

CHEMBIO DIAGNOSTICS, INC.  
Form 10KSB  
March 30, 2006

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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, 2005

**[ ] 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 (State or jurisdiction of incorporation or organization)	88-0425691 (I.R.S. Employer Identification No.)
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3661 Horseblock Road, Medford, NY (Address of principal executive offices)	11763  (Zip Code)
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Registrant's telephone number, including area code (631) 924-1135

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

Title of each class	Name of each exchange on which registered
None	None

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

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\$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 X

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the 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 X No \_\_\_

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B (Sec. 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. [ X ]

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

State issuer's revenues for its most recent fiscal year: \$3,940,730.

As of March 22, 2006, the registrant had 9,178,764 common shares outstanding, and the aggregate market value of the common shares held by non-affiliates (\*) was approximately \$4,235,651. This calculation is based upon the closing sale price of \$0.58 per share on March 22, 2006.

\* Without asserting that any of the issuer's directors or executive officers, or the entities that own 1,875,918 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) and its subsidiaries, develop, manufacture, and market lateral flow rapid diagnostic tests that detect infectious diseases. These tests are sold in the U.S. and/or internationally to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments. The products are made under the label of Chembio Diagnostic Systems, Inc. (CDS) or the private labels of its distributors or their customers. The products are used in the diagnosis of infectious diseases and other conditions in humans and animals. The Company's main products presently commercially available are its three HIV Rapid Tests (SURE CHECK(R) HIV and HIV 1/2 STAT-PAK(TM) and HIV 1/2 STAT-PAK Dipstick) and its rapid test for Chagas Disease. The Company sold in 2004 substantially all of the remaining business related to its private label pregnancy test and is focusing on the products mentioned above.

#### HIV Rapid Tests

We continue to believe our revenue growth in 2006 will come primarily from 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 which can take at least several days to process. The increased availability, greater efficacy, and reduced costs for anti-retroviral treatments (ARVs) for HIV is also having a tremendous impact on the demand for being tested, as the stigma associated with the disease is lessened and the ability to resume normal activities is substantially improved.

Our SURE CHECK HIV rapid test eliminates the need for a separate sample collection system when used to collect finger-stick whole blood samples. We believe this improves ease of use and safety. Our HIV 1/2 STAT-PAK and HIV 1/2 STAT-PAK Dipstick, like all competitive rapid HIV tests, require that the finger-stick whole blood sample first be transferred to the test device. HIV 1/2 STAT-PAK is value priced and more flexible than SURE CHECK for samples of venous whole blood, plasma and serum as well as finger-stick whole blood. HIV 1/2 STAT-PAK Dipstick is our most economical format and also flexible as to the aforementioned sample types. This product was designed in order to provide a low cost product with performance equal to our other products for resource-constrained markets in the developing world. All three of our HIV tests use a standardized test strip which we developed by using patented materials licensed non-exclusively to us from third parties as well as our own proprietary know-how and trade secrets. All three of our rapid HIV tests are qualitative yes/no tests for the detection of antibodies to HIV 1 & 2.

#### Regulatory Status:

The Company has made substantial progress toward FDA approval of its SURE CHECK HIV and HIV 1/2 STAT-PAK products. A pre-approval inspection of its facility was conducted in the third quarter of 2005 and based upon communications with the agency the Company believes it has met the requirements of an "approvable" Pre-Marketing Approval (PMA) application, and expects to be so advised by the FDA during the first half of the second quarter of 2006; the Company further expects to complete the full process during the first half of 2006, which would include receipt from the FDA of a waiver under the Clinical Laboratory Improvement Act ("CLIA"). A CLIA waiver is essential in order to market the product into public health clinics and physicians offices where the level of training is less than clinical laboratories and hospitals. The Company is nearing completion of the CLIA waiver studies so it will be in a position to submit its waiver application immediately upon receipt of the PMA license from the FDA.

The Company's HIV products currently qualify under U.S. FDA export regulations to sell, subject to any required approval by the importing country, to customers outside the U.S. To date we have received approval from a number of potential importing countries, although Brazil and Uganda are the only countries in which we have significant sales. Our HIV 1/2 STAT-PAK and HIV 1/2 STAT-PAK Dipstick products were also evaluated by the World Health Organization in 2004 and as a result in 2005 they were qualified for inclusion in the WHO Bulk Procurement Scheme, which is a pre-requisite for these products being eligible for procurements from programs funded by the United Nations and their partners' programs. SURE CHECK HIV and HIV 1/2 STAT-PAK are also eligible for procurements pursuant to the President's Emergency Plan for AIDS Relief ("PEPFAR") as a result of a "waiver" status granted these products by the United States Agency for International Development.

**Partners Involved in the Product:**

In 2004 we entered into a thirteen-year supply and technology transfer agreement with FIOCRUZ-Bio-Manguinhos, an affiliate of the Ministry of Health of Brazil relating to our HIV 1/2 STAT-PAK product. FIOCRUZ-Bio-Manguinhos will supply this product, which will eventually be produced 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, 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. At the same time, we are identifying and appointing distributors in these regions, and are engaged with the multitude of stakeholders that are responsible for the delivery of rapid testing and related services in the markets. Our focus is on those African countries that are receiving funding from PEPFAR and other large relief programs.

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

For the US market, we are in discussions with potential marketing partners and direct customers in the United States as we near US FDA approval.

**CHAGAS RAPID TEST**

Chembio has 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. Chagas Disease is endemic only in regions of Latin America yet there are an estimated 16-18 million Chagas Disease cases resulting in approximately 20,000 deaths annually, with an estimated 300,000 new cases each year. It is transmitted by a parasitic bug which lives in cracks and crevices of poor-quality houses usually in rural areas, through blood transfusion or congenitally from infected mother to fetus. There is an effective therapy available to treat the early chronic phase, but it only eliminates the infection if administered to children that are diagnosed with it. Chagas STAT-PAK is the only rapid test for Chagas disease to have performed well in multi-center studies in endemic regions of Latin America.

The Company received, in January of 2006, an order for \$1.2 million to supply its Chagas Disease rapid test to be delivered in the first half of 2006. This procurement is being made by the Pan American Health Organization, headquartered in Washington D.C., which is affiliated with the World Health Organization. The procurement will be used to implement a nationwide Chagas screening program for all children under the age of 10 in endemic regions of Bolivia. The Company is actively looking at developing additional business opportunities for this product in Bolivia, and other markets in Latin America that are impacted by this disease.

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 test. 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 during 2004 and 2005. The extent to which we will derive a benefit from sales of these products is difficult to estimate because of uncertainties in regulatory changes, product pricing, manufacturing cost changes, and patent litigation.

As described below, we also have other commercially available products, such as rapid tests for Lyme disease and other products, the aggregate of whose revenues are currently not material to us. We also are involved, as described

below under “Research and Development,” in the development of new products.



## **Lateral Flow Technology**

All our current products employ lateral flow technology, which 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 the strip downstream from the point of application. 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 allows the development of 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 microliters of whole blood easily obtained with a finger prick, or alternatively, serum or plasma), stable (24 months at room temperature storage in the case of our HIV tests), and highly reproducible.

We can 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 below] in our diagnostic tests using our proprietary latex conjugate 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 HIV rapid test which we believe is easier to use than other finger-stick whole blood rapid tests. SURE CHECK 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. *Please refer to the section entitled “Legal Proceedings” for a discussion of the legal issues we face with regard to SURE CHECK.*

During 2005 we developed a patent-pending lateral flow platform, which we believe provides several advantages for next generation product development (See “*Intellectual Property*”).

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.

## **Target Market**

### **HIV Rapid Tests**

We believe that the prevention and treatment goals that have been established by large programs financed to thwart the spread of HIV will drive the growth and demand for rapid HIV tests geometrically in the coming years. Chembio is one of only two US-based manufacturers of rapid HIV tests and the only one with products that it believes can meet the various demands of the global market.

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 (also a confirmatory rapid test will be needed in the case of a positive result) over the next three years in order to insure that treatment targets are achieved<sup>1</sup>. This is not just because of the

continuing growth in the epidemic, but more importantly, because anti-retroviral treatments are available, affordable and are being funded, so that people actually have a reason to be tested.

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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

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 UNAIDS “3 by 5” initiative<sup>2</sup>, The Global Fund<sup>3</sup>, and the U.S. Presidential Emergency Plan for AIDS Relief<sup>4</sup>, which will provide treatment to five million people, and in order to identify these five 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. As of the end of 2004 (which is the latest data the Company has available to it), there were an estimated 40 million people infected with HIV/AIDS worldwide, of which an estimated 6 million were in need of antiretroviral therapy. The number of people in need of treatment will continue to grow as infection rates increase significantly worldwide, and there is little expectation for an effective vaccine anytime soon. As such, 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<sup>5</sup>.

FDA approval for two of our rapid HIV tests is anticipated in the first half of 2006, and this will enable us to participate in the U.S. market as well, which is estimated to become at least a \$50 million market during the next few years<sup>6</sup>. The U.S. market opportunity has been developing first in the public health and hospital emergency room segments, and as a result of increased advocacy for routine testing, will likely increase and expand use of this technology into the physician’s office, prisons, and other venues. In his State of the Union Address this year, President Bush called on Congress to reform and reauthorize the Ryan White CARE Act, which among other things provides counseling and testing for those in greatest need of HIV/AIDS assistance. The President has also proposed to direct a total of more than \$90 million to the purchase and distribution of rapid HIV test kits, facilitating the testing of more than 3 million additional Americans. Test kits would be distributed in areas of the country with the highest rates of newly discovered HIV cases and the highest suspected rates of undetected cases. We are also in preliminary discussions with a US marketing partner to serve these markets.

Finally, based upon recent pronouncements, we believe that the over the counter market is also likely to open up in the U.S., which would expand the U.S. market very significantly. We are already developing OTC opportunities outside the US, and we will consider adding an oral fluid feature to our product lines as such a feature may offer greater convenience provided there is equal performance when using oral fluid samples.

**Chagas Rapid Test.** Chembio had developed this test several years ago but the market for the product was not meaningful as most prevention efforts, which were minimal, were made using laboratory tests used for blood bank screening of blood. However, there has now been a greater interest in Chembio’s 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%, shows that the test is a good alternative to standard laboratory testing methods.

#### **Other Products Under Development.**

Chembio is 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. Chembio’s TB products will leverage several years of basic NIH-funded research by Chembio’s scientists in TB and, if successfully completed, will result in products applicable to both human and veterinary TB, while also leveraging a marketing and distribution capability which the Company has been developing for its HIV products.

Tuberculosis is also a problem in a number of animal species either because of potential transmission to humans, costs to agricultural production or because of the impact on the cost of the animals 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. Under rules established by the Animal and Plant Health Inspection Service, a state can lose the right to move cattle across state lines if TB is detected in two or more herds as has recently happened in Texas and Michigan. TB control of meat at slaughterhouses is dependent upon visual inspection. The Company believes that a rapid test could complement or supplant these visual inspections.

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<sup>2</sup> [www.unaids.org/en/treat3millionby2005initiative.asp](http://www.unaids.org/en/treat3millionby2005initiative.asp)

<sup>3</sup> [www.theglobalfund.org/en](http://www.theglobalfund.org/en)

<sup>4</sup> [www.usaid.gov/our\\_work/global\\_health/aids/pepfar.html](http://www.usaid.gov/our_work/global_health/aids/pepfar.html)

<sup>5</sup> [www.unaids.org/html/pub/global-reports/bangkok/unaidsglobalreport2004\\_en\\_html.htm](http://www.unaids.org/html/pub/global-reports/bangkok/unaidsglobalreport2004_en_html.htm)

<sup>6</sup> Market research prepared for Chembio

Chembio has already completed development of a rapid lateral-flow test for the detection of TB in Non-Human Primates (PrimaTB STAT-PAK), and has a similar test near completion for multiple host species, including cattle, deer, elephant and other exotic wildlife. The tests can use serum, plasma, whole blood or “meat juice” samples and provide results within 20 minutes. The Company believes, subject to USDA approvals, that commercialization of these products can begin in early 2007.

