.80. The fair values of these warrants are \$364,268. The effect of this transaction was reflected in Additional Paid in Capital.

In March 2005, the Company re-priced certain warrants - see note 6.

During 2005, the Company issued warrants to purchase 133,656 shares of Common Stock at exercise prices from \$0.55 to \$0.70 per share to a distributor as payment for commissions. The value of these warrants was expensed.

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

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

**Dividends:** Holders of series A preferred stock are entitled to an 8% per annum dividend per share. The dividend accrues and is payable semi-annually either in cash, in shares of series A preferred stock or in shares of common stock. In June 2006, the Series A Preferred Stock was amended to provide, among other amendments that dividends in Preferred or Common Stock would be based on a 10 day volume weighted average market price at the time of the dividend. Accrued but unpaid dividends are also payable upon the conversion or redemption of the shares of series A preferred stock and upon our liquidation, dissolution or winding up.

In the event the Company elects to pay any dividend in shares of common stock or in shares of series A preferred stock, so long as Vicis Capital Master Fund owns any shares of series A preferred stock, Vicis Capital Master Fund will receive such dividend in cash unless it otherwise notifies the Company no later than five (5) trading days prior to the date of the applicable dividend payment. Such payment to Vicis Capital Master Fund will not affect the Company's election to make the applicable dividend payment in stock so long as the only holder receiving the dividend payment in cash is Vicis Capital Master Fund. To date all dividends have been paid in Common Shares, except \$60,000 which was paid in cash to Vicis Capital Master Fund.

**Conversion:** Series A preferred stock is convertible, at the option of the holders, into shares of Common Stock at a conversion price of \$0.60 per share. Based on its original purchase price of \$30,000 per share, each share of Series A

Preferred Stock is convertible into 50,000 shares of Common Stock.

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
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Redemption: The holders have the right, under certain conditions, to require redemption of all or a portion of such holder's shares of Series A Preferred Stock. As of December 31, 2006 and 2005 such conditions no longer applied; accordingly, no accretion is being made to bring the value up to its redemption value. The liquidation preference is \$30,000 per share plus accrued and unpaid dividends, presently \$400 per share, an aggregate for all such shares of \$4,557,604. As of December 31, 2005, the unpaid dividends were \$394 per share, an aggregate for all such shares of \$4,822,957. Accrued but unpaid dividends of \$55,971 and \$62,528 are included in the preferred stock carrying value as at December 31, 2006 and 2005, respectively.

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

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. Some key features of the Series B Preferred Stock are as follows:

Dividends: The 9% Series B Preferred Stock accrues dividends at 9% per annum, payable semi-annually. Dividends are payable in Series B Preferred Stock, Common Stock or in cash. In June 2006, the Series B Preferred Stock was amended to provide, among other amendments that the dividend could be paid in Common Stock (in addition to Preferred Stock or cash) and that dividends in Preferred or Common Stock would be based on a 10 day volume weighted average market price at the time of the dividend. The majority investor in the Series B financing has the option as it pertains to its dividend payment to choose cash or Preferred or Common shares. The Company has the option to choose cash or Preferred or Common shares as to the balance of the dividends. To date all dividends have been paid in Preferred or Common Shares, except \$140,226 which was paid in cash at the option of the majority investor.

In the event any dividend is issued, any holder of the majority of the outstanding series B preferred stock at the dividend payment date, may elect whether to receive dividends on series B preferred stock in cash, in common stock or in shares of series B preferred stock in its sole discretion.

Conversion: The Series B Preferred Stock is convertible, at the option of the holders, into shares of Common Stock at a conversion price of \$.61 per share. Based on the original purchase price of \$50,000 per share, each share of Series B Stock is convertible into 81,967 shares of Common Stock.

Redemption: The holders have the right, under certain conditions, to require redemption of all or a portion of such holder's shares of Series B Preferred Stock. As of December 31, 2006 and 2005 such conditions no longer applied; accordingly, no accretion is being made to bring the value up to its redemption value. The liquidation preference is \$50,000 per share plus accrued and unpaid dividends, presently \$2,300 per share, an aggregate for all such shares of \$5,958,848. As of December 31, 2005, the unpaid dividends were \$2,270 per share, an aggregate for all such shares of \$5,341,896. Accrued but unpaid dividends of \$262,053 and \$232,016 are included in the preferred stock carrying value as at December 31, 2006 and 2005, respectively. The 2006 accrued but unpaid dividend was paid on January 2,

2007 by the issuance of 345,579 shares of Common Stock.

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
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As per EITF 00-27 "Application of Issue 98-5 to Certain Convertible Instruments", the Company evaluated the Series B Preferred Stock transaction that occurred in January 2005 and found that there was an associated beneficial conversion feature totaling \$2,437,035; the preferred stock was further discounted by this amount. The beneficial conversion amount was then accreted back to the preferred stock in accordance with the conversion provision which allowed for 100% to be converted immediately. The Company also evaluated the Series B Preferred Stock transaction that occurred on March 30, 2006, see above, and found that there was an associated beneficial conversion feature totaling \$463,434; the preferred stock was further discounted by this amount. The beneficial conversion amount was then accreted back to the preferred stock in accordance with the conversion provision which allowed for 100% to be converted immediately.

