

Chembio Diagnostics Inc.  
Form 10KSB  
March 31, 2005

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

**FORM 10-KSB**

**xANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2004

**oTRANSITION 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.)

3661 Horseblock Road, Medford, NY  
(Address of principal executive  
offices)

11763  
(Zip Code)

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

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

Title of each class

Name of each exchange on which  
registered

None

None

Securities  
registered  
pursuant to  
Section 12(g)  
of the Act:  
Common  
Stock, \$0.01  
par value  
(Title of Class)

Indicate by check mark 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

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to file such report), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. [  ]

State issuer's revenues for its most recent fiscal year: \$3,305,932.

As of March 28, 2005, the registrant had 7,048,086 common shares outstanding, and the aggregate market value of the common shares held by non-affiliates was approximately \$ 5,497,507. This calculation is based upon the closing sale price of \$0.78 per share on March 28, 2005.

- Without asserting that any of the issuer's directors or executive officers, or the entities that own 2,173,184, and 229,464 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

We are a developer and manufacturer of lateral flow rapid diagnostic tests that detect infectious diseases. Our products are sold through private distributors as well as public health and non-governmental organizations. The main products that we actively market and that are commercially available today are our three HIV Rapid Tests (Sure Check™ HIV and HIV 1/2 Stat-Pak and HIV 1/2 Stat-Pak Dipstick).

#### **HIV Rapid Tests Commercially Available**

HIV Rapid Tests (Sure Check™ HIV; HIV 1/2 Stat-Pak; HIV 1/2 Stat-Pak Dipstick). Rapid Tests for detection of antibodies to HIV 1 and 2 in finger-stick whole blood, venous whole blood, serum and plasma

#### **Regulatory Status**

We 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 is the only country in which we have significant sales. In December 2004 we completed clinical trials for Sure Check™ HIV and HIV 1/2 Stat-Pak in the U.S. for FDA approval for sales in the U.S. with results that we believe will exceed the performance requirements for U.S. FDA approval. We are pursuing FDA approval for these products and on February 17, 2005 we submitted our Pre-Marketing Approval application to the FDA. Our HIV 1/2 Stat-Pak and HIV 1/2 Stat-Pak Dipstick products were also evaluated by the World Health Organization in 2004. In January 2005 we received a final report that confirms that these products meet the performance criteria 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. We have also received confirmation from the United States Agency for International

#### **Partners Involved in the Product**

Thirteen-year supply and technology transfer agreement with FIOCRUZ-Bio-Manguinhos, an affiliate of the Ministry of Health of Brazil. FIOCRUZ-Bio-Manguinhos will supply product to Brazilian public health market and potentially other markets in the region. Other marketing partners are being actively pursued with a principal focus on those countries that are receiving funding from the United States pursuant to the Presidential Emergency Plan for AIDS Relief and from the United Nations programs and partners.

Development that our Sure Check™  
HIV and HIV 1/2 Stat-Pak have  
met the criteria for being eligible  
for procurements pursuant to the  
President's Emergency Plan for  
AIDS Relief

A majority of our revenues historically 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, 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. We believe that this will result in a substantial reduction of our revenues from these products during 2005 and beyond. 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 Chagas disease, Lyme disease and other products, the aggregate of whose revenues are not material to us.

We also are involved, as described below under "Research and Development," in the development of new products.

**HIV RAPID TESTS:** We believe that our growth will initially come from sales of our rapid HIV tests. Rapid HIV tests help address the problem that a large percentage of individuals tested in public health settings do not return or call back for test results from laboratory tests as they can take at least several days to process. We believe that this group comprises a significant amount of all new infections. We are pursuing FDA approval for these products and on February 17, 2005 we submitted our Pre-Marketing Approval application to the FDA. We have been manufacturing and selling these products since 2001, pursuant to FDA export regulations, to customers in several countries outside the United States. Subject primarily to satisfactory completion of our manufacturing facility inspection in accordance with FDA requirements, we believe that FDA approval can be achieved in 2005.

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 other competitive rapid HIV tests, require that the finger-stick whole blood sample first be transferred to the test device. However, HIV 1/2 Stat-Pak is value priced and more flexible than Sure Check™ for samples of venous whole blood, plasma and serum. HIV 1/2 Stat-Pak Dipstick is our most economical format and also flexible as to sample types. 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.

**CHAGAS RAPID TEST:** Chembio has completed development of a rapid test for the detection of antibodies to Chagas Disease. This product was developed in collaboration with a consortium of researchers in Latin America. Chagas Disease is found only in Latin America and is named after Carlos Chagas, a Brazilian doctor who first described the disease about 100 years ago. There are estimated to be 16-18 million Chagas Disease cases globally resulting in 21,000 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.

### **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, which 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™.*

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.** Market growth in the demand for rapid testing for HIV and tuberculosis in affected developing countries is largely dictated by the availability of donor funds such as those funds administered and distributed pursuant to the United States Presidential Emergency Plan for Aids Relief, the Joint United Nations Programme on HIV/AIDS, and other governmental and non-governmental programs that fund testing for HIV and tuberculosis. According to the Joint United Nations Programme on HIV/AIDS 2004 Report on the Global AIDS Epidemic, knowledge of HIV status is the gateway to AIDS treatment. The Joint United Nations Programme on HIV/AIDS report further states that a routine offer of HIV testing by health care providers should be made to all patients in sexually transmitted disease clinics, maternal and child health clinics, and health care settings where HIV is prevalent. In 2003 the World Health Organization and the Joint United Nations Programme on HIV/AIDS announced the “Three by Five” initiative, with the goal of treating three million people living with HIV/AIDS by the end of 2005. According to the Global Business Coalition on HIV/AIDS, to achieve having 3 million people on treatment by 2005, each day 5,000 people need to be brought onto treatment and kept on it. In order to achieve this, the Global Business Coalition on HIV/AIDS states that each day about 500,000 people will need to be tested. This estimate assumes that in high prevalence countries about 50,000 people would test positive and that 10% of those, approximately 5,000 people, will require immediate access to life-saving medications.

**Tuberculosis Rapid Tests.** Also according to the Joint United Nations Programme on HIV/AIDS 2004 Report on the Global AIDS Epidemic, in many countries where AIDS has hit hardest, tuberculosis is the leading cause of death in people living with HIV. In HIV positive patients, the reliability of existing diagnostic methods is reduced. The Joint United Nations Programme on HIV/AIDS report states that intensifying tuberculosis case-finding in HIV testing and counseling centers and in other HIV service outlets is essential. Detection of antibodies to active pulmonary tuberculosis in blood samples has never been achieved to a level of accuracy for this diagnostic method to be used effectively in countries with prevalence of this disease. Our efforts are focused on establishing clinical data that show that our test can detect a statistically meaningful number of patients that are not detected from the standard sputum smear method. We also intend to develop a dual parameter HIV/TB test once we establish the clinical performance of our TB test on a stand alone basis.

**Chagas Rapid Test.** Chembio had developed this test several years ago but the market for the product was not meaningful as most prevention efforts 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 the need to screen in rural populations. 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.** Our products under development with partners in the areas of mad cow disease, dental bacteria, veterinary tuberculosis, and cerebral spinal fluid leak detection reflect our business strategy of leveraging our core competency, which is in the development and manufacture of lateral flow rapid diagnostic tests, and diversifying our markets beyond the HIV, human tuberculosis and Chagas Disease markets, which are primarily donor-funded markets. We do not necessarily have an expertise in assessing the markets in each of these new product undertakings, and so we often are relying on the market knowledge and position that our chosen partners have in these fields.



## **Distribution Channels**

We seek to establish product development, exclusive manufacturing and/or technology transfer collaborations with organizations that are well positioned to access the markets for these products as well as strong distribution partners as is warranted.

In February of 2004 we signed an agreement with FIOCRUZ-Bio-Manguinhos, an affiliated entity of the Brazilian Ministry of Health. This agreement provides for a three-year period during which Chembio will transfer its know-how for the production and assembly of its HIV 1/2 Stat-Pak and during which period Bio-Manguinhos will purchase a minimum of approximately 1 million tests from us. The know-how transfer process has begun. The tests that will be purchased will initially be fully completed and assembled at Chembio, but will increasingly during this three-year period have components assembled and manufactured by Bio-Manguinhos in Brazil. Chembio will receive a royalty of 5% on net sales for ten years following completion of the technology transfer. Approximately 450,000 tests were purchased through December 31, 2004, and we anticipate receiving orders for an additional 300,000 units in the first half of 2005.