### **Distribution Channels & Marketing Strategy**

Approval from the FDA of our HIV rapid tests will not only permit sales in the U.S. but will also enhance marketing capability in the international markets. HIV 1/2 STAT-PAK and HIV 1/2 STAT-PAK Dipstick were recently made part of the World Health Organization (WHO) 2005 Bulk Procurement Scheme and, together with SURE CHECK HIV, the USAID blanket waiver list. These are both critically important for international sales. The WHO’s endorsement is required for virtually all international procurements by governmental and non-governmental organizations. The USAID waiver allows our products to be procured with USAID and CDC (i.e., PEPFAR) funding even without FDA approval which, as mentioned above, is pending.

Our marketing strategy is to:

- Expand our international sales effort and strategic partnerships in the 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 recently established 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 Southeast Asia, China, and South America for our HIV and/or Chagas Disease tests, as well as other new tests that we have under development.
- Launch our rapid HIV tests in the US and Europe. We anticipate FDA approval during the first half of 2006. Our products will be marketed initially in the public health and hospital markets, through our own direct sales people and/or with marketing and distribution partners with whom we are currently in discussion. Once we obtain approval we will move aggressively on approval in Europe.
- Pursue potential OTC marketing in the U.S. and internationally. There is discussion now to allow over-the-counter sale of HIV rapid tests in the U.S. as well as in other markets.
- Launch in 2006 our initial veterinary TB product, Prima TB Stat Pak(TM), within our growing line of veterinary TB tests. We anticipate USDA approval of our initial product, a nonhuman primate TB test, in late 2006. 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 Chembio’s business strategy.

**Clinton Foundation HIV/AIDS Initiative** - In January 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 US-based manufacturer) to be recommended by CHAI for sales of HIV rapid tests. While CHAI is not a procurer of the tests per se, it is an increasingly 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** - In addition, the Company is committed to securing alliances and technology-transfer agreements with government agencies and commercial entities. For example, Chembio 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 a three-year period, Chembio will transfer its proprietary technology related to HIV 1/2 STAT-PAK to Bio-Manguinhos in exchange for commitments to purchase at least one million rapid tests. This purchase commitment was met during 2005, though we expect substantial additional procurements prior to the completion of the technology transfer agreement, currently anticipated for early 2007. Thereafter Bio-Manguinhos will have the right to produce its own rapid tests and Chembio will receive royalties for ten years.

**Other Partnerships in Development** - Chembio is applying its Brazilian success to other areas of the world. The Company will endeavor to partner with qualified entities that will assemble and package semi-finished tests produced by Chembio under Chembio's quality control in the U.S. These unique arrangements would create an effective public-private partnership with local governments and ensure the availability of rapid HIV tests. This will foster self-reliance in these countries, create local jobs and contribute to their economic and technological growth.

## 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 and tuberculosis, 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 is instrumental in our obtaining the collaborations we have and that we continue to pursue.

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 HIV. See "Governmental Regulation" for definition of pre-marketing approval. For this reason, during 2004 and 2005 we hired employees and consultants that collectively have that experience from other companies. 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 as we get closer to FDA approval of our rapid HIV tests and/or as we complete the development of, and the requisite regulatory approvals related to, our other products, including those that we have under development. ( See Management's Discussion And Analysis Of Financial Condition And Results Of Operations - *Overview* and in particular the last paragraph)

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 complete effectively for the same individuals to the extent that a competitor uses its substantial resources to attract any such individuals. With respect to the availability of patent protection, we do not have our own portfolio of patents or the financial resources to develop and/or acquire a portfolio of patents similar to those of our larger competitors. We have been able to obtain patent protection by entering into licensing arrangements.

Competitive factors specifically related to our HIV tests are product quality, price and ease of use. Product quality for an HIV rapid 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 business model position us well to compete effectively and win a meaningful share of this expanding market.



The leading products in the international market are UniGold(R), produced by Trinity Biotech in Ireland, and Determine(R), produced by Abbott Diagnostics in Tokyo. The Abbott Determine business was sold to Inverness Medical Innovations last year, although Abbott retained the distribution rights to the Determine product for approximately three years. Determine and UniGold have well established presences in many of the developing world markets, often as the screening and confirmatory tests, respectively. Inverness' Organics subsidiary in Israel has a rapid test, Double Check Gold, and this is one of the other three 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 WHO. In the developed world, particularly the United States, our competitors are Orasure Technologies with OraQuick(R), and, to a much lesser degree Trinity with its UniGold(R) product, both of which are FDA-approved, CLIA-waived products. We do not believe Inverness plans to submit either the Determine or the Organics product to the FDA.

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 one 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 focusing on building its brand and market share in the US market, and successfully so; its developing world sales are not significant as we believe its product is not suitable and not 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.

Chembio's HIV products' shelf life is 24 months, which is double that of UniGold and four times that of Orasure's product. We expect that our products will be approved by the FDA for finger-stick whole blood, venous whole blood, serum, and plasma. Our Sure Check format is extremely convenient, easier to use than OraQuick on finger-stick whole blood sample, much more cost competitive, and provides a safe, closed system. 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. None of the competitors to the best of our knowledge has actually done a technology transfer which we can now replicate in markets of our choosing.

We believe that Chembio is in a leadership position as it relates to our rapid tuberculosis test even though the product is still under evaluation and not ready for marketing. 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 Chembio is 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***).

### **HIV (See section entitled *General*)**

Our HIV development efforts are on developing different specialty next generation rapid tests such as tests for accurately screening newborns and confirmatory tests. Prototypes have been developed using our patent-pending

lateral flow technology (See *Intellectual Property*).

**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 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 WHO to switch from the current methodologies to our test or to any of the other tests in this evaluation.

In addition to our research and development efforts for tuberculosis tests for humans, we have developed a test for detecting active pulmonary tuberculosis in non-human primates (monkeys). We submitted this product for approval to the United States Department of Agriculture during the first quarter of 2005, and we expect to obtain approval of this product during the latter part of 2006. We are also engaged in collaborations related to the detection of active pulmonary tuberculosis in other animals as we can leverage our current technology for additional species. We do not anticipate any material revenues from these efforts during 2006.

During 2005 and 2004, \$1,364,898 and \$1,508,849, respectively, was spent on research and development activities. A significant portion of these expenditures have been on our human and non-human primate tuberculosis product development efforts.

## **Employees**

At December 31, 2005, we employed 64 people, including 62 full-time employees. In May 2004, we entered into employment agreements with Lawrence Siebert, President and Chairman, Avi Pelossof, VP Sales, Marketing and Business Development, and Javan Esfandiari, Director of research and development.

## **Governmental Regulation**

The Company's existing and proposed diagnostic products are regulated by the U.S. Food and Drug Administration (FDA), U.S. 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. The Company's FDA and USDA regulated products require some form of action by each agency before they can be marketed in the United States and after approval or clearance, The Company must continue to comply with other FDA requirements applicable to marketed products, e.g., CLIA regulations (for medical devices). Both before and after approval or clearance, failure to comply with the FDA's requirements can lead to significant penalties.

Most of the Company's 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.

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 U.S. Department of Health and Human Services (via the FDA) applicable to the category of examination or procedure performed. Although a certificate is not required for the Company, it considers the applicability of the requirements of CLIA in the design and development of its products. The statutory definition of "laboratory" is very broad, and many of our customers are considered labs. A CLIA waiver will remove certain quality control and other requirements that must be met for certain customers to use the Company's products and this is in fact critical to the marketability of a product into the point of care diagnostics market.

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.

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

The Company's HIV rapid tests have been evaluated and approved for marketing in several foreign jurisdictions, including Mexico, India, and other nations in the developing world. Chembio completed clinical trials for the SURE CHECK HIV and 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. CLIA waiver studies are substantially completed. The Company believes that it will receive an approval of its PMA and a CLIA waiver during the first half of 2006. The Company also had its first veterinary tuberculosis rapid test under review by the USDA and expects to have its facility inspected by this agency during 2006 in connection with that submission.

## **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: (1) to pursue licenses, trade secrets, and know-how within the area of lateral flow technology, and (2) to develop and acquire proprietary positions to reagents and new hardware platforms for the development and manufacture of rapid diagnostic tests.

### *Trade Secrets and Know-How*

We believe that we have developed a substantial body of trade secrets and know-how relating to the development of lateral flow diagnostic tests, including but not limited to the sourcing and optimization of materials for such tests, and how to maximize sensitivity, speed-to-result, specificity, stability and reproducibility. The Company possesses

know-how to develop tests for multiple conditions using colored latex which is proprietary. Our buffer formulations enable extremely long shelf lives of our HIV rapid tests and we believe that this provides us with an important competitive advantage.

*Lateral Flow Technology and Reagent Licenses*

Although we own no patents covering lateral flow technology, we have obtained a non-exclusive license from Abbott Laboratories to a portfolio of its lateral flow patents. The issue of potential patent challenges is ongoing for us as well as for our competitors, and we continue to monitor the situation, consult with patent counsel, and seek licenses and/or redesigns of products that we believe to be in the best interests of Chembio Diagnostics, Inc. and our stockholders. Because of the costs and other negative consequences of time-consuming litigation regardless of whether we would ultimately prevail, if we foresee a significant possibility of patent infringement litigation, our first priority will be to attempt to obtain a license on reasonable terms. Nevertheless there is no assurance that Abbott's lateral flow patents may not be challenged or that licenses 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 our HIV rapid test products and other products such that a license would not be necessary. However, this alternative could delay or limit our ability to sell these products in the United States and other markets, which would adversely affect our results of operations, cash flows and business.

During 2005 the Company has made substantial additions to its intellectual property portfolio as a result of the development of a new rapid test platform that has shown improved sensitivity as compared with conventional platforms in a number of preliminary studies using well characterized HIV, Tuberculosis and other samples. This technology has formed the basis of two patent applications that were filed earlier this year and will likely result in additional applications covering additional uses of this technology platform. The Company anticipates signing new development projects based upon these new technologies in the near future that will provide new product applications and marketing opportunities. The Company believes that this new lateral flow platform is outside of the scope of currently issued patents in the field of lateral flow technology, thereby offering the possibility of a greater freedom to operate. There is no assurance that the patent application will be granted, or that its claims won't be modified upon review, or that Chembio's patents or its products incorporating the patent claims will not be challenged at any time. We have also filed two patents relating to our veterinary tuberculosis rapid tests and improvements to the sample collection method in our Sure Check HIV device.

The peptides used in our HIV rapid tests are patented by Adaltis Inc. and are licensed to us under a 10-year license agreement dated August 30, 2002 which was recently amended. We also have licensed the antigens used in our tuberculosis and Chagas disease tests. We have negotiated license agreements related to intellectual property rights associated with HIV- 1 and HIV-2 and expect to conclude these agreements during 2006.

**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, for a number of diseases and for pregnancy.

**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	Anti-Retroviral Treatments for AIDS
CD-4	The CD4+ T-lymphocyte is the primary target for HIV infection because of the affinity of the virus for the CD4 surface marker. Measures of CD4+ T-lymphocytes are used to guide clinical and therapeutic management of HIV-infected persons.
CDC	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	U.S. 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	

	A procedure pursuant to which an immunodiagnostic test is performed on a particular specimen in order to obtain the desired reaction.
REAGENT	A chemical added to a sample under investigation in order to cause a chemical or biological reaction which will enable measurement or identification of a target substance.
RETROVIRUS	A type of virus which contains the enzyme Reverse Transcriptase and is capable of transforming infected cells to produce diseases in the host such as AIDS.
Ryan White CARE Act	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.
SAB	Staff Accounting Bulletin
SENSITIVITY	Refers to the ability of an assay to detect and measure small quantities of a substance of interest. The greater the sensitivity, the smaller the quantity of the substance of interest the assay can detect. Also refers to the likelihood of detecting the antigen when present.
SFAS	Statement of Financial Accounting Standards
SPECIFICITY	The ability of an assay to distinguish between similar materials. The greater the specificity, the better an assay is at identifying a substance in the presence of substances of similar makeup.
SPUTUM	Expectorated matter; saliva mixed with discharges from the respiratory passages
TB	Tuberculosis (TB) is a disease caused by bacteria called Mycobacterium tuberculosis. The bacteria usually attack the lungs. But, TB bacteria can attack any part of the body such as the kidney, spine, and brain. If not treated properly, TB disease can be fatal. TB is spread through the air from one person to another. The bacteria are put into the air when a person with active TB disease of the lungs or throat coughs or sneezes. People nearby may breathe in these bacteria and become infected.
TESTING ALGORITHM	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.
UNAIDS	Joint United Nations Program on HIV/AIDS
USAID	United States Agency for International Development
USDA	U.S Department of Agriculture
WHO	World Health Organization

**ITEM 2. DESCRIPTION OF PROPERTY**

Our administrative offices and research facilities are located in Medford, New York. We lease approximately 14,000 square feet of industrial space for \$8,167 per month. The space is utilized for R&D (approximately 1,600 square feet), offices (approximately 4,700 square feet) and production (approximately 7,700 square feet). The lease term expires on April 30, 2007. 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. Other than as set forth below, 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 to our interest. The outcome of the open unresolved legal proceeding set forth below is presently indeterminable. We do not believe the potential outcome from this legal proceeding will significantly impact our financial position, operations or cash flows.