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

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. See note 13(b) for information on the warrants. A summary of the significant terms as amended on October 5, 2006 are as follows:

**Dividends.** Holders of series C preferred stock are entitled to a 7% per annum dividend per share. The dividend accrues and is payable semi-annually in cash or in shares of common stock, at our option. Accrued but unpaid dividends are also payable upon the conversion or redemption of the shares of series C preferred stock and upon a liquidation event.

**Conversion.** The series C preferred stock is convertible, at the option of the holders, into shares of our common stock at a conversion price of \$.80 per share. Based on the original purchase price of \$50,000 per share, each share of series C preferred stock is convertible into 62,500 shares of our common stock.

**Redemption:** The holders have the right, under certain conditions, to require redemption of all or a portion of such holder's shares of Series C Preferred Stock. The redemption value is the greater of (i) 130% of the stated value or \$65,000 and (ii) the product of (a) daily volume weighted average price of the Company's common stock and (b) a quotient of \$65,000 divided by the then existing conversion price, plus accrued and unpaid dividends and all liquidated damages.

**Liquidation preference:** The liquidation preference is \$50,000 per share plus accrued and unpaid dividends and all liquidated damages. The liquidation preference is \$50,000 per share plus accrued and unpaid dividends, presently \$894.44 per share, an aggregate for all such shares of \$8,397,583. Accrued but unpaid dividends of \$147,583 are included in the preferred stock carrying value as at December 31, 2006.

The Company has accounted for the Series C Offering pursuant to the provisions of Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities" and EITF 00-19: "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock" ("EITF 00-19"). The Company has allocated the value received between the preferred stock and the related warrants. The allocated value for the preferred stock and the related warrants were \$6,851,285 and \$1,398,715, respectively. Further, the Company has determined that the redemption feature in the Series C Preferred Stock needs to be bifurcated and has valued the same at \$449,677. The warrant value and the value of the redemption feature is treated as a discount and the preferred stock is reflected net of this discount. Due to the contingent redemption feature, the Series C Preferred Stock is reflected as temporary equity. The Series C Preferred Stock is not currently redeemable and there is no likelihood that it will become redeemable; accordingly, no accretion is being made to bring the



carrying value up to its redemption value. The liability for the value of the redemption feature will be “marked to market” in future accounting periods until such time as the redemption is exercised or the feature meets the criteria for equity classification. See footnote 13(b) for the valuation of warrants.

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
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In addition, as per EITF 00-27 "Application of Issue 98-5 to Certain Convertible Instruments", the Company evaluated the Series C Preferred Stock transaction that occurred in September 2006 and found that there were associated beneficial conversion features totaling \$1,723,715; the preferred stock was further discounted by this amount. The beneficial conversion amount related to the valuation of the preferred stock was then accreted back to the preferred stock in accordance with the conversion provision which allowed for 100% to be converted immediately. The accretion was reflected as dividend expense.

**NOTE 14 — COMMITMENTS AND CONTINGENCIES:**

***Employment Contracts:***

The Company has contracts with two key employees. The contracts call for salaries presently aggregating \$400,000 per year. One contract expires in May of 2007 and one contract expires in May of 2008.

***Pension Plan:***

The Company has a 401(k) plan established for its employees. The Company has the option to make matching contributions to the plan. The Company has not elected to make any matching contributions for the years ended December 31, 2006 and 2005 and accordingly no expense has been recorded.

***Obligations Under Operating Leases:***

The Company leases office and manufacturing facilities. The current lease expires on April 30, 2007. The following is a schedule of future minimum rental commitments:

Year ending December 31,

2007	47,823
	\$47,823

The Company has an option to renew the lease for an additional two year term. The Company intends to exercise this option and therefore the additional minimal commitments would be \$68,641 for 2007 (total \$116,464 with above), \$104,677 for 2008 and \$35,178 for 2009.

Rent expense aggregated \$100,500 and \$97,000 for the years ended December 31, 2006 and 2005, respectively.

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
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***Economic Dependency:***

The Company had sales to four customers each in excess of 10% of total sales in the year ended December 31, 2006. Sales to these customers aggregated approximately \$1,530,000, \$1,223,000, \$1,092,000 and \$814,000, respectively. This represents approximately 74% of total sales.

The Company had sales to three customers each in excess of 10% of total sales in the year ended December 31, 2005. Sales to these customers aggregated approximately \$1,125,000, \$474,000 and \$412,000, respectively. This represents approximately 60% of total sales.

The Company had purchases from one vendor in excess of 10% of total purchases for the year ended December 31, 2006. Purchases from this vendor aggregated approximately \$244,000.

The Company had no purchases from any vendor in excess of 10% of total purchases for the year ended December 31, 2005.

***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.

**NOTE**

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**LITIGATION:**

On September 29, 2006, the Company and StatSure Diagnostic Systems, Inc. ("StatSure") entered into a Settlement Agreement pursuant to which all matters in their litigation regarding StatSure's barrel patent and other matters were settled. In addition the parties entered into the Joint HIV Barrel Product Commercialization Agreement, which provides that the parties will equally share in the profits relating to all HIV Barrel Products after reimbursement to the Company of its manufacturing and related costs, as defined, and that they will act jointly in the HIV barrel field. The settlement combines each company's HIV barrel intellectual property, including an exclusive manufacturing license from StatSure to the Company of its barrel patent for all HIV applications, thereby ensuring the Company's exclusive right to manufacture.