We are seeking to leverage the experience we have in Brazil by establishing other local assembly and technology transfer collaborations for our HIV tests where local demand and labor conditions justify such ventures. We are also seeking to have our HIV tests evaluated and used in programs for voluntary counseling and testing and prevention of mother to child transmission testing. The programs we are pursuing are overseen and/or led by the United States Centers for Disease Control Global Aids Program, the United States Agency for International Development, United Nations-affiliated programs including the World Health Organization, the health ministries and national AIDS control organizations in the host countries, and many other local and multi-national non-governmental and private organizations. The main programs that are administered by these organizations are the Presidential Emergency Plan for AIDS Relief and the United Nations Global Fund for HIV/AIDS, TB and Malaria, respectively, and they constitute a large percentage of the world wide funding for HIV prevention and treatment programs in the developing world. As a result of evaluations undertaken in 2004 by these agencies, we have been notified by the United States Agency for International Development and the World Health Organization that our HIV rapid tests are eligible for procurements made through their programs. This eligibility was critical to our actively pursuing participation in these programs, and we are now actively pursuing such participation. Our distribution and marketing strategy for our existing HIV rapid tests and for our human tuberculosis rapid tests under development will include seeking direct purchases by governmental and non-governmental organizations, commercial relationships with distributors, and/or partnering for local production and assembly in key markets.

The market for the non-human primate tuberculosis test that we have developed, and for which we will begin clinical testing by the first quarter of 2005, primarily consists of pharmaceutical research facilities and zoos. This market represents a small number of total customers. Accordingly, we are considering a direct marketing strategy as well as considering working with a distributor of products to this customer base.

In the case of our mad cow and dental bacteria products that are still under development (see "Research & Development"), if we are successful in completing those products in collaboration with others, and if the products receive the requisite regulatory clearances, then we will have the right to manufacture them and the collaborating entities will have marketing and distribution rights.

## **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:

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- 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, particularly where we can have our product development efforts funded on a project or milestone basis. We believe that our proprietary know-how in lateral flow technology has been instrumental in our obtaining the collaborations we have developed in mad cow disease and dental bacteria.

We have 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, we have hired employees and consultants that collectively have that experience with other companies. We believe this will be very helpful in our obtaining these approvals and in ensuring that we manufacture our products in accordance with FDA 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.

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 HIV 1/2 Stat-Pak, HIV 1/2 Stat-Pak Dipstick, and Sure Check™ HIV rapid tests are very competitive with the best products in the market on the basis of these competitive factors.

Significant direct competitors for our Sure Check™ and HIV 1/2 Stat-Pak rapid HIV tests are Abbott Diagnostics, Orasure Technologies, Inc. and Trinity Biotech Plc. Orasure and Trinity have HIV rapid tests that are FDA approved. In addition there are a number of other companies that have HIV rapid tests, including others based in the U.S., that are seeking FDA approval.

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**

Our research and development activities have been in four areas, all related to lateral flow rapid diagnostic product development: HIV, Bovine Spongiform Encephalopathy, which is also known as mad cow disease, dental bacteria, and tuberculosis. We have also entered into research and development collaboration with The State University of New

York at Stony Brook for the development of a marker for the detection of Cerebral Spinal Fluid Leak and also have begun other preliminary collaborations that are related to new lateral flow platforms and related instrumentation.

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We have collaborated with Prionics AG, Zurich, Switzerland since late 2002 to develop and produce certain components of a rapid test for mad cow disease to be marketed by Prionics and/or their distributors under their name. In March 2004 we signed a contract to be one of two contract manufacturers of this product following Prionics' transfer of the completed product know-how to us and approval of the product in Europe. These steps are in process but have not been completed. The contract is for three years, which begins when the product approval is granted in Europe. Although we expected that the technology transfer and European regulatory approval would be completed in 2004, and that initial sales would occur in 2005, we cannot estimate the timing and extent of these events as there are many factors that are beyond our control that could delay this timetable, including delays or changes in regulatory requirements, delays in the technology transfer or changes to the product specifications. In this connection, on February 14, 2005, we entered into a license agreement by which Prionics will license certain technology owned by Chembio. The agreement provides for certain additional milestones for technology transfer which will need to be successfully concluded in order for the Supply Agreement to be maintained in full force and effect, as Prionics has indicated that it needs Chembio's technology in order to complete the know-how transfer in a way such that the product can be manufactured reproducibly.

Moreover, even once the product is approved in Europe, we do not control the marketing of the product, and we will have limited information about the marketing and distribution strategy of Prionics AG, including competitive products, market size and Prionics' existing market share, although we do expect to receive supply requirements forecasts from Prionics if and when the technology transfer is complete and the product is approved.

In the dental bacteria test, we have a contract with Ivoclar-Vivadent, Schaan, Liechtenstein to develop a rapid test that can detect different levels of bacteria found in saliva samples that have been found to be associated with tooth decay. The test employs intellectual property developed at the University of California Los Angeles Dental School for which Ivoclar-Vivadent is the exclusive licensee. Our contract with Ivoclar-Vivadent provides for a three-phase development program for which we are being compensated a total of \$180,000. We are now in the second phase but have experienced some delays related to non-specific binding for one of the antibodies provided Chembio. We are currently discussing next steps with representatives of each of the aforementioned parties.

If the development program results in a completed product in accordance with Ivoclar-Vivadent's specifications, then we will be the exclusive manufacturer and Ivoclar-Vivadent will have exclusive marketing and distribution rights. The contract is for five years and may be renewed by Ivoclar-Vivadent for an indefinite number of two-year renewals. Our contract with Ivoclar-Vivadent contemplates that the product development was to be completed in 2004, and that regulatory approvals and products launch would occur in 2005. However, there are factors beyond our control that make it impossible to predict the timing, nature and extent of revenues from this product, if any.

Our tuberculosis rapid tests for humans are being designed to significantly increase the accuracy of existing tuberculosis screening methods. Our initial tuberculosis test was developed pursuant to a Phase I and II Small Business Innovative Research grant from the National Institute of Health with Public Health Research Institute, Newark, New Jersey that was in place from 1998 until 2002, and our test was completed in 2003. In 1998 we entered into a license agreement with Public Health Research Institute which provides for us to pay a royalty on sales of our antibody detection tuberculosis tests that incorporate any of the antigens covered by the agreement. A study of our serological test for active pulmonary tuberculosis in humans by Sumitomo Seiyaku Biomedical of Japan has shown that sensitivity can increase from 45% to 82% when used in combination with the sputum smear method (the current standard in high incidence settings), and from 45% to 91% when used with the two-step confirmatory combination of sputum smear and culture testing. However, several other studies have shown less favorable results. We know that serological testing for tuberculosis is very complex and challenging, and we therefore believe that much further testing in a variety of geographic settings will be needed in order to confirm the performance of this test across diverse populations. Our test is being included in an evaluation being conducted by the Institute of Tropical Medicine, Antwerp, Belgium on behalf of the World Health Organization during the first half of 2005. The timing and results of this evaluation cannot be predicted and therefore the timing and extent of any sales that would be derived from this

product can also not be estimated at this time.

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 are planning to submit this product for approval to the United States Department of Agriculture during the first quarter of 2005. 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. However, we do not anticipate any material revenues from these efforts during 2005.

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Our HIV development efforts are on a next generation rapid test that can detect cases even earlier than all currently marketed rapid tests do without compromising the specificity of the test. A prototype has been developed and needs to undergo substantial revision and optimization. No reagent license agreements are in place with regard to the materials used in this prototype at this time. We do not anticipate any material sales from this product line in 2005 and most of 2006.

The foregoing research and development efforts are summarized below:

<b>Existing or Proposed Product</b>	<b>Regulatory Status</b>	<b>Development Status</b>	<b>Partners involved in the development or marketing of the products</b>
Rapid test for detection of Bovine Spongiform Encephalopathy, also known as mad cow disease, in cattle	Not yet submitted for approval	Under development	Prionics AG, Zurich, Switzerland
Dental Bacteria Test	Not yet submitted for approval	Phase 2 (Optimization of Test)	Ivoclar-Vivadent, AG, Schaan Liechtenstein
Tuberculosis Stat Pak II- rapid diagnostic test for detection of antibodies to active pulmonary tuberculosis in human whole blood samples	Not yet submitted for approval	Product validation completed	Public Health Research Institute and Statens Serum Institute
TBD Non-Human Primate Rapid Tuberculosis Test for the detection of antibodies to active pulmonary tuberculosis in non-human primate whole blood samples	Not yet submitted for approval	Product validation completed	Sequella Corporation, Rockville, Maryland
Combination HIV/Tuberculosis Rapid Test for the detection of antibodies to active pulmonary tuberculosis and HIV in human whole blood samples using different color latex test lines	Not yet submitted for approval	Initial Prototype	None
New Generation HIV Test	Not yet submitted for approval	Initial Prototype	None
Cerebral Spinal Fluid Leak Test	Not yet submitted for approval	Initial R&D on Monoclonal Antibodies	State University of New York at Stony Brook

During 2004 and 2003, \$1,433,403 and \$313,891, 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.