Saliva Diagnostic Systems, Inc. Dispute.

The Company is involved in a patent litigation with Saliva Diagnostic Systems, Inc. ("SDS"), the assignee of a patent related to a method for collecting samples. The Company has requested relief from the court that its Sure Check HIV test does not infringe SDS's patent, that such patent is invalid, and that it is unenforceable due to inequitable procurement. SDS has answered and counterclaimed, alleging that the Company has infringed the patent, which the Company has denied. In the years 2001 through 2003, the Company paid royalties to SDS and took several other actions based upon SDS's representations regarding its alleged patent.

In response to the Company's aforementioned request for relief, the Court has decided that it is not yet prepared to rule on the significant issues in the case. The Company does not believe that the Court's decision adversely affects the strength of its position. Accordingly, we are not presently appealing this decision, although we believe we have a meritorious basis for future appeal. The discovery phase of the litigation is proceeding pursuant to a scheduling order and trial is presently expected to convene in late 2006.

**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 following table 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>2005</b>		

First Quarter	\$0.90	\$0.50
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Second Quarter	\$0.87	\$0.54
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Third Quarter	\$0.66	\$0.52
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Fourth Quarter	\$0.62	\$0.30
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<b>Fiscal Year</b>	<b>High Bid</b>	<b>Low Bid</b>
<b>2004</b>		

First Quarter	\$3.00	\$0.34
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Second Quarter	\$2.00	\$1.00
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Third Quarter	\$1.54	\$1.01
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Fourth Quarter	\$1.29	\$0.55
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Trades of our common stock are subject to Rule 15c-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 December 31, 2005, there were approximately 322 record owners of our common stock.

## **Dividends**

The Company has never paid cash dividends on its common stock and has no plans to do so in the foreseeable future. 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 our series A and series B preferred stock also prohibit us from making any distribution with respect to any equity securities that by their terms do not rank senior to the series A or series B preferred stock.

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

On October 26, 2005, the Company issued an option to acquire 10,000 shares of common stock to Allen Moore, a member of the Company's Advisory Committee. The exercise price of the option is \$.48 per share, one-half of the option is exercisable immediately and one-half becomes exercisable on the first anniversary of the grant date. The option expires on October 26, 2010. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance.

On November 17, 2005, the Company entered into a contract with Bio Business Science and Development, LTDA, a consulting company, and as part of the terms of this contract the Company issued a warrant to acquire 39,006 shares of common stock to the consulting company as a portion of the compensation for services to be performed. The conversion price for the warrant is \$.55 per share, and the warrant expires on November 17, 2010. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance.

On December 1, 2005, the Company entered into a contract with The Investor Relations Group, a consulting company, and as part of the terms of this contract the Company issued 25,000 shares of common stock and a warrant to acquire 25,000 shares of common stock to the consulting company as a portion of the compensation for services to be performed. The conversion price for the warrant is \$.70 per share and the warrant expires on November 30, 2010. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance.

On December 16, 2005, the Company issued an option to acquire 15,000 shares of common stock to each of the Company's non-employee directors: Alan Carus, Gary Meller, and Gerald Eppner. The exercise price of each option is \$.35 per share, and each option is exercisable immediately. Each option expires on December 16, 2010. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance.

## **ITEM 6.MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION ANDRESULTS 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 the actual results, performance, or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Specifically, 1) our ability to obtain necessary regulatory approvals for our products; and 2) our ability to increase revenues and operating income, is dependent upon our ability to develop and sell our products, general economic conditions, and other factors. You can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continues" or the negative of these terms or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

## OVERVIEW

The following management discussion and analysis relates to the business of Chembio Diagnostics, Inc. (the Company) and its subsidiaries, which develop, manufacture, and market lateral flow rapid diagnostic tests that detect infectious diseases. These tests are sold in the U.S. and/or internationally to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments. The products are made under the label of Chembio Diagnostic Systems, Inc. (CDS) or the private labels of its distributors or their customers. The products are used in the diagnosis of infectious diseases and other conditions in humans and animals. The Company’s main products presently commercially available are its three HIV Rapid Tests (SURE CHECK(R) HIV, HIV 1/2 STAT-PAK(TM) and HIV 1/2 STAT-PAK Dipstick) and our rapid test for Chagas Disease. In 2005, the Company sold substantially all of the business related to its private label pregnancy test and is focusing on the products mentioned above.

The Company has made substantial progress toward FDA approval of its SURE CHECK HIV and HIV 1/2 STAT-PAK products. A pre-approval inspection of its facility was conducted in the third quarter of 2005 and based upon communications with the agency the Company believes it has met the requirements of an “approvable” Pre-Marketing Approval (PMA) application, and expects to be so advised by the FDA during the first half of the second quarter of 2006. The Company further expects to complete the full process during the second quarter of 2006, which would include receipt from the FDA of a waiver under the Clinical Laboratory Improvement Act (“CLIA”). A CLIA waiver is essential in order to market the product into public health clinics and physicians offices where the level of training is less than clinical laboratories and hospitals. The Company is nearing completion of the CLIA waiver studies so it will be in a position to submit its waiver application immediately upon receipt of the PMA license from the FDA.

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”). The historical information presented for periods prior to the Merger is based on the activities of CDS. For financial reporting purposes, the acquisition has been treated as a recapitalization of Chembio Diagnostics, Inc., with CDS as the acquiror. The earnings per share presented in the statement of operations for periods prior to 2005 reflect the shares outstanding as if the merger had taken place as of January 1, 2004.

The financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern. Although the Company’s revenues and gross margins increased significantly in 2005 as compared to 2004, it has sustained significant operating losses in 2005 and 2004. At December 31, 2005, the Company had a positive stockholders’ equity of \$1,052,703 and working capital of \$650,000. The Company believes its resources are sufficient to fund its needs through early 2006 and it is considering alternatives to provide for its capital requirements for the balance of 2006 and



beyond in order to continue as a going concern. Its 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) its 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 sufficient capital.

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. The Company is continuing to pursue additional financing opportunities in order to provide for its longer term financing needs.

## **RESULTS OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2005 AS COMPARED WITH THE YEAR ENDED DECEMBER 31, 2004**

### **Revenues:**

Revenues are comprised of \$3,359,532 in net product sales, \$250,000 in license revenue and \$331,198 in grants and development income for the year ended December 31, 2005 as compared with \$2,749,143 in net product sales, no license revenue and \$556,789 in grant and development income for the year ended December 31, 2004. The increase in sales is attributable to increased sales of our HIV product of \$1,158,000 which was partially offset by decreased sales of our pregnancy test kit of \$443,000 and decreases in other product sales aggregating \$94,000. The increase in license revenue of \$250,000 is due to a technology transfer agreement. The Company does not expect that this particular license revenue will continue in the future. The decrease in grant and development income of \$225,591 was due to grants received in 2004 that weren't continued or awarded in 2005. A substantial portion of the grant-related income is not expected to continue in 2006.

Net product sales for 2005 increased 22% compared to 2004. HIV net product sales increased 93% in 2005 compared to 2004. The Company believes that sales of its HIV products will continue to increase in 2006 both as a result of the international marketing strategies that were implemented in 2005 and from the sales to the United States market after anticipated approval from the U.S. Food and Drug Administration (FDA). The Company also received its first significant order for its Chagas test (Chagas is a disease which is primarily found in Latin America), in the amount of \$1.2 million which it expects to ship in the first half of 2006.

Net product sales for the three months ended December 31, 2005 increased 27% to \$1,356,000 compared to the same period in 2004. HIV product sales increased 64% to \$1,223,000 for the three months ended December 31, 2005 compared to the same period in 2004.

### **Gross Margin:**

Gross margin on net product sales for the year ended December 31, 2005 was 22.3%, as compared to 5.4% for the year ended December 31, 2004. 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; in addition, because sales volume in 2004 was lower, fixed overhead expenses per dollar of sales were disproportionately high.

The gross margin on net product sales for the three months ended December 31, 2005 improved to 38.1% from 30.8% in the comparable 2004 period.

### **Research and Development:**

Research and development expenses for the year ended December 31, 2005 were \$1,364,898 compared with \$1,508,849 for the year ended December 31, 2004. This category includes costs incurred for regulatory approvals, product evaluations and registrations. Expenses for Clinical & Regulatory Affairs, totaled \$411,000 for the year ended December 31, 2005, a decrease of \$472,000 compared to the year ended December 31, 2004. This category also includes costs for clinical studies which decreased by \$437,000 and a reduction in outside regulatory consultants of \$77,000. The costs related to the clinical trials and consulting in 2004 were related to the evaluation of the Company's HIV tests in preparation of its FDA Pre-Marketing Approval ("PMA") application submitted in February of 2005. Expenses other than Clinical & Regulatory increased \$329,000 and were related to increased salaries and wage-related costs of \$211,000 for new hires in the R&D group, increased travel and entertainment of \$46,000 and grant payments to a university of \$35,000.

The Company presently plans to increase its spending on research and development because it believes such spending will result in the development of new and innovative products. The Company will continue to focus its development efforts on its tuberculosis related products and new lateral flow technologies, some of which have patents pending.

The Company currently has 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**

The Company has filed an application with the United States Department of Agriculture (USDA) to license its rapid test, Prima TB STAT-PAK(TM). A final set of clinical trials is scheduled for the second quarter of 2006, that, if successful, would lead to a conditional license (the ability to sell the product commercially with USDA approval on an order by order basis) by late in the fourth quarter of 2006. The Company anticipates that additional commercialization will begin in the first quarter of 2007, although there are no assurances that it will be successful.

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

Chembio has completed development and is approaching the final validation stage on a series of rapid lateral-flow tests for the detection of veterinary TB in multiple host species including; cattle, cervids, badgers, camels, elephants, and exotic wildlife species. The name for the technology is VETTB STAT-PAK(TM). Application to the USDA is targeted for the third quarter of 2006 for all species. The Company anticipates commercialization of these products to start in the first quarter of 2007, although there are no assurances that it will be successful.

### **New Generation Rapid Tests Based Upon Patent Pending Platform**

The Company has done substantial laboratory work on prototypes of its new patent-pending lateral flow rapid test platform. This work has confirmed the advantages of this new platform in terms of sensitivity to weak and early sero-conversion samples. The Company believes that this platform may provide the level of sensitivity that will be needed in order to complete development of a human TB rapid test which could not be achieved with sufficient sensitivity based upon the existing platform.

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

Selling, general and administrative expense increased \$966,637 to \$3,265,235 in the year ended December 31, 2005 compared with 2004. This increase was attributable to increased staff in the accounting, administration and sales and marketing departments of \$375,000 and related recruiting expenses of \$89,000. Increased sales resulted in an increase in royalties and commissions of \$319,000. In addition there was an increase of \$174,000 in costs regarding investor relations, \$62,000 of which resulted from an increase in the number of members of the Company's Board of Directors, \$22,000 from increased insurance liability cost, \$34,000 related to Sarbanes-Oxley compliance and increased legal and accounting expenses of \$237,000 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 in officers' salaries of \$240,000, mostly due to the inclusion in 2004 of the cost of common stock issued to a former officer.

As the Company's sales of its HIV rapid test products increase, it expects 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. At the end of 2005, the Company renegotiated one of its license agreements to provide for a decrease of 50% in the royalty rate, from 10% to 5% of sales of HIV products, in exchange for \$350,000 in up front cash payments. Such payment is being amortized over the life of the royalty agreement.

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

Interest expense decreased by \$174,875 for the year ended December 31, 2005 compared with the year ended December 31, 2004. This was primarily attributable to the conversion during 2004 of \$1,694,000 of existing debt of Chembio Diagnostic Systems, Inc, into Series A Preferred Stock. Interest income for the year December 31, 2005 increased \$32,000 due to the availability of additional funds. In addition, approximately \$22,000 and \$209,000 is attributable to settlements of old outstanding payables due that were settled during the years 2005 and 2004, respectively and are reflected in other income as settlement of accounts payable.

### **LIQUIDITY AND CAPITAL RESOURCES**

The Company had a working capital surplus of \$650,000 at December 31, 2005 and a working capital deficiency of \$452,000 at December 31, 2004. On January 28, 2005, the Company completed a private placement offering which raised \$5,047,500 before costs in the form of 9% Convertible Series B Preferred Stock and associated warrants ("Series B Offering"). The proceeds from the Series B Offering have been and are being used primarily for general corporate purposes including for sales and marketing, research and development, and intellectual property, and also for working capital, investor relations, and capital expenditures.



The following table lists the future payments required on the Company's debt and any other contractual obligations as of December 31, 2005:

<b>OBLIGATIONS</b>	<b>Total</b>	<b>Less than 1 Year</b>	<b>1-3 Years</b>	<b>4-5 Years</b>	<b>Greater than 5 Years</b>
Long Term Debt(1)	\$ 220,812	\$ 120,000	\$ 100,812	\$ -	\$ -
Capital Leases (2)	\$ 82,785	\$ 38,368	\$ 44,417	\$ -	\$ -
Operating Leases	\$ 124,950	\$ 99,837	\$ 25,113	\$ -	\$ -
Other Long Term Obligations(3)	\$ 899,092	\$ 644,367	\$ 126,600	\$ 25,000	\$ 103,125
<b>Total Obligations</b>	<b>\$ 1,327,639</b>	<b>\$ 902,572</b>	<b>\$ 296,942</b>	<b>\$ 25,000</b>	<b>\$ 103,125</b>

- (1) This represents accrued interest which is currently being paid out at the rate of \$10,000 per month.  
(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 *Overview* and in particular the last paragraph.

During 2006, the Company expects to start marketing its SURE CHECK HIV and HIV 1/2 STAT-PAK in the U.S. as it has made substantial progress toward its FDA approval of these products as set for the in the second paragraph of Overview above..

Based upon the expected FDA approval and CLIA waivers referred to above, the Company is developing plans for marketing its HIV products in the U.S. and is considering entering into marketing arrangements with major companies who distribute diagnostic products in the U.S.

A recent development of note is the White House 2007 budget request for \$90 million to test an additional three million Americans using rapid HIV tests. Also, the Company has been following with great interest the consideration by an FDA advisory committee of the conditions under which rapid HIV tests could be approved for direct over-the-counter sales to U.S. consumers. On March 10, 2006, proposed guidelines will be presented to this committee. While the Company believes that both President Bush's budget request and the possibility for over-the-counter approval bode well for the expansion of the U.S. rapid HIV test market, there are still many obstacles and uncertainties to be overcome before these items become a reality and can result in realizable opportunities for the Company, and there are no assurance that they will be realized.

During 2005, the Company established offices in Nigeria and Tanzania which it believes will be significant in its continuing efforts to become part of the national testing protocols in many countries in Africa. The Company's STAT-PAK is designated as the confirmatory test in all of the national rapid HIV testing protocols in the Republic of Uganda and was just recently 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. The Company is making good progress towards having its HIV products designated in other countries where it has focused its efforts. The Company has registered its products and has established distribution partners in certain of these countries and is in negotiations to do so in other countries. The Company believes that its strategy of establishing offices in these challenging markets is a very effective way to obtain sustainable and supportable business. The Company is also actively looking at several new opportunities for establishing distribution and/or local assembly programs for its rapid HIV tests with strong local partners such as it has done in Brazil.

In early 2006, Chembio was named as 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, the Company has agreed to offer its HIV STAT-PAK Dipstick, Chembio's lowest cost HIV rapid test product, at a reduced price in the expectation that the Company will receive significant order volume not otherwise obtainable; this should result in efficiencies of scale that will more than justify the reduced sales price. If these order volumes are not realized, the Company has the right to terminate the agreement or renegotiate pricing. Chembio is the only U.S.-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, the Company is now actively engaged with CHAI in developing sales opportunities in a many of these 50+ countries. Although in some of these countries the Company has already made substantive sales efforts, there are many more where this is not the case. There is no commitment or assurance that either the Company's direct efforts to establish additional distributors and/or local assembly, or its activities through CHAI will materialize into meaningful sales.

The Company's technology transfer and supply agreement in Brazil is moving forward. The Company shipped 704,000 HIV rapid tests in 2005, a 254,000 test increase over the quantity sold in 2004. The Company expects to deliver components for an additional 800,000 tests during all of 2006, although there is no assurance that this will occur.

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

In September 2005, the Company hired a senior diagnostics marketing executive to focus on its Tuberculosis products, both for veterinary and human TB. The Company's Non-human primate Tuberculosis product is currently under review by the United States Department of Agriculture (USDA) and it expects USDA approval toward the end of 2006 provided its tests meet certain performance and other criteria; and it plans to submit additional veterinary TB products to the USDA this year, including a cattle TB test, subject to having the necessary performance data of which there is no assurance.

During the second quarter of 2005 the Company filed a patent application for a new lateral flow device and method which it believes will provide it with proprietary intellectual property to develop a pipeline of products that it believes will have improved performance over currently available lateral flow technologies. The Company is continuing to refine this device and it believes it will be the basis for new product developments that can address significant needs for screening of tuberculosis and other infectious diseases that occur in markets that the Company is already serving with its HIV rapid tests.

### **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.

The Company believes that there are several accounting policies that are critical to understanding its 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 -*

The Company sells its products directly through its sales force and through distributors. Revenue from direct sales of its product is recognized upon shipment to the customer. Income from research grants when earned. Grants are invoiced after expenses are incurred. 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.

#### *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. The Company's 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.

*Allowance for doubtful accounts -*

The Company's policy is to review its accounts receivable on a periodic basis, no less than monthly. On a quarterly basis an analysis is made of the adequacy of its allowance for doubtful accounts and adjustments are made accordingly. The current allowance is approximately 1.6% of accounts receivable.

*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 the Company does not become profitable it may be unable to utilize its deferred tax asset, which approximates \$6,128,000 at December 31, 2005.

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, the Company determined that it was appropriate to establish a valuation allowance for the full amount of its deferred tax assets.

The above listing is not intended to be a comprehensive list of all of the Company's 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 the Company's 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, the Company conducted an evaluation under the supervision and with the participation of the principal executive officer and principal financial officer, of the Company's 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 the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in reports that it files or submits 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 the Company's internal controls over financial reporting during the Company's most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

**ITEM 8B.**

**OTHER INFORMATION**

Not applicable.

**PART III**

**ITEM DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS;**

**9. COMPLIANCE WITH SECTION 16(A) OF THE EXCHANGE ACT**

**Directors and Executive Officers**

**Lawrence A. Siebert (49)**, 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 (49)**, 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.

**Avi Pelossof (43)**, Vice President Sales, Marketing and Business Development. Mr. Pelossof joined Chembio Diagnostic Systems Inc. in 1996 and has been responsible for developing Chembio Diagnostic System's marketing strategy and collaborations. From 1991 to 1996, he was Managing Director and co-founder of The IMS Group, Inc., which provided strategic marketing advisory services to companies involved in Latin American markets including Chembio Diagnostics, Inc. Prior to IMS he was a Citibank Vice President in the International Corporate Finance Group focused on Latin America. Mr. Pelossof received his MBA in finance and international business from New York University in 1986 and a BA with Distinction in economics from the University of Michigan in 1984.

**Javan Esfandiari (39)**, Director of Research & 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.

**Rick Bruce (51)**, Vice President, Operations. Mr. Bruce was hired in April 2000 as Director of Operations. He is responsible for production, maintenance, inventory, shipping, receiving, and warehouse operations. Prior to joining Chembio Diagnostic Systems Inc., he held director level positions at Wyeth Laboratories from 1984 to 1993. From 1993 to 1998, he held various management positions in the Operations department at Biomerieux. From 1998 to 2000, he held a management position at V.I. Technologies. Mr. Bruce has over 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 (54)**, 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 (43)**, 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. Since 2003, he has been a guest instructor for "drug development process" and "FDA regulations", a BioScience Certificate program at New York State University of Stony Brook.

**Alan Carus, CPA (67)**, 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.

**Gerald A. Eppner (66)**, Director. Mr. Eppner was elected to our Board of Directors on March 15, 2005. Mr. Eppner is Counsel in the Corporate and Finance Department of Kaye Scholer where his practice includes matters under the federal securities laws. He has engaged in private law practice in New York City for over 40 years and retired as a partner in Cadwalader, Wickersham & Taft at the end of 2004 and as Senior Counsel to that firm in 2005. Mr. Eppner is Vice Chairman and General Counsel of Emeritus Capital Partners, LLC, a New York City-based capital strategies firm that specializes in large asset-based securitizations and secondary market intermediation of senior life settlement insurance portfolios. He is also a Managing Director of Access Equity Partners, LLC, a New York-and Chicago-based venture capital firm. Prior to coming to New York, Mr. Eppner was an employee of agencies and departments of the United States government.

#### **Section 16(a) Beneficial Ownership Reporting Compliances**

Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), requires the Company's directors, executive officers and holders of more than 10% of the Company's common stock to file with the Securities and Exchange Commission initial reports of ownership and reports of changes in ownership of common stock and other equity securities of the Company. The Company believes that during the year ended December 31, 2005, its officers, directors and holders of more than 10% of the Company's common stock complied with all Section 16(a) filing requirements, except the following filings were filed late: (i) Form 4 for Gerald Eppner filed on March 25, 2005; (ii) Form 4 for Gary Meller filed on March 25, 2005; (iii) Form 4 for Alan Carus filed on April 22, 2005; (iv) Form 4 for Richard Larkin on May 17, 2005; (v) Form 4 for Avi Pelossof filed on May 17, 2005; (vi) Form 4 for Lawrence Siebert filed on May 17, 2005; (vii) Form 4 for Lawrence Siebert filed on November 17, 2005.

**Code of Ethics**

The Company has adopted a code of ethics that applies to its principal executive officer, principal financial officer, principal accounting officer, controller, and persons performing similar functions. A copy of the Company's code of ethics is filed as Exhibit 14.1 to this Form 10-KSB.

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

The Company's board of directors has established an audit committee. Alan Carus, Gerald A. Eppner and Dr. Gary Meller each serve on the audit committee. The Company's board of directors has determined that Alan Carus is an audit committee financial expert.

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

The following table summarizes the annual compensation paid to Chembio Diagnostics, Inc.'s named executive officers for the three years ended December 31, 2005, 2004 and 2003:

Name and Position	Year	Annual Compensation		Long-Term Compensation Awards—Securities Underlying Stock Options
		Salary		
Lawrence A. Siebert, President, CEO, Chairman of Board of Chembio Diagnostics, Inc. <sup>(1)</sup>	2005	\$	160,151	—
	2004		145,994	160,000
	2003		140,641	—
Avi Pelosof, Vice President of Chembio Diagnostics, Inc. <sup>(2)</sup>	2005	\$	154,165	50,000
	2004		154,635	250,000
	2003		83,077	—
Javan Esfandiari, Vice President of Chembio Diagnostic Systems, Inc. <sup>(3)</sup>	2005	\$	155,046	50,000
	2004		129,323	110,000
	2003		88,269	—
Richard Bruce, Vice President of Chembio Diagnostic Systems, Inc. <sup>(4)</sup>	2005	\$	116,765	25,000
	2004		114,286	35,000
	2003		110,326	—
Richard J. Larkin, CFO of Chembio Diagnostics, Inc. <sup>(5)</sup>	2005	\$	123,673	50,000
	2004		97,385	—
	2003		19,594	50,000

(1) Mr. Siebert currently is a director, the President and Chief Executive Officer of Chembio Diagnostics, Inc., and the President of Chembio Diagnostic Systems Inc. The compensation information represents compensation earned while employed by Chembio Diagnostic Systems Inc. In 2004, Mr. Siebert received, prior to the merger, 50,000 options exercisable at \$0.75 and 10,000 options exercisable at \$1.00. In addition as part of his contract signed in May 2004, Mr. Siebert received 50,000 options with an exercise price of \$1.20 per share, becoming exercisable in May 2005 and 50,000 options with an exercise price of \$1.50 per share becoming exercisable in May of 2006.