**Research & Development Expenditures**

	<b>2004</b>	<b>2003</b>
Human Tuberculosis	\$ 99,675	\$ 59,491
Veterinary Tuberculosis	354,473	116,239
HIV	823,596	36,400
Dental, Mad Cow, and Other	155,659	101,761
<b>Totals</b>	<b>\$ 1,433,403</b>	<b>\$ 313,891</b>

**Employees**

At December 31, 2004, we employed 60 people, including 58 full-time employees. In May 2004, we entered into employment agreements with Lawrence Siebert, President and Chairman, Avi Pelosof, VP Sales, Marketing and Business Development, and Javan Esfandiari, Director of research and development. We also entered into an employment agreement with Mark L. Baum, a member of our board of directors, to provide advice and guidance with respect to 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.



## **Governmental Regulation**

All of Chembio's existing and proposed diagnostic products are regulated by the FDA, U.S. Department of Agriculture, 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. All of Chembio's FDA - and U.S. Department of Agriculture - regulated products require some form of action by that agency before they can be marketed in the United States, and, after approval or clearance, Chembio must continue to comply with other FDA requirements applicable to marketed products. Both before and after approval or clearance, failure to comply with the FDA's requirements can lead to significant penalties.

Most of Chembio'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 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.

Biologic products must be the subject of an approved biologics license application before they can be marketed. The FDA approval process for a biologic product is similar to the pre-market approval process, involving a demonstration of the product's safety and effectiveness based in part on both preclinical and clinical studies.

Chembio's HIV rapid tests are considered by FDA to be a biologic and will therefore be submitted to the biologics division of FDA, the Center for Biologics Evaluation and Research.

Every company that manufactures biologic products or 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 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 applicable to the category of examination or procedure performed. Although a certificate is not required for Chembio, Chembio considers the applicability of the requirements of the Clinical Laboratory Improvement Act in the design and development of its products. A Clinical Laboratory Improvement Act waiver will remove certain quality control and other requirements that must be met for certain customers to use Chembio'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) accords to 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 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 premarket 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.

Chembio 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 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. The extent of potentially adverse governmental regulation affecting Chembio that might arise from future legislative or administrative action cannot be predicted.

Chembio'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 has received an FDA Investigational Device Exemption to begin clinical trials for the Sure Check™ HIV and HIV 1/2 Stat Pak rapid tests and is currently beginning clinical trials as the initial step toward FDA approval of these products.

In October of 2004 the Company issued a voluntary recall of approximately 100,000 pregnancy tests. As a precautionary measure, the recall was expanded on November 3, 2004 to include approximately 215,000 additional pregnancy tests. These recalls resulted from a determination that we made that the seals on some of the pouches that were used for packaging pregnancy tests during a certain period from March through August were in many cases deficient, resulting in product degradation in certain cases. Although our investigation established that some of the lots pouched within this time period were within specification, we decided, as a precautionary measure, to recall all of them. The deficiency has been corrected, we have revalidated our entire pouching operation, and we also increased final product testing as well. As of December 31, 2004 the Company has estimated the total impact of this recall to be approximately \$100,000 which includes an accrual of \$60,264 as of December 31, 2004.

## **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.

*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.

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. We also have licensed the antigens used in our tuberculosis and Chagas disease tests.

**Legal Issues**

*FTC Matter*

On February 27, 2001, a "Stipulated Final Order for Permanent Injunction and Other Equitable Relief" was signed and entered by the United States District Court for the Eastern District of New York. The stipulation is a settlement agreement between Chembio Diagnostics, Inc. and the United States Federal Trade Commission arising out of certain events that occurred in 1999. The events resulted in allegations by the FTC that Chembio Diagnostics, Inc. misrepresented performance claims relating to a previous generation of its HIV test kits. Chembio Diagnostics, Inc. denied these allegations. Nevertheless, due to the nature of the product and other circumstances, this matter consumed a very substantial amount of Chembio Diagnostics, Inc.'s resources from mid-1999 through the beginning of 2001. Because an even greater expense would have had to be incurred in litigating this matter against an agency with virtually unlimited resources and because Chembio Diagnostics, Inc. was able to negotiate a settlement that it deemed acceptable and in Chembio Diagnostics, Inc.'s best interest, the settlement was concluded. The stipulation requires Chembio Diagnostics, Inc., among other things, to not misrepresent product performance claims, to not make any claims without "competent and reliable scientific evidence" as substantiation for such claims and to also comply with mandated record keeping, notification, and monitoring provisions. The settlement agreement further provides that Chembio Diagnostic Systems Inc. must provide all of its principals, officers, directors, managers and all other employees of Chembio Diagnostic Systems Inc. having responsibilities related to Chembio Diagnostic Systems Inc.'s business with a copy of the settlement agreement and must have them acknowledge the receipt of the settlement agreement. The settlement specifically states that Chembio Diagnostic Systems Inc. does not admit that it made any statements or took any other action that was a violation of law. The record-keeping, notification and monitoring provisions of the stipulation have a term of five years from the date of the stipulation, or February 27, 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.

### **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 \$7,224 per month. The space is utilized for R&D (approximately 1,500 square feet), offices (approximately 2,700 square feet) and production (approximately 9,800 square feet). The lease term expires on April 30, 2005. We are completing a new lease for two years with an option for two more years. The rent in this new lease is expected to be \$8,167 per month. We believe the space is adequate for our immediate needs. 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. Please refer to the section of this prospectus entitled "Description of business—Our business following the merger—Certain legal and intellectual property issues" for a discussion of some of the legal issues we face. 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 Dispute.* An integral part of our business plan is the manufacture and sale of our Sure Check™ HIV rapid test product which incorporates a sample collection method that provides conveniences in terms of ease of use and safety. Until May 2003, Sure Check™ was known as "Hema Strip." Hema Strip was manufactured by Chembio Diagnostic Systems Inc. pursuant to a manufacturing agreement between Chembio Diagnostic Systems Inc. and Saliva Diagnostic Systems, Inc. The contract with Saliva Diagnostic was based upon, among other things, a patent that Saliva Diagnostic owns that was represented by Saliva Diagnostic to cover the sample collection method employed by the Hema Strip and which patent Saliva Diagnostic also represented to be valid and enforceable. Saliva Diagnostic unilaterally terminated the manufacturing agreement and alleged patent infringement by Chembio Diagnostic Systems Inc. We believe that the aforementioned patent did not cover the sample collection method used by the Hema Strip. We also believe that the Saliva Diagnostic patent was not valid due to the existence of previously uncited prior art.

On March 17, 2004, Saliva Diagnostic made further allegations of patent infringement against Chembio Diagnostic Systems Inc. In connection with the foregoing, Chembio Diagnostic Systems Inc. filed a complaint against Saliva Diagnostic in the United States District Court for the Eastern District of New York on March 18, 2004 (Civil Action No. 04-1149-JS-ETB). The complaint asks the court for declaratory and other relief that our Sure Check™ HIV test does not infringe the Saliva Diagnostic patent, that the Saliva Diagnostic patent is invalid, and that the Saliva Diagnostic patent is unenforceable due to inequitable procurement. On April 8, 2004, Saliva Diagnostic filed its answer and counterclaim, alleging that we were infringing on the Saliva Diagnostic Patent. We filed our Reply to Counterclaim on May 3, 2004, denying the allegation of infringement of the Saliva Diagnostic Patent. Briefs regarding the meaning of the claims of the Saliva Diagnostic Patent were filed February 28, 2005, and oppositions to those briefs were filed on March 9, 2005. A ruling on the meaning of the claim terms will then be issued by the court. Fact discovery is due to be completed by March 31, 2005, but may be extended depending on the date the court issues the claim construction ruling.



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

There were no matters submitted to a vote of security holders during the Company's fourth quarter ended December 31, 2004.

**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 2004</b>	<b>High Bid</b>	<b>Low Bid</b>
First Quarter	\$3.00	\$0.34
Second Quarter	\$2.00	\$1.00
Third Quarter	\$1.54	\$1.01
Fourth Quarter	\$1.29	\$0.55

  

<b>Fiscal Year 2003</b>	<b>High Bid</b>	<b>Low Bid</b>
First Quarter	\$0.34	\$0.17
Second Quarter	\$0.51	\$0.17
Third Quarter	\$0.34	\$0.17
Fourth Quarter	\$1.36	\$0.17

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). The Penny Stock Rules 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, 2004, there were approximately 104 record owners of our common stock.