(2) Mr. Pelosof currently is a Vice President of both Chembio Diagnostics, Inc. and Chembio Diagnostic Systems, Inc. The compensation information represents compensation earned while employed by Chembio Diagnostic Systems Inc. In 2004, Mr. Pelosof received, prior to the merger, 40,000 options exercisable at \$0.75 and 10,000 options exercisable at \$1.00. In addition as part of his contract signed in May 2004, Mr. Pelosof received 100,000 options exercisable at \$0.60 per share, becoming exercisable in May 2004, 50,000 options exercisable with an exercise price of \$0.90 per share, becoming exercisable in May 2005 and 50,000 options with an exercise price of \$1.35 per share becoming exercisable in May of 2006. In May 2005, Mr. Pelosof received 25,000 options with an exercise price of \$0.80 per share, becoming exercisable in January 2006 and 25,000 options with an exercise price of \$0.80 per share becoming exercisable in January of 2007.



- (3) Mr. Esfandiari currently is a Vice President of Chembio Diagnostics, Inc. and Chembio Diagnostic Systems, Inc. The compensation information represents compensation earned while employed by Chembio Diagnostic Systems Inc. In 2004, Mr. Esfandiari received, prior to the merger, 30,000 options exercisable at \$0.75 and 5,000 options exercisable at \$1.00. In addition as part of his contract signed in May 2004, Mr. Esfandiari received 25,000 options exercisable at \$0.90 per share, becoming exercisable in May 2005, 25,000 options with an exercise price of \$1.20 per share, becoming exercisable in May 2006 and 25,000 options with an exercise price of \$1.50 per share becoming exercisable in May of 2007. In May 2005, Mr. Esfandiari received 25,000 options with an exercise price of \$0.80 per share, becoming exercisable in January 2006 and 25,000 options with an exercise price of \$0.80 per share becoming exercisable in January of 2007.
- (4) Mr. Bruce currently is a vice president of Chembio Diagnostic Systems Inc. The compensation information represents compensation earned while employed by Chembio Diagnostic Systems Inc. Mr. Bruce received, prior to the merger, 20,000 options exercisable at \$0.588, 10,000 options exercisable at \$0.75 and 5,000 options exercisable at \$1.00. In May 2005, Mr. Bruce received 12,500 options with an exercise price of \$0.80 per share, becoming exercisable in January 2006 and 12,500 options with an exercise price of \$0.80 per share becoming exercisable in January of 2007.
- (5) Mr. Larkin currently is the Chief Financial Officer of both Chembio Diagnostics, Inc. and Chembio Diagnostic Systems, Inc. The compensation information represents compensation earned while employed by Chembio Diagnostic Systems Inc. In 2003, Mr. Larkin received, prior to the merger, 50,000 options exercisable at \$0.45. In May 2005, Mr. Larkin received 25,000 options with an exercise price of \$0.80 per share, becoming exercisable in January 2006 and 25,000 options with an exercise price of \$0.80 per share becoming exercisable in January of 2007.

The following table sets forth certain information regarding stock options granted to the named executive officers during the year ended of December 31, 2005.

Individual Grants				
Name	Number of Securities Underlying Options/SARs Granted (#)	Percentage of Total Options/SARs Outstanding	Exercise or Base Price (#/Sh)	Expiration Date
Avi Pelossof	25,000	1.75%	0.80	5/17/10
Avi Pelossof	25,000	1.75%	0.80	5/17/10
Javan Esfandiari	25,000	1.75%	0.80	5/17/10
Javan Esfandiari	25,000	1.75%	0.80	5/17/10
Richard Bruce	12,500	.87%	0.80	5/17/10
Richard Bruce	12,500	.87%	0.80	5/17/10
Richard J. Larkin	25,000	1.75%	0.80	5/17/10
Richard J. Larkin	25,000	1.75%	0.80	5/17/10

There were no options were exercised by the named executive officers in the last fiscal year.

### Employment Agreements

**Mr. Siebert.** On May 5, 2004, Mr. Siebert and the Company entered into an employment agreement, effective May 10, 2004, which terminates on May 10, 2006. 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 \$150,000 per year, subject to periodic review by the Board of Directors of the Company. 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 and is entitled to receive a base compensation of \$120,000 per year, with annual salary increases of not less than five percent, and subject to periodic review by the Board of Directors of the Company. 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. 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 and is entitled to receive a base compensation of \$115,000 per year, subject to periodic review by the Board of Directors of the Company. 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.

**Director Compensation**

All non-employee directors are paid an annual retainer of \$18,000, paid 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 chair director 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 meeting of the Board of Directors 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 the Company's 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 December 31, 2005.

<b>Name and Address of Beneficial Owner</b>	<b>Number of Shares Beneficially Owned</b>	<b>Percent of Class</b>
Lawrence Siebert (1) 3661 Horseblock Road Medford, NY 11763	1,996,139	22.51%
Avi Pelosof (2) 3661 Horseblock Road Medford, NY 11763	524,314	5.97%
Javan Esfandiari (3) 3661 Horseblock Road Medford, NY 11763	142,080	1.65%
Richard Bruce (4) 3661 Horseblock Road Medford, NY 11763	88,000	1.03%
	80,763	.94%

Richard J. Larkin

(5)

3661 Horseblock

Road

Medford, NY

11763

Alan Carus <sup>(6)</sup>	39,000	.46%
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3661 Horseblock

Road

Medford, NY

11763

Gary Meller <sup>(7)</sup>	39,000	.46%
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3661 Horseblock

Road

Medford, NY

11763

Gerald Eppner <sup>(8)</sup>	39,000	.46%
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3661 Horseblock

Road

Medford, NY

11763

All officers and directors as a group <sup>(9)</sup>	2,948,296	30.83%
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Mark Baum <sup>(10)</sup>	1,562,963	16.73%
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580 Second

Street, Suite 102

Encinitas, CA

92024

Thunderbird	487,504	5.74%
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Global

Corporation <sup>(11)</sup>

c/o The Baum

Law Firm

580 Second

Street, Suite 102

Encinitas, CA

92024

Daniel Gressel	462,501	5.42%
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<sup>(12)</sup>

460 E. 79<sup>th</sup>

Street, Apt. 17B

New York, NY

10021

Tomas Haendler	454,720	5.33%
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<sup>(13)</sup>

31 Cogswell

Lane

Stamford, CT

06902



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 term “named executive officer” refers to our chief executive officer and each of our other executive officers who received at least \$100,000 of compensation in 2005.

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 or series B preferred stock convert shares of the series A or series B 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.

- ( Includes 170,000 shares issuable upon exercise of options exercisable within 60 days and 207,566 warrants. Does 1) not include 50,000 shares issuable upon exercise of options that are not exercisable within the next 60 days. Also 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 conversion of any of those shares of series A or series B preferred stock or exercise of those warrants would result in the holder beneficially owning in excess of 4.99% of the then issued and outstanding shares of common stock outstanding at that time.
- ( Includes 275,000 shares issuable upon exercise of options exercisable within 60 days and 22,555 shares issuable 2) upon exercise of warrants. Does not include 50,000 shares issuable upon exercise of options that are not exercisable within the next 60 days. Also does not include 10,078 shares issuable upon conversion of series A preferred stock and 12,095 shares issuable upon exercise of warrants because conversion of any of those shares of series A preferred stock or exercise of any of those warrants would result in the holder beneficially owning in excess of 4.99% of the then issued and outstanding shares of common stock outstanding at that time.
- ( Includes 120,000 shares issuable upon exercise of options exercisable within 60 days and 2,007 shares issuable 3) upon exercise of warrants. Does not include 75,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
- ( Includes 82,500 shares issuable upon exercise of options exercisable within 60 days and 500 shares issuable upon 4) exercise of warrants. Does not include 12,500 shares issuable upon exercise of options that are not exercisable within the next 60 days
- ( Includes 75,000 shares issuable upon exercise of options exercisable within 60 days and 250 shares issuable upon 5) exercise of warrants. Does not include 25,000 shares issuable upon exercise of options that are not exercisable within the next 60 days. Also does not include 30,236 shares issuable upon conversion of series A preferred stock and 25,196 shares issuable upon exercise of warrants because conversion of any of those shares of series A preferred stock or exercise of any of those warrants would result in the holder beneficially owning in excess of 4.99% of the then issued and outstanding shares of common stock outstanding at that time.
- ( 6) Includes 39,000 shares issuable upon exercise of options exercisable within 60.
- ( 7) Includes 39,000 shares issuable upon exercise of options exercisable within 60.
- ( 8) Includes 39,000 shares issuable upon exercise of options exercisable within 60.
- ( 9) Includes footnotes (1)-(8).
- (10) 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 conversion of any of those shares of series A preferred stock or exercise of those warrants would result in the holder beneficially owning in excess of 4.99% of the then issued and outstanding shares of common stock outstanding at that time.

(11) Does not include 251,963 shares issuable upon conversion of series A preferred stock and 302,356 shares issuable upon exercise of warrants because conversion of any of those shares of series A preferred stock or exercise of any of those warrants would result in the holder beneficially owning in excess of 4.99% of the then issued and outstanding shares of common stock outstanding at that time. Gustavo Montilla may be deemed to have voting or investment control over the shares held by Thunderbird Global Corporation.

(12) Includes 42,065 shares issuable upon exercise of warrants exercisable within 60 days.

(13) Includes 38,197 shares issuable upon exercise of options exercisable within 60 days. Does not include 35,556 shares issuable upon conversion of series A preferred stock and 53,334 shares issuable upon the exercise of warrants because conversion of any of those shares of series A preferred stock or exercise of any of those warrants would result in the holder beneficially owning in excess of 4.99% of the then issued and outstanding shares of common stock outstanding at that time.

### Equity Compensation Plan Information

Equity Compensation Plan Information			
Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders	1,285,750	\$1.20	1,714,250
Equity compensation plans not approved by security holders	--	--	--
<b>Total</b>	<b>1,285,750</b>	<b>\$1.20</b>	<b>1,714,250</b>



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

Mark L. Baum, our former president prior to the merger and a former director of Chembio Diagnostics, Inc., entered into a nine-month employment agreement with Chembio Diagnostics, Inc., 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 Chembio Diagnostics, Inc. 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 Chembio Diagnostics, Inc. On March 18, 2005, as compensation for Mr. Baum's service on the Board of Directors of Chembio Diagnostics, Inc., 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 Chembio Diagnostics, Inc. 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 Chembio Diagnostics, Inc.'s series A preferred stock, together with warrants to acquire 1,800,000 shares of common stock at \$.90 per share, pursuant to Chembio Diagnostics, Inc.'s private placement of its 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 Chembio Diagnostics, Inc.'s common stock. The remaining debt of \$234,062 held by Mr. Siebert was exchanged on December 29, 2004 into 7.80208 shares of Chembio Diagnostics, Inc.'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 Chembio Diagnostics, Inc.'s private placement of its series A preferred stock on May 5, 2004. Approximately \$236,852 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 Chembio Diagnostics, Inc.'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 Chembio Diagnostics, Inc.'s series A preferred stock, together with warrants to acquire 56,520 shares of common stock at \$.90 per share, pursuant to Chembio Diagnostics, Inc.'s private placement of its 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.

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 and not repaid totaled

\$182,181 as of December 31, 2005.

Richard J. Larkin, the Chief Financial Officer of Chembio Diagnostics, Inc., 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 Chembio Diagnostics, Inc.'s series A preferred stock, together with warrants to acquire 30,240 shares of common stock at \$.90 per share, pursuant to Chembio Diagnostics, Inc.'s private placement of its 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.