## Dividends

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

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

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

The certificates of designation authorizing 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

There have been no sales of unregistered securities within the last three years, which would be required to be disclosed pursuant to Item 701 of Regulation S-B, except for the following:

On May 5, 2004, pursuant to the Agreement and Plan of Merger (the "Merger Agreement"), dated as of March 3, 2004, as amended as of May 3, by and among privately held Chembio Diagnostic Systems Inc. ("Chembio Diagnostic Systems"), a Delaware corporation, Chembio Diagnostics, Inc. (formerly, Trading Solutions.com, Inc.), a publicly traded Nevada corporation ("the Company"), and New Trading Solutions, Inc., a wholly owned subsidiary of the Company ("Merger Sub"), the Merger Sub merged with and into Chembio Diagnostic Systems, with Chembio Diagnostic Systems remaining as the surviving corporation (the "Merger"). Pursuant to the Merger, the Company issued 4,000,000 shares of its restricted common stock, 704,000 options and warrants to purchase 690,000 shares of its common stock to the stockholders of Chembio Diagnostic Systems in exchange for 100% of their issued and outstanding common stock, options and warrants to purchase Chembio Diagnostic Systems' common stock. The Company relied on Regulation D promulgated under Section 4(2) of the Act and on Section 4(2) of the Act as the basis for its exemption from registration of this offering. 44 accredited and only 3 non-accredited investors received securities of the Company in the Merger. All of the stockholders of Chembio Diagnostic Systems, including the non-accredited investors, were provided with an information statement meeting the informational requirements of Rule 502 (b)(2) of the Securities Act.

On May 5, 2004 the Company issued warrants to designees of H.C. Wainright & Co., Inc. to purchase 751,667 shares of our common stock and to designees of Wellfleet Partners, Inc. to purchase 183,333 shares of our common stock, our placement agents in the series A preferred stock private placement, at exercise prices of \$0.72 and \$1.08. In addition, designees of Wellfleet Partners received 59,000 shares of common stock and an individual finder received 6,667 shares of common stock.



At or about the time of the Merger, the Company consummated three private placements of its 8% Series A Convertible Preferred Stock as follows: (i) shares of series A preferred and warrants were sold for cash (the “Cash Offering”); (ii) shares of series A preferred and warrants were exchanged, as described herein, for conversion of the Bridge Notes (the “Bridge Conversion Offering”), and (iii) shares of series A Preferred and warrants were exchanged, as described herein, for conversion of the existing debt of Chembio Diagnostic Systems (the “Existing Debt Exchange Offering”). These placements are described below:

- (i) *The Cash Offering.* A total of 73.33330 shares of series A preferred stock and warrants to acquire 4,400,000 shares of common stock at \$.90 per share were issued pursuant to the Cash Offering in May 2005 for total consideration of \$2,200,000. The Company relied on Regulation D promulgated under Section 4(2) of the Act and on Section 4(2) of the Act as the basis for its exemption from registration of this offering. Nine accredited and zero non-accredited investors received securities of the Company in the offering. All of the investors, including the non-accredited investors, were provided with an information statement meeting the informational requirements of Rule 502 (b)(2) of the Securities Act.
- (ii) *The Bridge Conversion Offering.* On March 22, 2004, Chembio Diagnostic Systems completed a private placement (the “Bridge Financing”) of \$1,000,000 in face amount of Convertible Notes (the “Bridge Notes”). The Bridge Financing provided for the Bridge Note holders to elect whether to convert the Bridge Notes into shares of the Company’s series A preferred stock (together with warrants to acquire shares of the Company’s common stock) or into shares of the Company’s common stock at the effective time of the Merger. As a result, \$672,000 in principal amount of the Bridge Notes, together with accrued and unpaid interest, was converted into 33.83632 shares of the Company’s series A preferred stock (together with warrants to acquire an additional 2,030,217 shares of the Company’s common stock at \$.90 per share). The balance of the Bridge Financing, or \$328,000, was converted into 826,741 shares of the Company’s common stock. The Company relied on Regulation D promulgated under Section 4(2) of the Act and on Section 4(2) of the Act as the basis for its exemption from registration of this offering. 33 accredited and zero non-accredited investors received securities of the Company in the offering. All of the investors, including the non-accredited investors, were provided with an information statement meeting the informational requirements of Rule 502 (b)(2) of the Securities Act.
- (iii) *The Existing Debt Exchange Offering.* Pursuant to the Existing Debt Exchange Offering, which was consummated at the effective time of the Merger, the Company issued 44.40972 shares of series A preferred stock and warrants to acquire 2,664,584 shares of common stock at \$.90 per share in exchange for the conversion of \$1,332,292 of Chembio Diagnostic Systems’ debt existing on its balance sheet as of December 31, 2003. On December 29, 2004 the Company converted \$361,559 of additional debt into 12.05199 shares of series A preferred stock and associated warrants to purchase 723,120 shares of common stock. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration. Eleven accredited and zero non-accredited investors received securities of the Company in these offerings. All of the investors were provided with an information statement meeting the informational requirements of Rule 502 (b)(2) of the Securities Act.

In May 2004, the Company issued options to acquire 100,000 shares of common stock to Lawrence Siebert, of which 50,000 options vest in one year with an exercise price of \$1.20 per share and of which 50,000 options vest in two years with an exercise price of \$1.50 per share. In May 2004, the Company issued options to acquire 200,000 shares of common stock to Avi Pelosof, of which 100,000 options are immediately exercisable with an exercise price of \$0.60 per share, of which 50,000 options vest in one year with an exercise price of \$0.90 per share, and of which 50,000 options vest in two years with an exercise price of \$1.35 per share. The Company also issued options to acquire 75,000 shares of common stock to Javan Esfandiari, one-third of which vests in one year with an exercise price of \$0.90 per share, one-third of which vests in two years with an exercise price of \$1.20 per share, and one-third of which vests in three years with an exercise price of \$1.50 per share.

Also in May, 2004, the Company issued 25,000 shares of common stock and options to acquire 150,000 shares of common stock with an exercise price of \$0.60 per share to a consultant for services performed. One-quarter of these options vested on July 1, 2004, and an additional one-quarter vests every six months until January 1, 2006. The Company also issued options to acquire 30,000 shares to a second consultant for services performed, of which 2,500 options vest each month beginning June 15, 2004 with an exercise price of \$1.00 per share.

In June 2004, the Company issued options to acquire 20,000 shares of common stock with an exercise price of \$1.00 per share to a consultant for services performed. The Company issued to this same consultant options to acquire 20,000 shares of common stock with an exercise price of \$1.50 and options to acquire 5,000 shares of common stock at \$2.00 per share, all of which vest in one year.

In early June 2004, the Company agreed with Patton Boggs LLP, a law firm providing legal services to the Company, that the Company would pay for \$27,989 of its outstanding bill for previously provided legal services with 37,319 shares of the Company's restricted common stock. The Company relied on Regulation D promulgated under Section 4(2) of the Act and on Section 4(2) of the Act as the basis of its exemption from registration for this transaction. The firm receiving the shares is an accredited investor.

The Company issued 303,145 shares of common stock on November 15, 2004 as payment of dividends on the series A preferred stock. No cash was exchanged in this issuance. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance. The investors in the issuance were accredited investors of the Company.

On December 9, 2004, the Company entered into a contract with an investor relations company, as part of the terms of this contract the Company issued 56,250 shares of common stock. No cash was exchanged in this issuance. The Company issued an additional 20,000 shares of common stock to the investor relations company on March 9, 2005. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance. The investor in the issuance was an accredited investor of the Company.

On December 13, 2004 the Company issued options to purchase 50,000 shares of common stock (25,000 exercisable immediately and 25,000 exercisable July 1, 2005 with an exercise price of \$1.00 and \$1.50 per share respectively. The options expire on December 13, 2011) to an employee. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance. The investor in the issuance was an accredited investor of the Company.

On December 30, 2004 a major shareholder exercised warrants to purchase 66,869 shares of common stock. The exercise price was \$0.45 per share and the Company received \$30,091 in cash for this exercise. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance. The investor in the issuance was an accredited investor of the Company.

On January 28, 2005, the Company sold for \$5,000,000, in a private placement, 100 shares of our 9% Series B Convertible Preferred Stock together with warrants to purchase 7,786,960 of the Company's common stock. For each \$.61 invested in this Private Placement, an investor received (a) \$.61 of face amount of series B preferred stock, which is convertible into one share of the Company's common stock, and (b) a five-year warrant to acquire .95 of a share of the Company's common stock. Each full share of the series B preferred stock was purchased for \$50,000, with fractional shares of Series B Stock being purchased by investments of less than \$50,000. In connection with the private placement, the Company issued to the placement agent, Midtown Partners & Co., LLC, or its designees, shares of series B preferred stock in an aggregate amount equal to 5% of the amount of cash proceeds from the private placement, together with accompanying warrants to purchase common stock. The Company also issued to Midtown Partners & Co., LLC, or its designees, warrants to purchase 737,712 shares of the Company's common stock exercisable for a period of five years from their issuance and have an exercise price of \$.80 per share. The Company relied on Section 4(2) of the Securities Act of 1933 and Rule 506 promulgated thereunder as the basis for its exemption from registration of this issuance. All of the investors in the offering are accredited investors as defined under Rule 501 promulgated under the Securities Act of 1933.

In connection with the series B private placement, three of the investors in the series A preferred stock collectively purchased a .95 share of series B preferred stock, convertible into 77,868 shares of common stock, together with

warrants to acquire 73,972 shares of common stock. In addition, one investor in our series A preferred stock converted all of his interests in the series A preferred stock for a .4 share of series B preferred stock, convertible into 32,786 shares of common stock, together with warrants to acquire 38,933 shares of common stock.



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

This discussion and analysis should be read in conjunction with the accompanying Consolidated Financial Statements and related notes. Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of any contingent liabilities at the financial statement date and reported amounts of revenue and expenses during the reporting period. On an on-going basis we review our estimates and assumptions. Our estimates were based on our historical experience and other assumptions that we believe to be reasonable under the circumstances. Actual results are likely to differ from those estimates under different assumptions or conditions, but we do not believe such differences will materially affect our financial position or results of operations. Our critical accounting policies, the policies we believe are most important to the presentation of our financial statements and require the most difficult, subjective and complex judgments, are outlined below in "—Critical Accounting Policies," and have not changed significantly.

In addition, certain statements made in this report may constitute "forward-looking statements". These forward-looking statements involve known or unknown risks, uncertainties and other factors that may cause 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 Diagnostic Systems, Inc., our 100% wholly-owned subsidiary. Prior to our merger with Chembio Diagnostics Systems, Inc. in early May 2004, we had no assets or liabilities and no operations. As a result of the merger, we added the assets, liabilities and business and operations of Chembio Diagnostics Systems, Inc. We sold substantially all of the business related to our private label pregnancy test and we are focusing on developing products and then obtaining applicable clearances or approvals in the areas of rapid tests for HIV, tuberculosis, mad cow disease and dental disease. We either have or are pursuing collaborative agreements that may include distribution arrangements in each of these areas. We believe that our research and development, manufacturing overhead, selling, marketing and general and administrative costs will increase as we create the necessary infrastructure to focus in these new areas.

**RESULTS OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2004 AS COMPARED WITH THE  
YEAR ENDED DECEMBER 31, 2003**

Revenues were \$3,305,932 for the year ended December 31, 2004 as compared with \$2,818,351 for the year ended December 31, 2003, representing an increase of \$487,581, or 17.3%. Revenues are comprised of \$2,749,143 in net sales and \$556,789 in grants and development income for the year ended December 31, 2004 as compared with \$2,542,621 in net sales and \$275,730 in grant and development income for the year ended December 31, 2003. The increase in revenues is primarily attributable to increased sales of our HIV products (\$730,844 increase) as well as increased income from contracts and grants (\$281,059 increase). The increases were partially offset by reduced pregnancy test kit sales (\$383,313 decrease). A substantial portion of the grant-related income will recur in 2005.

Cost of goods sold for the year ended December 31, 2004 was \$2,485,593, or 90.4% of net sales, as compared with \$2,153,454, or 84.7% of net sales, for the year ended December 31, 2003. The resulting decrease in gross margin is primarily attributable to ongoing under-utilization of manufacturing overhead as well as various charges and costs which were associated with the process of selling our pregnancy test business during 2004. These costs were higher than anticipated when we were required to continue to produce to maintain customers that were being transferred to the buyer after we had transferred labor cost-saving assembly equipment to the buyer. This occurred because of delays in product registration by the buyer that were not anticipated. The impact of these factors was particularly evident in the third quarter when we had very low product sales volume, an unfavorable product sales mix, and costs associated with the product line transfer. We also took a \$41,000 reserve against certain inventory for product related to our pregnancy test business at year-end considered obsolete. In addition, charges aggregating \$100,000 were taken in connection with the voluntary recall of pregnancy tests that we undertook during the fourth quarter. Finally, we had increased costs due to the creation of separate quality assurance and quality control departments and the hiring of a new manager to head up the quality assurance department.

Research and development expenses for the year ended December 31, 2004 were \$1,433,403, or 43.4% of revenues, compared with \$313,891, or 11.1% of revenues, for the year ended December 31, 2003. Clinical & Regulatory Affairs, which totaled \$846,969 for the year ended December 31, 2004, accounted for most of this increase. This cost category includes costs incurred for regulatory approvals, clinical studies, product evaluations and registrations. The HIV rapid test clinical studies were completed in December 2004 and these costs are expected to return to substantially reduced levels in the first quarter of 2005. The balance of the increase in expense and associated percentage of revenues is due primarily to increased salaries and wages and related costs of each of the members of the research and development group subsequent to September 30, 2003, as new grants and development contracts were awarded and also due to the addition of an R&D Technician hired in late 2003 for the purpose of fulfilling obligations under grants from the National Institute of Health and World Health Organization as well as other product development contracts.

The status of each of our major research and development projects is as follows:

<b>Project</b>	<b>Rapid Test for Mad Cow Disease</b>
Current status	We are waiting for technology transfer from Prionics AG in order to begin production scale-up, validation and regulatory submission. In February 2005 we entered into a license agreement with Prionics AG related to our licensing certain technology that Prionics desired in order for Prionics to complete the technology transfer to Chembio. Please see footnote 17 (b) of our financial statements.
Nature, timing and estimated costs of the efforts necessary to complete	The timing of production scale-up and validation is anticipated to be approximately three to six months from the date of the completion of the technology transfer. Thereafter, we will incur costs to establish the production capacity required for this product, which we presently anticipate to be approximately \$100,000.
Anticipated completion date	Not known
Risks and uncertainties associated with completing development on schedule, and the consequences to operations, financial position and liquidity if not completed timely	We are relying on technology developed by Prionics and so there is a risk that the product validation will encounter difficulties that at present are not known or foreseeable. The risks associated with the product involve regulatory and technology risks.
Timing of commencement of expected material net cash inflows	It is not known or estimable when net cash inflows from this project will commence due to the uncertainties associated with the completion of the product, regulatory submissions, and the nature and timing of Prionics' distribution network

<b>Project</b>	<b>Dental Bacteria Test</b>
Current status	We expected to complete Phase 2 of the Project Plan (Optimization of Test) and move into Phase 3 (Scale Up of Production and validation) in 2004. However, one of the monoclonal antibodies exhibited a strong unspecific agglutination to other proteins, i.e. to the secondary antibodies being coated on the membrane of the strip test. We are therefore discussing strategies in order to reduce this phenomenon and work will be continued at UCLA and at IVAG, but not at Chembio, because such work is not be covered by the existing budget. We are also considering another detection system which could be applied instead of the lateral flow system and antibodies conjugated to latex beads. Such a system could be based on antibodies labeled with fluorescence markers. However, a correspondent reader would have to be used for an analysis of the risk of caries (dental decay).
Nature, timing and estimated costs of the efforts necessary to complete	In April 2004, Chembio received 80% of the Phase 2 project funding of \$65,000, or \$52,000 and this reflected the estimate of the costs anticipated to be incurred to complete Phase 2 during a three to five month period. It is now assumed that Phase 2 will not be satisfactorily completed and that any additional funding from Ivoclar-Vivadent will be pursuant to a new development contract, which is under discussion. Chembio has completed the level of effort needed to earn the 80% funded.
Anticipated completion date	It is not known at this time whether or how long it will take to develop the product or obtain regulatory approvals in the US, Europe, Japan and other potential markets
Risks and uncertainties associated with completing development on schedule, and the consequences to operations, financial position and liquidity if not completed timely	Technical challenges remain that must be overcome in order for this product to meet the performance specifications that Ivoclar Vivadent had set forth in the Agreement. If we do not achieve the performance specifications, the product will not be completed.
Timing of commencement of expected material net cash inflows	It is not known or estimable when net cash inflows from this project will commence due to the uncertainties associated with the completion of the product, regulatory submissions, and the nature and timing of Ivoclar-Vivadent's distribution network and strategy.