Avi Pelossof, the vice president of sales and marketing of Chembio Diagnostics, Inc., invested \$4,000 in Chembio Diagnostics, Inc. 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 Chembio Diagnostics, Inc.'s series A preferred stock, together with warrants to acquire 22,555 shares of common stock at \$.90 per share, pursuant to Chembio Diagnostics, Inc.'s private placement of its 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.

## ITEM 13.

## EXHIBITS

Number	Description
2.1(2)	Agreement and Plan of Merger dated as March 3, 2004 (the "Merger Agreement"), by and among the Registrant, New Trading Solutions, Inc. ("Merger Sub") and Chembio Diagnostic Systems Inc.
2.2(1)	Amendment No. 1 to the Merger Agreement dated as May 1, 2004, by and among the Registrant, Merger Sub and Chembio Diagnostic Systems Inc.
3.1(7)	Articles of Incorporation, as amended.
3.2(2)	Bylaws.
3.3(1)	Amendment No. 1 to Bylaws dated May 3, 2004.
4.2(1)	Certificate of Designation of the Relative Rights and Preferences of the series A convertible preferred stock of the Registrant.
4.3(1)	Registration Rights Agreement, dated as of May 5, 2004, by and among the Registrant and the Purchasers listed therein.
4.4(1)	Lock-Up Agreement, dated as of May 5, 2004, by and among the Registrant and the shareholders of the Registrant listed therein.
4.5(1)	Form of Common Stock Warrant issued pursuant to the Stock and Warrant Purchase Agreement.
4.6(1)	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.
4.7(1)	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.
4.8(4)	Form of Warrant issued to Placement Agents pursuant to the Series A Convertible Stock Private Placement
4.9(5)	Certificate of Designation of Preferences, Rights, and Limitations of Series B 9% Convertible Preferred Stock of the Registrant.
4.10(5)	Form of Common Stock Warrant issued to Midtown Partners & Co., LLC
4.11(5)	Form of Common Stock Warrant issued pursuant to the Securities Purchase Agreement.
4.12(5)	Registration Rights Agreement, dated as of January 26, 2005, by and among the Registrant and the purchasers listed therein.
10.2(3)	Employment Agreement between the Registrant and Lawrence A. Siebert dated as of May 5, 2004.
10.3(3)	Employment Agreement between the Registrant and with Avi Pelossof dated as of May 5, 2004.
10.4(3)	Employment Agreement between the Registrant and with Javan Esfandiari dated as of May 5, 2004.
10.5(1)	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.
10.6(3)	License and Supply Agreement dated as of August 30, 2002 by and between Chembio Diagnostic Systems Inc. and Adaltis Inc.
10.8(4)	Contract for Transfer of Technology and Materials with Bio-Manguinhos.

- 10.9(6) Agreement with Abbott Laboratories.
- 10.10(5) Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of January 26, 2005, by and among the Registrant and the purchasers listed therein.
- 10.11(6) Amendment No. 1 to Securities Purchase Agreement, dated as of January 28, 2005 by and among the Registrant and the purchasers listed therein.
- 10.12(6) Equity Exchange Agreement, dated as of January 28, 2005, by and between the Registrant and Kurzman Partners, LP.
- 10.13(8) 1999 Equity Incentive Plan
- 14.1 Ethics Policy
- 21 List of Subsidiaries.
- 23.1 Consent of Lazar, Levine & Felix LLP, Independent Accountants.
- 31.1 Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(1) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on May 14, 2004.

(2) Incorporated by reference to the Registrant's registration statement on Form SB-2 filed with the Commission on August 23, 1999.

(3) Incorporated by reference to the Registrant's registration statement on Form SB-2 filed with the Commission on June 7, 2004.

(4) Incorporated by reference to the Registrant's registration statement on Form SB-2/A filed with the Commission on August 4, 2004.

(5) Incorporated by reference to the Registrant's current report on Form 8-K filed with the Commission on January 31, 2005.

(6) Incorporated by reference to the Company's registration statement of Form SB-2 filed with the Commission on March 28, 2005.

(7) Incorporated by reference to the Registrant's Annual report on Form 10-KSB filed with the Commission on March 31, 2005.

(8) Incorporated by reference to the Registrant's Proxy Statement filed with the Commission on May 11, 2005.

**ITEM 14.**

**PRINCIPAL ACCOUNTANT FEES AND SERVICES**

**Audit Fees**

For the years ended December 31, 2005 and December 31, 2004, Lazar, Levine & Felix LLP, the Company's principal accountants, billed the Company \$99,000 and \$92,000, respectively, for fees for the audit of the Company's annual financial statements and review of financial statements included in the Company's Forms 10-QSB and 10-KSB.

**Audit-Related Fees**

For the years ended December 31, 2005 and December 31, 2004, Lazar, Levine & Felix LLP, did not provide the Company with any assurances or related services reasonably related to the performance of the audit or review of the Company's financial statements that are not reported above under "Audit Fees."

**Tax Fees**

For the years ended December 31, 2005 and December 31, 2004, Lazar, Levine & Felix LLP billed the Company \$9,100 and \$14,008, respectively, for professional services for tax compliance, tax advice, and tax planning.

**All Other Fees**

For the years ended December 31, 2005 and December 31, 2004, Lazar, Levine & Felix LLP billed the Company \$17,700 and \$48,890 for fees associated with the preparation and filing of the Company's registration statements, responses to SEC comment letters, and other related matters.

**Audit Committee Pre-Approval Policies**

The Audit Committee (and prior to the adoption of the Audit Committee, the Board of Directors) approves in advance all audit and non-audit services performed by 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 30, 2006                      By /s/ Lawrence A. Siebert  
 Lawrence A. Siebert  
 President, Chief Executive Officer and  
 Chairman of the Board

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

Signatures	Title	Date
<u>/s/ Lawrence A. Siebert</u> Lawrence A. Siebert	Chief Executive Officer, President and Chairman Of The Board (Principal Executive Officer)	March 30, 2005
<u>/s/ Richard J. Larkin</u> Richard J. Larkin	Chief Financial Officer (Principal Financial & Accounting Officer)	March 30, 2005
<u>/s/ Alan Carus</u> Alan Carus	Director	March 30, 2005
<u>/s/ Gary Meller</u> Dr. Gary Meller	Director	March 30, 2005

/s/ Gerald Director March  
A. Eppner 30,  
Gerald A. 2005  
Eppner

**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 sheet of Chembio Diagnostics, Inc. and Subsidiaries (the "Company") as of December 31, 2005 and the consolidated statements of operations, stockholders' equity (deficit) and cash flows for the two years in the period ended December 31, 2005. 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, 2005, and the consolidated results of its operations and its cash flows for the two years in the period ended December 31, 2005 in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that Chembio Diagnostics, Inc. and Subsidiaries will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations. If such losses continue and the Company is unable to raise sufficient capital, its ability to continue as a going concern would be in doubt. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**LAZAR LEVINE & FELIX LLP**

**/s/ LAZAR LEVINE & FELIX LLP**

New York, New York  
February 3, 2006

<b>CHEMBIO DIAGNOSTIC SYSTEMS, INC. AND SUBSIDIARIES</b>			
<b>CONSOLIDATED BALANCE SHEET</b>			
<b>AS OF DECEMBER 31, 2005</b>			
<b>- ASSETS -</b>			
<b>CURRENT ASSETS:</b>			
Cash		\$	232,148
Accounts receivable, net of allowance for doubtful accounts of \$20,488			1,255,073
Inventories			687,983
Prepaid expenses and other current assets			292,989
<b>TOTAL CURRENT ASSETS</b>			<b>2,468,193</b>
<b>FIXED ASSETS, net of accumulated depreciation</b>			
			438,632
<b>OTHER ASSETS:</b>			
			109,581
		\$	3,016,406
<b>- LIABILITIES AND STOCKHOLDERS' EQUITY -</b>			
<b>CURRENT LIABILITIES:</b>			
Accounts payable and accrued liabilities		\$	1,477,925
Current portion of accrued interest payable			120,000
Current portion of obligations under capital leases			38,368
Payable to related party			182,181
<b>TOTAL CURRENT LIABILITIES</b>			<b>1,818,474</b>
<b>OTHER LIABILITIES:</b>			
Obligations under capital leases, net of current portion			44,417
Accrued interest, net of current portion			100,812
<b>TOTAL LIABILITIES</b>			<b>1,963,703</b>
<b>COMMITMENTS AND CONTINGENCIES</b>			

<b>STOCKHOLDERS' EQUITY</b>				
Preferred Stock – 10,000,000 shares authorized:				
Series A 8% Convertible - \$.01 par value: 158.68099 shares issued and outstanding. Liquidation preference \$4,822,957			<b>2,628,879</b>	
Series B 9% Convertible - \$.01 par value: 102.19760 shares issued and outstanding. Liquidation preference-\$5,341,896			<b>3,173,239</b>	
Common stock - \$.01 par value; 100,000,000 shares authorized 8,491,429 shares issued and outstanding.			<b>84,914</b>	
Additional paid-in capital			<b>14,034,099</b>	
Accumulated deficit			<b>(18,868,428)</b>	
<b>TOTAL STOCKHOLDERS' EQUITY</b>			<b>1,052,703</b>	
		<b>\$</b>	<b>3,016,406</b>	
The accompanying notes are an integral part of these financial statements.				

<b>CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES</b>					
<b>CONSOLIDATED STATEMENTS OF OPERATIONS</b>					
<b>FOR THE YEARS ENDED</b>					
		<b>December 31, 2005</b>		<b>December 31, 2004</b>	
<b>REVENUES:</b>					
Net sales		\$	3,359,532	\$	2,749,143
License revenue			250,000		-
Research grants and development income			331,198		556,789
<b>TOTAL REVENUES</b>			<b>3,940,730</b>		<b>3,305,932</b>
Cost of sales			2,608,584		2,601,847
<b>GROSS PROFIT</b>			<b>1,332,146</b>		<b>704,085</b>
<b>OVERHEAD COSTS:</b>					
Selling, general and administrative expenses			3,265,235		2,298,598
Research and development expenses			1,364,898		1,508,849
			4,630,133		3,807,447
<b>LOSS FROM OPERATIONS</b>			<b>(3,297,987)</b>		<b>(3,103,362)</b>
<b>OTHER INCOME (EXPENSES):</b>					
Settlement of accounts payable			21,867		209,372
Interest income			39,803		8,126
Interest (expense)			(15,683)		(190,558)
Loss on retirement of fixed assets			-		(22,469)
<b>LOSS BEFORE INCOME TAXES</b>			<b>(3,252,000)</b>		<b>(3,098,891)</b>
Income taxes			-		-
<b>NET LOSS</b>			<b>(3,252,000)</b>		<b>(3,098,891)</b>
Dividends payable in stock to preferred stockholders			818,321		240,001
Dividend accreted to preferred stock for associated costs and a beneficial conversion feature			2,698,701		1,703,072

<b>NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS</b>		\$	(6,769,022)		\$	(5,041,964)	
<b>Basic and diluted loss per share</b>		\$	(0.88)		\$	(0.85)	
<i>Weighted number of shares outstanding, basic and diluted</i>			7,705,782			5,966,769	
The accompanying notes are an integral part of these financial statements.							

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<b>CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES</b>							
<b>CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)</b>							
<b>FOR THE YEAR ENDED DECEMBER 31, 2004</b>							
	<b>Series A Preferred Stock</b>		<b>Common Stock</b>		<b>Additional paid in capital</b>	<b>Accumulated Deficit</b>	<b>Total</b>
	<b>Shares</b>	<b>Amount</b>	<b>Shares</b>	<b>Amount</b>	<b>Amount</b>	<b>Amount</b>	<b>Amount</b>
<b>Balance at December 31, 2003</b>	-	\$ -	4,902,608	\$ 49,026	\$ 4,550,975	\$ (7,057,442)	\$ (2,457,441)
<b>Preferred Stock Issued:</b>							
For cash	73.33330	2,200,000	-	-	(418,862)	-	(418,862)
Conversion of debt	90.29853	2,372,958	-	-	-	-	-
Allocation of fair value to warrants	-	(1,920,460)	-	-	1,920,460	-	1,920,460
Allocation of value of beneficial conversion	-	(1,964,740)	-	-	1,964,740	-	1,964,740
Accretion of preferred dividend	-	58,114	-	-	-	(240,001)	(240,001)
Accretion of beneficial conversion	-	1,703,072	-	-	-	(1,703,072)	(1,703,072)
<b>Common Stock Issued:</b>							
Conversion of debt	-	-	826,741	8,267	322,430	-	330,697
For Fees	-	-	65,667	657	(657)	-	-
Upon conversion of Preferred	(1.25942)	(21,914)	62,971	630	21,284	-	21,914

Preferred dividend	-	-	303,145	3,031	178,856		181,887
For services	-	-	679,142	6,791	358,454	-	365,245
<b>Warrants and options:</b>							
Issued for services	-	-	-	-	91,589	-	91,589
Exercised	-	-	66,869	669	29,422	-	30,091
To debt holders, pre-merger	-	-	-	-	60,650	-	60,650
<b>Net loss for 2004</b>	-	-	-	-	-	(3,098,891)	(3,098,891)
<b>Balance at December 31, 2004</b>	<b>162.37241</b>	<b>\$ 2,427,030</b>	<b>6,907,143</b>	<b>\$ 69,071</b>	<b>\$ 9,079,341</b>	<b>\$ (12,099,406)</b>	<b>\$ (2,950,994)</b>
The accompanying notes are an integral part of these financial statements.							