<b>Project</b>	<b>Rapid Test for the detection of antibodies to active pulmonary tuberculosis in non-human primate whole blood samples</b>
Current status	Product validation completed
Nature, timing and estimated costs of the efforts necessary to complete	We have substantially completed preparation of the documentation that is required in order to submit an application to the United States Department of Agriculture for the approval of the product and of our facility where it will be manufactured. We have engaged an outside consultant that was previously employed by the USDA to assist our internal staff in this submission. We anticipate that the application will be submitted to the USDA by the end of March 2005.
Anticipated completion date	We anticipate that we could have USDA approval by the end of 2005.
Risks and uncertainties associated with completing development on schedule, and the consequences to operations, financial position and liquidity if not	The requirements for clinical testing and the outcomes of such clinical testing can not be known at this time, and this information poses substantial risk and uncertainty as to whether or when this product will contribute to the operations, financial position and liquidity.

completed timely

Timing of commencement of expected material net cash inflows	It is not known or estimable when net cash inflows from this project will commence due to the uncertainties associated with the completion of the product, regulatory submissions, and without further progress on a distribution strategy.
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The other tuberculosis products that are under development, as well as the combination HIV/tuberculosis rapid test and the New Generation Rapid HIV Test, are either at an early stage of research and development, have a limited amount of resources being applied, and/or involve a substantial amount of uncertainty as to the completion of the product. There is no expectation of material revenues in 2005 from any of these products.

Selling, general and administrative expense increased \$1,288,113 to \$2,490,298 for the year ended December 31, 2004 compared with \$1,202,185 for the year ended December 31, 2003. This increase is primarily attributable to \$305,198 of non-cash expenses reflecting the fair value of common stock and options issued as compensation to employees during the first and second quarters of 2004, \$62,450 for recruiting expenses incurred in the hiring of quality, manufacturing and regulatory personnel and \$186,485 additional costs for marketing consultants. Also driving this increase were \$164,000 in cash salary increases to employees (the addition of a new Chief Financial Officer as well as general increased salary to administrative and marketing personnel), and increased legal and accounting expenses of \$188,400 relating to the merger, registration process and required quarterly SEC filings. Increased commissions relating to the Bio-Manguinhos contract totaled \$271,300. The balance of the increase, or \$110,280, is primarily attributable to increased travel costs related to HIV rapid test marketing efforts.

Components of other income and expense include the following; interest expenses decreased by \$17,974 for the year ended December 31, 2004 compared with the year ended December 31, 2003. This was primarily attributable to the conversion of \$1,332,292 of existing debt of Chembio Diagnostic Systems, Inc, at the time of the merger which reduced interest expense by \$78,624. This was offset by a non-cash expense related to the issuance of 140,000 warrants to existing debt holders of Chembio Diagnostic Systems, Inc. which increased interest expense by \$60,650. Additional components of other income and expense include the retirement and transfer of assets in the fourth quarter of 2004 which resulted in a loss of \$22,469. In addition, approximately \$209,000 is attributable to settlements of old outstanding payables due that were settled during the second quarter of 2004 are reflected in other income as forgiveness of debt.

## LIQUIDITY AND CAPITAL RESOURCES

We began to improve our liquidity and capital resources position during the first quarter of 2004 as a result of the completion of a \$1,000,000 convertible bridge note offering in March in anticipation of our merger. As a result of the completion of the merger, \$328,000 of the \$1,000,000 of convertible bridge notes was converted into 826,741 shares of common stock at \$.40 per share, and the balance of \$672,000 was converted into 33.83682 shares of series A preferred stock. Simultaneous with that conversion, 73.33330 shares of series A preferred stock were issued for \$2,200,000 in cash, and an additional \$1,332,292 of debt to our note holders was converted into 44.40972 additional shares of the series A preferred stock. The values mentioned above for the series A preferred stock have been allocated between the series A preferred stock and the detachable warrants. Together, before accounting for costs and expenses associated with these transactions, these events resulted in recording new redeemable preferred stock and equity capital of approximately \$4,532,292 (\$2,200,000 cash, \$1,000,000 from converted bridge debt and \$1,332,292 from converted existing debt). In addition on December 29, 2004 the balance of debt to our note holders, \$361,559, was converted into 12.05199 shares of the series A preferred stock.

During the year ended December 31, 2004, we used \$2,647,807 cash in operations, \$60,552 to acquire fixed assets, \$55,410 to fund capital lease payments, and \$67,434 to fund obligations to our bank existing as of December 31, 2003. The cash was funded primarily from the \$1,000,000 of convertible notes issued during March, the accrual of interest on all debt due for both term debt and convertible debt, discounts from the settlement of accounts payable of \$209,000, the sale of \$2,200,000 of series A preferred stock and the issuance of common stock and options to some of our employees that had a value of \$305,198.

We had a working capital deficiency of \$730,738 at December 31, 2003 and a working capital deficiency of \$452,136 at December 31, 2004. This decrease in our working capital deficiency is due to the completion of the convertible note offering as well as the completion of the series A offering. Our current assets increased 56.7% to \$1,211,060 at December 31, 2004 from \$772,680 at December 31, 2003. This increase is also primarily attributable to the completion of the convertible note offering in March and the series A preferred offering in May.

Compared with corresponding balances at December 31, 2003, current liabilities as of December 31, 2004 increased 10.6% to \$1,663,196, long-term liabilities decreased 85.9% to \$287,217, and total liabilities decreased 45.0% to \$1,950,413. The increase in current liabilities is due to the classification of \$120,000 of accrued interest as short term. This is due to the agreement subsequent to the balance sheet date to pay \$10,000 of this accrued amount monthly. The decrease in long-term liabilities is attributable primarily to the completion of the merger where \$1,332,292 of debt was converted into series A preferred stock and the additional conversion of \$361,559 of debt into series A preferred stock at the end of December 2004.

On January 28, 2005, subsequent to the balance sheet date, we 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 will be 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.

We anticipate that the funds from the Series B offering will be enough to fund our needs through the end of 2006 by which time we expect to be profitable; however this depends on several factors. These factors primarily include (1) whether we can generally achieve revenue growth and the extent to which, if any, that revenue growth improves operating cash flows; (2) our investments in research and development, facilities, marketing, regulatory approvals, and other investments we may determine to make, and (3) the investment in capital equipment and the extent to which it improves cash flow.

We currently have paid for or committed to purchasing fixed assets aggregating \$72,000. This equipment will allow us to increase the lot size of our HIV products as well as increasing or throughput capacity. In addition, we are

considering additional fixed asset purchases for the future, but we have no firm commitments at this time.

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Our cash requirements depend on numerous factors, including product development activities, penetration of the direct sales market, market acceptance of new products, and effective management of inventory levels in response to sales forecasts. We expect to devote capital resources to improve our sales and marketing efforts, continue our product development, expand manufacturing capacity and continue research and development activities. We will examine other growth opportunities, including strategic alliances, and we expect any such activities will be funded from existing cash and cash equivalents, as well as utilization of the funds provided from the Series B offering. We believe that our current cash balances, and cash generated from future operations, will be sufficient to fund operations through the end of 2006.

Beyond 2006, it is expected that our cash flow from operations, along with anticipated exercise of outstanding warrants and options (due to the improving operation picture) will be sufficient to fund our expected growth.

The following table lists the future payments required on our debt and any other contractual obligations as of December 31, 2004:

OBLIGATIONS	Total	Less than			Greater than	
		1 Year	1-3 Years	4-5 Years	5 Years	
Working Capital Line	\$ 45,000	\$ 45,000	—	—	—	—
Long Term Debt(1)	\$ 332,950	\$ 120,000	\$ 120,000	\$ 92,950	—	—
Capital Leases (2)	\$ 125,296	\$ 51,029	\$ 74,267	—	—	—
Operating Leases	\$ 28,896	\$ 28,896	—	—	—	—
Other Long Term Obligations(3)	\$ 976,000	\$ 478,167	\$ 347,833	\$ 25,000	\$ 125,000	—
Total Obligations	\$ 1,508,142	\$ 723,092	\$ 542,100	\$ 117,950	\$ 125,000	—

(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 licenses and employment contracts.

## CHEMBIO'S PLAN OF OPERATIONS FOR THE NEXT TWELVE MONTHS

During 2004 and to date in 2005, we successfully completed several important milestones that we believe were fundamental to our being able to achieve significant growth from our HIV products. These milestones include:

- Completion of clinical trials for our HIV rapid tests in the United States and submission of this data with our Pre-Marketing Approval application to the United States Food and Drug Administration.
- Achieving "waiver" status with the United States Agency for International Development for procurements being made under the Presidential Emergency Plan for AIDS Relief which enables our products to be procured pending FDA approval.
- Achieving inclusion on the World Health Organization Bulk Procurement Scheme for our HIV rapid test. This provides United Nations funded programs the ability to purchase our products and is perceived by many countries as tantamount to a regulatory approval even though it is not.
  - Completion of the Series B Five Million Dollar Private Placement of Convertible Preferred Stock

As a result of the achievement of these milestones, our marketing and business development efforts, which we had begun while these milestones had not yet been achieved, can be implemented with much greater effort and results. Our efforts are still aimed toward participating in the various initiatives publicly announced for the implementation of voluntary counseling and testing (VCT), pre-natal testing for mother to child transmission, and other programs that are taking root globally. A significant portion of the capital currently available to us will be used to provide the marketing and business development resources needed to achieve wider distribution of our products in the global market.





We also are working on completing the development of the mad cow, dental bacteria and tuberculosis rapid tests that are under product development agreements and/or research grants. We believe that these products can begin to produce revenues in 2005.

Our cash requirements depend on numerous factors, including product development activities, penetration of the direct sales market, market acceptance of new products, and effective management of inventory levels in response to sales forecasts. We expect to devote capital resources to continue our product development, expand manufacturing capacity and continue research and development activities. We will examine other growth opportunities, including strategic alliances, and we expect any such activities will be funded from existing cash and cash equivalents, as well as issuance of additional equity or additional borrowings, subject to market and other conditions. We believe that our current cash balances, and cash generated from future operations, will be sufficient to fund operations through the end of 2006. We therefore expect that we will not be required to sell additional equity or obtain additional credit facilities in the near term. One of the terms of the series B financing provides for an additional funding of \$1,000,000 if we are able to achieve certain sales and gross margin levels during 2005. We don't anticipate requiring any additional capital unless we are unable to grow our product revenues the way we anticipate we will. We may not in fact be able to grow our product revenues to those levels, or we may face expenses or other circumstances such that we will have additional financing requirements. In such event, the amount of additional capital we may need to raise will depend on a number of factors. These factors primarily include the extent to which we can achieve revenue growth, the profitability of such revenues, operating expenses, research and development expenses, and capital expenditures. Given the number of product development programs that we have ongoing and not complete, and the dependence we have on factors outside of our control such as government and other donor funding for HIV rapid tests, as well as the success of our marketing partners such as Prionics and Ivoclar-Vivadent, it is not possible to predict the extent or cost of these additional financing requirements, if any.

Notwithstanding the numerous factors that our cash requirements depend on, and the uncertainties associated with each of the major revenue opportunities that we have, we believe that our plan of operation can build long-term value if we are able to demonstrate clear progress toward our objectives, particularly FDA approval of our HIV rapid tests. We expect to obtain approval of our Sure check™ and HIV Stat Pak products by the end of 2005 and we believe that this will represent significant value. We believe that our international sales efforts for our HIV tests will succeed based upon the market need, the performance of our products, their competitive pricing, the distribution and marketing channels we are pursuing, and the quality of our professional staff.

Progress in our contract development and manufacturing initiatives our non-human primate tuberculosis test, and new research and development would also likely lend credibility to our plan to become profitable. We anticipate that we will hire several new members to our sales, marketing, research and development, regulatory and administrative staff during the course of 2005 in order to fully implement our plans for growth.

### **Critical Accounting Policies and Estimates**

The preparation of our 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 our financial statements and accompanying notes. Actual results could differ materially from those estimates.

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

#### *Revenue Recognition -*

We sell our products directly through our sales force and through distributors. Revenue from direct sales of our product is recognized upon shipment to the customer. We recognize income from research grants when earned. Grants are invoiced after expenses are incurred. Some grants are funded up front; these funds are then deferred until earned.

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*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. Research and development costs for 2004 increased 357% over 2003. This increased costs by over \$1,000,000, a majority of this increase was due to clinical trials which are not expected to recur at the levels incurred in 2004.

*Valuation of Inventories -*

Inventories are stated at the lower of cost or market, using the first-in, first-out method (FIFO) to determine cost. Our policy is to periodically evaluate the market value of the inventory and the stage of product life cycle, and record a reserve for any inventory considered slow moving or obsolete. For example if we considered another 10% of reserve for inventory as slow moving or obsolete, we would have taken an additional charge of approximately \$60,000 based on December 31, 2004 balances.

*Allowance for doubtful accounts -*

Our policy is to review our accounts receivable on a periodic basis, no less than monthly. On a quarterly basis an analysis is made of the adequacy of our allowance for doubtful accounts and adjustments are made accordingly. Our current allowance is approximately 10% of accounts receivable, we hope to be able to reduce this percentage in future periods.

*Income Taxes -*

We account for income taxes under SFAS No. 109, "Accounting for Income Taxes." SFAS No. 109 requires the asset and liability method of accounting for deferred income taxes. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities. Deferred tax assets or liabilities at the end of each period are determined using the tax rate expected to be in effect when taxes are actually paid or recovered. For example, if we do not become profitable we may be unable to utilize our deferred tax asset, which approximates \$4,700,000 at December 31, 2004.

SFAS 109 also requires that a valuation allowance be established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence needs to be considered, including a company's current and past performance, the market environment in which the company operates, length of carryback and carryforward periods and existing contracts that will result in future profits.

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

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

**ITEM 7.**

**FINANCIAL STATEMENTS**

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

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

Not applicable.

**ITEM 8A. CONTROLS AND PROCEDURES**

As of the end of the period covered by this report, 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 9. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(A) OF THE EXCHANGE ACT**

**Directors and Executive Officers**

**Lawrence A. Siebert (48)**, President 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 (48)**, 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 (42)**, 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 (38)**, Director of Research & Development. 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 (50)**, 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.

**Mark L. Baum (32)**, Director. Mr. Baum was elected to our Board of Directors on December 11, 2003. Mr. Baum has more than 11 years experience in creating, financing and growing development stage enterprises in a variety of industries. Mr. Baum has participated in numerous public spin-offs, venture fundings, private-to-public mergers, corporate restructurings, asset acquisitions and asset divestitures. Mr. Baum is a licensed attorney in the State of California and the principal attorney for The Baum Law Firm, a firm which he founded in 1998. Mr. Baum's law practice focuses on securities laws and related issues for small-cap and micro-cap publicly reporting companies. In 2002, Mr. Baum founded Business Consulting Group Unlimited, Inc., a Southern California-based merchant banking firm.

**David Gates (54)**, VP of Regulatory Affairs, QA and QC. Dr. Gates joined Chembio in August 2004. His background includes almost twenty years of in-vitro diagnostic and medical device experience in R&D, Process Development, Regulatory Affairs and Quality Management. During that time he has held vice-president level positions at Metragenix, director level positions in Quality Management and Regulatory compliance at BD Diagnostic Systems and a broad range of high-level management positions at Difco Laboratories. He earned his Regulatory Affairs Certification in 1991 and has served as an Industrial Representative to the FDA Microbiology Advisory Panel (1996-2000). He has a PhD from University of Tennessee (Microbiology) and held a post-doctoral fellowship at State University of New York at Stony Brook (Molecular/Cellular Biology).

**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.

**Gerald A. Eppner (65)**, Director. Mr. Eppner was elected to our Board of Directors on March 15, 2005. Mr. Eppner is a partner at Cadwalader, Wickersham & Taft, a law firm based in New York City, New York. Mr. Eppner has experience in domestic and international corporate and securities law matters. Mr. Eppner has been in private practice in New York City since 1966. For more than five years prior to 1966, Mr. Eppner was an employee of certain 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, 2004, 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 3 for Richard J. Larkin filed on July 1, 2004; (ii) Form 3, for Avi Pelosof filed on July 2, 2004; and (iii) Form 3 for Lawrence A. Siebert filed on July 7, 2004. This disclosure is based on a review of the forms submitted to the Company during, and with respect to, its fiscal year ended December 31, 2004.

**Code of Ethics**

The Company currently does not have a Code of Ethics that applies to the Company's principal executive and financial officers. The Company plans to establish and adopt a code of ethics in the second quarter of the current fiscal year.

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

The Company currently does not have an audit committee and has not made a determination of whether there is a financial expert. The Company plans to establish an audit committee during the second quarter of the current fiscal year.