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS 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
Balance at December 31, 2004	-	\$ -	-	\$ -	6,907,143	\$ 69,071	\$ 9,079,341	\$ (12,099,406)	\$ (2,950,900)
Adjustment to correct classification of Series A preferred to permanent equity	162.37241	2,427,030	-	-	-	-	-	-	2,427,030
Preferred Stock Issued:									
for cash	-	-	100.95000	5,047,500	-	-	(321,639)	-	4,725,861
fees	-	-	4.98000	249,000	-	-	(249,000)	-	-
Exchanged in Series A preferred to Series B preferred	(0.66666)	(11,600)	0.40000	20,000	-	-	(8,400)	-	-
Location of value to grants	-	-	-	(2,349,893)	-	-	2,349,893	-	-
Location of value of beneficial version	-	-	-	(2,437,035)	-	-	2,437,035	-	-
Series B preferred dividend	-	-	4.06988	435,509	-	-	-	(435,509)	-
Correction of beneficial version	-	261,666	-	2,437,035	-	-	-	(2,698,701)	-
Common Stock Issued:									
Conversion of preferred	(3.02476)	(52,631)	(8.20228)	(228,877)	823,654	8,237	273,271	-	-



ies A ferred ndend			4,414			630,632	6,306	372,092	(382,812)	
services	-	-	-	-	-	95,000	950	52,300	-	53,2
<b>arrants and ions:</b>										
ed for vices	-	-	-	-	-	-	-	90,288	-	90,2
rcised	-	-	-	-	-	35,000	350	24,850	-	25,2
ancelled	-	-	-	-	-	-	-	(65,932)	-	(65,9
<b>loss for 5</b>	-	-	-	-	-	-	-	-	(3,252,000)	(3,252,0
<b>ance at ember 31, 5</b>	158.68099	\$ 2,628,879	102.19760	\$ 3,173,239	8,491,429	\$ 84,914	\$ 14,034,099	\$ (18,868,428)	\$	1,052,7

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

<b>CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES</b>					
<b>CONSOLIDATED STATEMENTS OF CASH FLOWS</b>					
<b>FOR THE YEARS ENDED:</b>					
		<b>December 31, 2005</b>		<b>December 31, 2004</b>	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>				<b>(REVISED)</b>	
Net loss	\$	(3,252,000)		\$	(3,098,891)
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation and amortization		98,508			109,965
Loss on retirement of fixed assets		-			22,469
Provision for doubtful accounts		4,120			-1,136
Increase in accrued interest		-			93,918
Expenses related to shares, options and warrants issued for services		77,606			451,622
Changes in:					
Accounts receivable		(1,094,137)			118,814
Restricted cash		250,000			(250,000)
Inventory		(149,336)			(72,149)
Accounts payable and accrued expenses		212,939			(26,632)
Grant and other current liabilities		-			(12,648)
Other		(153,060)			(55,288)
<b>Net cash used in operating activities</b>		<b>(4,005,360)</b>			<b>(2,647,807)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>					
Acquisition of fixed assets		(348,741)			(60,552)
<b>Net cash used in investing activities</b>		<b>(348,741)</b>			<b>(60,552)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>					
Sale of Series B Preferred Stock and associated warrants, net of cash cost of financing of \$321,639		4,725,861			-
Payment of obligations to bank		-			(67,434)
Payment of capital lease obligation		(42,511)			(55,410)
Payment of accrued interest		(112,138)			-

Proceeds from working capital loan			<b>161,917</b>			295,000	
Payment of working capital loan			<b>(206,917)</b>			(250,000)	
Proceeds from sale of common stock including bridge loan			-			330,698	
Exercise of warrants			<b>25,200</b>			30,091	
Sale of Series A Preferred Stock including bridge loan, net of the cost of financing of \$418,856			-			2,460,251	
<b>Net cash provided by financing activities</b>			<b>4,551,412</b>			2,743,196	
<b>NET INCREASE IN CASH</b>			<b>197,311</b>			34,837	
Cash - beginning of the period			<b>34,837</b>			-	
<b>CASH - end of the period</b>		\$	<b>232,148</b>		\$	34,837	
<b>Supplemental disclosure of cash flow information:</b>							
Cash paid during the period for interest		\$	<b>124,805</b>		\$	1,985	
Cash paid during the period for corporate taxes			<b>3,763</b>			1,693	
<b>Supplemental disclosures for non-cash investing and financing activities:</b>							
Common Stock issued as payment for financing fees		\$	-		\$	39,400	
Warrants/Options issued as payment for consulting services			<b>24,363</b>			42,237	
Warrants issued for shareholder consent to merger						144,643	
Warrants issued as payment for financing fees			<b>364,268</b>			337,973	
Long term debt converted to Series A Preferred Stock			-			1,693,851	
Series B Preferred issued as payment for financing fees			<b>249,000</b>			-	
Series A Preferred and associated warrants exchanged for Series B Preferred and associated warrants			<b>20,000</b>			-	
Dividend and beneficial conversion accreted to Series A and Series B Preferred Stock			<b>3,517,022</b>			1,373,750	
Series B Preferred issued as payment of Series B dividend			<b>203,493</b>			-	

Common Stock issued as payment of Series A Preferred dividend			<b>378,398</b>			181,887	
The accompanying notes are an integral part of these financial statements.							

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2005 AND 2004**

<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 lateral flow rapid diagnostic tests that detect infectious diseases. These tests are sold in the U.S. and/or internationally to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments. The products are made under the label of Chembio Diagnostic Systems, Inc. (CDS) or the private labels of its distributors or their customers. The products are used in the diagnosis of infectious diseases and other conditions in humans and animals. The Companies main products presently commercially available are its three HIV Rapid Tests (SURE CHECK(R) HIV, HIV 1/2 STAT-PAK(TM) and HIV 1/2 STAT-PAK Dipstick) and its rapid test for Chagas Disease.

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern. Although the Company's revenues and gross margins increased significantly in 2005 as compared to 2004, it has sustained significant operating losses in 2005 and 2004. At December 31, 2005, the Company had a positive stockholders' equity of \$1,053,000 and working capital of \$650,000. The Company believes its resources are sufficient to fund its needs through early 2006 and it is considering alternatives to provide for its capital requirements for the balance of 2006 and beyond in order to continue as a going concern. The Company's 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) its 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 the Company will be successful in raising sufficient capital.

**RECENT DEVELOPMENTS:**

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. The Company is continuing to pursue additional financing opportunities in order to provide for its longer term financing needs. Approximately \$140,000 of these proceeds will be used to pay cash dividends which were accrued as of December 31, 2005.

<b>NOTE</b>	<b>2</b>	—	<b>SERIES B FINANCING:</b>
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On January 28, 2005, the Company completed a private placement of 9% Series B Convertible Preferred Stock and associated warrants for \$5,047,500. The purchase price per unit (one share plus associated warrants) was \$50,000 and a total of 100.95 shares and warrants to purchase 7,860,846 shares of Common Stock were issued in the transaction. In addition one Series A Preferred stockholder exercised its right to exchange \$20,000 worth of Series A 8 % Preferred Stock and associated warrants for .40 shares of 9% Series B Preferred Stock and warrants to purchase 31,146 shares of Common Stock.

Placement Agents were paid a cash commission of 5% of the gross cash proceeds and 4.98 shares of 9 % Series B Preferred Stock and warrants to purchase 388,588 shares of Common Stock. In addition, they received warrants to purchase 737,712 shares of Common Stock at an exercise price of \$0.80 per share. The warrants may not be exercised until the majority investor in the Series B financing has given notice of its intent to exercise its warrants. See also note 13.



**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2005 AND 2004**

**NOTE**                      **3**                      —                      **MERGER TRANSACTION:**

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"). The historical information presented for periods prior to the merger is based on the activities of CDS. For financial reporting purposes, the acquisition has been treated as a recapitalization of Chembio Diagnostics, Inc. with CDS, as the acquiror. The earnings per share presented in the statement of operations for periods prior to 2005 reflect the shares outstanding as if the merger had taken place as of January 1, 2004.

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.

**NOTE**                      **4**                      —                      **SIGNIFICANT ACCOUNTING POLICIES:**

**(a)**    ***Principles of Consolidation:***

The consolidated financial statements include the accounts of the Company, and its subsidiaries all wholly owned. 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.

**(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:*

The Company accounts for stock-based employee compensation under Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees", and its related interpretations. The Company has adopted the disclosure-only provisions of SFAS No. 123, as amended, "Accounting for Stock-Based Compensation." See also note 4(m).

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2005 AND 2004**

**(h)** *Statement 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.

**(j)** *Comprehensive Income:*

The Company adopted SFAS No. 130 "Reporting Comprehensive Income", which prescribes standards for reporting other comprehensive income and its components. The Company currently does not have any items of other comprehensive income and accordingly no separate statements are required.

**(k)** *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.

**(l)** *Fair Value:*

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

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

SFAS No. 154, Accounting Changes and Error Corrections - a replacement of APB Opinion No. 20 (Accounting Changes) and FASB No. 3 (Reporting Accounting Changes in Interim Financial Statements) was issued in June 2005. It changes requirements for the accounting for and reporting of a change in accounting principle. This Statement requires retrospective application to prior periods' financial statements of changes in accounting principle unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. When it is impracticable to determine the period-specific effects of an accounting change on one or more individual prior periods presented, this Statement requires that the new accounting principle be applied to the balances of assets and liabilities as of the beginning of the earliest period for which retrospective application is practicable and that a corresponding adjustment be made to the opening balance of retained earnings (or other appropriate components of equity or net

assets in the statement of financial position) for that period rather than being reported in an income statement. When it is impracticable to determine the cumulative effect of applying a change in accounting principle to all prior periods, this Statement requires that the new accounting principle be applied as if it were adopted prospectively from the earliest date practicable.

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2005 AND 2004**

SFAS No. 154 is effective for accounting changes and error corrections made in fiscal years beginning after December 15, 2005 (calendar year 2006). Early adoption is permitted.

A revision of SFAS No. 123 “Share-Based Payment” (No. 123R) was issued in December of 2004. The revised statement establishes standards for the accounting for transactions in which an entity exchanges its equity investments for goods and services. It also addresses transactions in which an entity receives goods or services that are exchanged for or that may be settled by the issuance of equity instruments. The statement does not change the accounting guidance for share-based payments with parties other than employees. 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). A public entity will initially measure the cost of employee services received in exchange for an award of an equity instrument based on its current fair value; the fair value of that award will be remeasured subsequently at each reporting date through the settlement date. Changes in fair value during the requisite service period will be recognized as compensation over that period. The grant-date fair value of employee share options and similar instruments will be estimated using option-pricing models adjusted for the unique characteristics of these instruments. The Company will be required to comply with this pronouncement for periods beginning after December 15, 2005. The adoption of SFAS 123R in 2006, is expected to have an impact on the results of operations of the Company which will be calculated starting in the first reporting period of 2006.

*(n)* ***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 apply; accordingly, the Series A and Series B Preferred have been reclassified to permanent equity at December 31, 2005.

*(o)* ***Reclassifications***

Prior years financial statements have been reclassified to conform with current year presentation.

*(p)* ***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>For the years ended</b>	
	<b>December 31, 2005</b>	December 31, 2004
Africa	\$ <b>802,925</b>	\$ 120,002
Asia	<b>124,467</b>	215,131
Australia	<b>10,585</b>	25,478

Europe	<b>125,135</b>	157,516
Middle East	<b>55,652</b>	69,737
North America	<b>503,456</b>	994,540
South America	<b>1,737,312</b>	1,166,739
	<b>\$ 3,359,532</b>	<b>\$ 2,749,143</b>

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
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(q) **Accounts payable and accrued liabilities**

Accounts payable and accrued liabilities:

Accounts payable - suppliers	\$ 550,247
Accrued commissions	171,587
Accrued royalties	381,510
Accrued payroll and other taxes	63,146
Accrued vacation	145,566
Accrued legal and accounting	50,024
Accrued expenses - other	115,845
<b>TOTAL</b>	<b>\$ 1,477,925</b>

(r) **Earnings Per Share**

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

	<b>For the years ended</b>	
	<b>December 31, 2005</b>	<b>December 31, 2004</b>
<b>Basic</b>	<b>7,705,782</b>	<b>5,966,769</b>
<b>Diluted</b>	<b>7,705,782</b>	<b>5,966,769</b>

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, 2005 and December 31, 2004 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>For the years ended</b>	
	<b>December 31, 2005</b>	<b>December 31, 2004</b>

<b>Stock</b>	<b>1,430,375</b>	1,300,250
<b>Options</b>		
<b>Warrants</b>	<b>21,327,972</b>	12,226,054
<b>Preferred</b>	<b>16,311,602</b>	8,118,611
<b>Stock</b>		

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

As part of the merger (see note 3), the Company adopted the 1999 Stock Option Plan (the “Plan”) of CDS covering 1,500,000 shares of Common Stock. Under the terms 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.

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The Company applies Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" and related Interpretations to account for the options issued to employees and or directors using the intrinsic value method. Had compensation cost for the options been determined using the fair value based method, as defined in Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"), the Company's net loss and loss per share would have been adjusted to the pro forma amounts indicated below. The Company adopted Statement of Financial Accounting Standards No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure - an amendment of FASB Statement No. 123" requiring interim period disclosure for the years ending after December 15, 2002. The effect of the fair value method allowed under SFAS 123 is shown below.

	<b>For the years ended</b>	
	<b>December 31, 2005</b>	<b>December 31, 2004</b>
Net loss attributable to common stockholders, as reported	\$ (6,769,022)	\$ (5,041,964)
Add: Stock-based compensation included in reported net loss	-	969
Deduct: Total stock based compensation expense determined under the fair value based method for all awards (no tax effect)	(180,195)	(490,348)
Pro forma net loss attributable to common stockholders	\$ (6,949,217)	\$ (5,531,343)
Net loss per share:		
Basic and diluted loss per share - as reported	\$ (0.88)	\$ (0.85)
Basic and diluted loss per share - pro forma	\$ (0.90)	\$ (0.93)

The fair value of each option grant was estimated on the date of the grant using the Black-Scholes option-pricing model with the following weighted-average assumptions:

- For the year ended December 31, 2005: expected volatility of 110.28%; risk-free interest rate of 3.69% to 4.46%; expected lives of 3 to 5 years and no dividends.
- For the year ended December 31, 2004: expected volatility of 82.6%; risk-free interest rate of 3.31%; expected lives of 4 to 7 years and no dividends.

The effects of applying SFAS 123 in the above pro forma disclosures are not indicative of future amounts since future amounts will be affected by the number of grants awarded and additional awards are generally expected to be made at varying prices.

The Company granted 481,500 options under the Plan during the year ended December 31, 2005 at exercise prices ranging from \$0.35 per share to \$0.80 per share.

Plan activity is summarized as follows:

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	<b>Number of shares</b>	<b>Weighted Average Exercise Price</b>
Options outstanding at December 31, 2003	365,000	\$ 2.75
Granted	740,000	0.95
Canceled	-	-
Exercised	-	-
Options outstanding at December 31, 2004	1,105,000	\$ 1.55
Granted	481,500	0.74
Canceled	(300,750)	1.75
Exercised	-	-
Options outstanding at December 31, 2005	1,285,750	\$ 1.20

Additional Plan information as of December 31, 2005 is as follows:

<b>Range of Exercise Prices</b>	<b>Options Outstanding</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Life (yrs)</b>	<b>Options Exercisable</b>	<b>Weighted Average Exercise Price</b>
\$2.17 — 4.00	202,500	\$3.12	2.05	202,500	\$3.08
\$0.90 — 1.50	310,000	\$1.20	5.40	160,000	\$1.02
\$0.75 — 1.50	530,750	\$0.79	4.60	176,000	\$0.76
\$0.35 — 0.60	242,500	\$0.52	5.12	222,500	\$0.51
	1,285,750	\$1.20	4.49	761,000	\$1.36



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**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, 2005 the stock price was less than the revised exercise price; therefore there was no adjustment to compensation is required. Such warrants remain unexercised as of December 31, 2005.

The Company has a liability to its President for i) 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) and ii) \$165,000 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 (see notes 2 and 9).

**NOTE    7    —    INVENTORIES:**

Inventories consist of:

Raw	
Materials	\$ 425,758
Work in	
Process	86,001
Finished	
Goods	176,224
	<b>\$ 687,983</b>

**NOTE    8    —    FIXED ASSETS:**

Fixed assets consist of:

Machinery and	
equipment	\$ 604,243
Furniture and	
fixtures	126,277
Computer and	
telephone	
equipment	94,283
Leasehold	
improvements	131,157
Tooling	41,900

	<b>997,860</b>
Less	
accumulated	
depreciation	
and	
amortization	(559,228)
	<b>\$ 438,632</b>

Included in the above fixed assets is \$74,183, net of accumulated depreciation of \$84,058, of assets held under capital leases as of December 31, 2005. Depreciation for the 2005 and 2004 years aggregated \$98,508 and \$109,965, respectively.

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**NOTE 9 — LONG-TERM DEBT:**

In connection with the Series B offering (see note 2) 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 \$2,950 in the 34<sup>th</sup> month. These payments are subordinate to the redemption rights of the Series B preferred stockholders. No interest accrues on this payable.

**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, 2005 were as follows:

Year ending December 31,

2006	\$ 45,546
2007	40,113
2008	7,260
	92,919
Less:	
imputed interest	10,134
Present value of future minimum lease payments	82,785
Less: current maturities	38,368
	\$ 44,417

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

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

In 2005 and 2004 the Company received research grants and development contracts in the amount of \$331,198 and \$556,789 respectively. A substantial portion of the revenues realized in 2005 is not expected to recur in 2006.

**NOTE 12 — INCOME TAXES:**

No provision for Federal income taxes was required for the years ended December 31, 2005 or 2004, due to the Company's operating losses. At December 31, 2005, the Company has unused net operating loss carryforwards of approximately \$14,500,000 which expire at various dates through 2024. 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 \$288,000.

As of December 31, 2005 and 2004, the deferred tax assets related to the aforementioned carryforwards 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, 2005</b>	December 31, 2004
Net operating loss carryforwards	<b>\$ 5,800,000</b>	\$ 4,424,000
Research and development credit	<b>288,000</b>	230,000
Other	<b>40,000</b>	73,000
Gross deferred tax assets	<b>6,128,000</b>	4,727,000
Valuation allowances	<b>(6,128,000)</b>	(4,727,000)
Net deferred tax assets	<b>\$ —</b>	\$ —

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**NOTE 13—STOCKHOLDERS' EQUITY:**

**(a) Common Stock**

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 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) Other Common Stock Options**

During 2005 the Company issued options to purchase 20,000 shares of Common Stock to advisory board members. These options were valued at \$6,969 and are being expensed over the vesting periods.

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

The Series A Preferred Stock was issued 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:** The 8% per annum dividend is payable semi-annually, in cash or, at the Company's option, in Common Stock. To date all dividends have been paid in Common Stock.

**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.

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. The Series A 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 value up to its redemption value (The liquidation preference is \$30,000 per share plus accrued and unpaid dividends, presently \$394.05 per share, an aggregate for all such shares of \$4,822,957). Accrued but unpaid dividends of \$62,528 are included in the preferred stock carrying value as at December 31, 2005.

As per EITF 00-27 "Application of Issue 98-5 to Certain Convertible Instruments" the Company evaluated the series A preferred stock transaction and found that there was an associated beneficial conversion feature totaling \$1,635,416; 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 20% to be converted immediately and 100% after the earlier of ten months from the merger or 6 months after the registration statement registering the underlying common shares became effective. The amount accreted back to the preferred and charged to dividends in 2005 was \$261,666.

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

The Series B Preferred Stock was issued at a face value of \$50,000 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 of the Series B Preferred Stock (see note 2) are as follows:

**Dividends:** The 9% Series B Preferred Stock accrues dividends at 9% per annum, payable semi-annually. Dividends are payable in either Series B Preferred Stock (plus associated warrants) or cash. The majority investor in the Series B financing has the option as it pertains to its dividend payment to choose cash or preferred shares. The Company has the option to choose cash or preferred shares as to the balance of the dividends. To date all dividends have been paid in Preferred Shares.

**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. The Series B preferred is not currently redeemable and there is no likelihood that it will become redeemable; 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 \$2,270.27 per share, an aggregate for all such shares of \$5,341,896). Accrued but unpaid dividends of \$232,016 are included in the preferred stock carrying value as at December 31, 2005. The accrued but unpaid dividend was paid on January 2, 2006 by the issuance of 4.60249 shares Series B Preferred Stock.

On July 1, 2005, the Company issued 4.06988 shares of Series B Preferred Stock as payment of dividends on the Company's Series B Preferred Stock. No cash was exchanged in this issuance.

As per EITF 00-27 "Application of Issue 98-5 to Certain Convertible Instruments" the Company evaluated the series B preferred stock transactions 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.

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**NOTE 14 — COMMITMENTS AND CONTINGENCIES:**

***Employment Contracts:***

The Company has contracts with three key employees. The contracts call for salaries presently aggregating \$420,000 per year. Two contracts expire in May of 2006 and one contract expires in May of 2007.

***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, 2005 and 2004 and accordingly no expense has been recorded.

***Obligations Under Operating Leases:***

The Company leases office and manufacturing facilities. The following is a schedule of future minimum rental commitments:

Year ending December 31,

2006	99,837
2007	25,113
	\$124,950

Rent expense aggregated \$97,000 and 88,000 for the years ended December 31, 2005 and 2004, respectively.

***Economic Dependency:***

The Company had sales to three customers 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.

The Company had sales to two customers in excess of 10% of total sales in the year ended December 31, 2004. Sales to these customers aggregated approximately \$1,071,000 and \$309,000, respectively.

The Company had no purchases from any vendor in excess of 10% of total purchases for the years ended December 31, 2005 and 2004.

***Governmental Regulation:***

All of the Company's existing and proposed diagnostic products are regulated by the Food and Drug Administration (FDA), U.S. 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:**

The Company is involved in a patent litigation with Saliva Diagnostic Systems, Inc. (“SDS”), the assignee of a patent related to a method for collecting samples. The Company has requested relief from the court that its Sure Check HIV test does not infringe SDS’s patent, that such patent is invalid, and that it is unenforceable due to inequitable procurement. SDS has answered and counterclaimed, alleging that the Company has infringed the patent, which the Company has denied. In the years 2001 through 2003, the Company paid royalties to SDS and took several other actions based upon SDS’s representations regarding its alleged patent.

In response to the Company’s aforementioned request for relief, the Court has decided that it is not yet prepared to rule on the significant issues in the case. The Company does not believe that the Court’s decision adversely affects the strength of its position. Accordingly, we are not presently appealing this decision, although we believe we have a meritorious basis for future appeal. The discovery phase of the litigation is proceeding pursuant to a scheduling order and trial is presently expected to convene in late 2006.

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**NOTE 16 ~~SUBSEQUENT~~ EVENTS**

(a) During January of 2006, holders of Series B Preferred shares converted 6.70680 shares into approximately 550,000 shares of Common Stock.

(b) Please see note 1 *Recent Developments*.

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