**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, 2004, 2003 and 2002:

Name and Position	Year	Annual Comp Salary	Long-Term Compensation Awards—Securities Underlying Stock Options
Lawrence A. Siebert, President, CEO, Chairman of Board of Chembio Diagnostic Systems Inc. <sup>(1)</sup>	2004	\$ 182,789	160,000
	2003	103,846	—
	2002	63,000	—
Javan Esfandiari, Vice President of Chembio Diagnostic Systems, Inc. <sup>(3)</sup>	2004	129,323	110,000
	2003	88,269	—
	2002	83,224	—
Rick Bruce, Vice President of Chembio Diagnostic Systems Inc. <sup>(4)</sup>	2004	114,286	35,000
	2003	110,326	—
	2002	106,240	—
Konstantin Lyashchenko, Research Director of Chembio Diagnostic Systems, Inc. <sup>(5)</sup>	2004	106,365	2,500
	2003	77,885	—
	2002	75,500	—
Mark L. Baum, President, Secretary and Director of Chembio Diagnostics, Inc. <sup>(6)</sup>	2004	40,000	—
	2003	—	—
	2002	—	—

(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. Pelossof 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. Pelossof 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. Pelossof 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.
- (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.
- (4) Mr. Lyashchenko currently is a Research Director of Chembio Diagnostic Systems, Inc. The compensation information represents compensation earned while employed by Chembio Diagnostic Systems Inc. In 2004, Mr. Lyashchenko received, prior to the merger, 2,500 options with an exercise price of \$1.00.
- (5) 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.
- (6) Mr. Baum currently is a director of Chembio Diagnostics, Inc. The compensation information represents compensation earned while employed by Chembio Diagnostics, Inc.

The following table sets forth certain information regarding stock options granted to the named executive officers as of December 31, 2004.

Name	Individual Grants			
	Number of Securities Underlying Options/SARs Granted (#)	Percentage of Total Options/SARs Granted to Employees in Fiscal Year	Exercise or Base Price (#/Sh)	Expiration Date
Lawrence A. Siebert	50,000	6.75%	1.20	5/27/11
Lawrence A. Siebert	50,000	6.75%	1.50	5/27/11
Lawrence A. Siebert	50,000	6.75%	0.75	5/04/11
Lawrence A. Siebert	10,000	1.35%	1.00	5/04/11
Avi Pelossof	100,000	13.51%	0.60	5/27/11
Avi Pelossof	50,000	6.75%	0.90	5/27/11
Avi Pelossof	50,000	6.75%	1.35	5/27/11
Avi Pelossof	40,000	5.40%	0.75	5/04/11
Avi Pelossof	10,000	1.35%	1.00	5/04/11
Javan Esfandiari	25,000	3.38%	0.90	5/27/11
Javan Esfandiari	25,000	3.38%	1.20	5/27/11
Javan Esfandiari	25,000	3.38%	1.50	5/27/11
Javan Esfandiari	30,000	4.05%	0.75	5/04/11
Javan Esfandiari	5,000	0.68%	1.00	5/04/11
Richard Bruce	20,000	2.70%	0.588	5/04/11
Richard Bruce	10,000	1.35%	0.75	5/04/11
Richard Bruce	5,000	0.68%	1.00	5/04/11

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Konstantin Lyashchenko	2,500	0.34%	1.00	5/04/11
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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, 2006. 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**

Please see "Certain Relationships and Related Transactions" for a discussion of Mr. Baum's employment agreement and warrants. All independent 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 independent 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. In addition, the independent 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. Additionally, the independent 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 independent director is the committee chairman.

**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, 2004.

<b>Name and Address of Beneficial Owner</b>	<b>Number of Shares Beneficially Owned</b>	<b>Percent of Class</b>
Lawrence Siebert <sup>(1)</sup> 75 Shady Knoll Drive Stamford, CT 06903	1,846,417	25.35%
Mark Baum <sup>(2)</sup> 580 Second Street, Suite 102 Encinitas, CA 92024	1,554,333	20.04%
Avi Pelosof <sup>(3)</sup> 51A Edgewood Road Port Washington, NY 11050	498,512	6.94%
Javan Esfandiari <sup>(4)</sup> 1Bowen Place Stonybrook, NY 11790	117,080	1.67%
Richard Bruce <sup>(5)</sup> 17 Amalia Lane Comack, NY 11725	75,500	1.08%
Konstantin Lyashchenko <sup>(6)</sup> 240 Mt. Vernon Pl. Apt#10-0 Newark, NJ 07106	10,500	.15%
All officers and directors as a group <sup>(7)</sup>	4,102,342	47.81%
Tomas Haendler <sup>(8)</sup> 31 Cogswell Lane Stamford, CT 06902	602,931	8.49%
Thunderbird Global Corporation <sup>(9)</sup> c/o The Baum Law Firm 580 Second Street, Suite 102 Encinitas, CA 92024	467,431	6.77%
Daniel Gressel <sup>(10)</sup> 460 E. 79 <sup>th</sup> Street, Apt. 17B New York, NY 10021	472,501	6.79%
H.C. Wainwright & Co., Inc. <sup>(11)</sup> 245 Park Avenue, 44 <sup>th</sup> Floor New York, NY 10167	390,867	5.36%

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 2004.

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.

- (1) Includes 170,000 shares issuable upon exercise of options exercisable within 60 days and 207,566 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 1,937,220 shares issuable upon conversion of series A preferred stock, 2,324,666 shares issuable upon exercise of warrants, 81,967 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.
- (2) 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.
- (3) Includes 250,000 shares issuable upon exercise of options exercisable within 60 days and 22,555 shares issuable 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.
- (4) Includes 95,000 shares issuable upon exercise of options exercisable within 60 days and 2,007 shares issuable upon exercise of warrants. Does not include 50,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
- (5) Includes 70,000 shares issuable upon exercise of options exercisable within 60 days and 500 shares issuable upon exercise of warrants.
- (6) Includes 5,000 shares issuable upon exercise of options exercisable within 60 days and 500 shares issuable upon exercise of warrants
- (7) Includes footnotes (1)-(6).
- (8) Includes 160,000 shares issuable upon exercise of options exercisable within 60 days and 38,197 shares issuable upon exercise of warrants. Does not include 44,450 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.
- (9) 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.
- (10) Includes 10,000 shares issuable upon exercise of options exercisable within 60 days and 42,065 shares issuable upon exercise of warrants.

- (11) Includes 390,867 shares issuable upon exercise of warrants. ZGNY Investments Limited Partnership may be deemed to have voting or investment control over the shares held by H.C. Wainwright & Co., Inc. Bryan Zwan may be deemed to have voting or investment control over ZGNY Investments Limited Partnership.

**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	–	–	–
Equity compensation plans not approved by security holders	2,145,250 (1)(2)	1.15	395,000
<b>Total</b>	<b>2,145,250</b>	<b>1.15</b>	<b>395,000</b>

(1) Includes warrants to purchase 850,000 shares of the Company's common stock at exercise prices from \$0.60 to \$0.90 pursuant to an employment agreement with Mr. Baum entered into in connection with the merger. Please see "Certain Relationships and Related Transactions" for a discussion of Mr. Baum's employment agreement and warrants.

(2) Includes options to purchase 190,250 shares of the Company's common stock to various consultants pursuant to consulting agreements. Please see Note 12(b) to the Company's financial statements on page F-21 for a description of the grant of these options.

**Summary Description of the Company's Equity Compensation Plan**

*1999 Stock Option Plan.* As a part of the merger, the Company assumed the 1999 Stock Option Plan (the "Plan") of Chembio Diagnostic Systems, Inc. The Plan was originally approved by the shareholders of Chembio Diagnostic Systems, Inc., but has not been separately approved by the Company's shareholders. Please see Note 3 to the Company's financial statements on page F-13 for a description of the Plan.

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

Mark L. Baum, our former president prior to the merger and a current 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 receives 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.

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 \$183,720 as of December 31, 2004.

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.

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.

**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	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

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Number	Description
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.
10.1(1)	Employment Agreement between the Registrant and Mark L. Baum dated as of May 5, 2004.
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	1999 Stock Option Plan.
21(6)	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)

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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.



**ITEM 14.**

**PRINCIPAL ACCOUNTANT FEES AND SERVICES**

**Audit Fees**

For the years ended December 31, 2004 and December 31, 2003, Lazar, Levine & Felix LLP, the Company's principal accountants, billed the Company \$92,000 and \$0, 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. Madsen & Associates, CPA's, Inc., the Company's principal accountants prior to June 1, 2003, billed the Company \$0 for fees for the review of financial statements included in the Company's Forms 10-QSB for the year ended December 31, 2003.

**Audit-Related Fees**

For the years ended December 31, 2004 and December 31, 2003, neither Lazar, Levine & Felix LLP nor Madsen & Associates, CPA's, Inc. 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 and are not reported above under "Audit Fees."

**Tax Fees**

For the years ended December 31, 2004 and December 31, 2003, Lazar, Levine & Felix LLP billed the Company \$14,008 and \$5,387, respectively, for professional services for tax compliance, tax advice, and tax planning. Madsen & Associates, CPA's, Inc. billed the Company \$0.

**All Other Fees**

For the years ended December 31, 2004 and December 31, 2003, Lazar, Levine & Felix LLP billed the Company \$48,890 and \$1,558 for fees associated with the preparation and filing of the Company's registration statements, responses to SEC comment letters, pro forma financial statements of the reverse merger, and other related matters. Madsen & Associates, CPA's, Inc. did not bill the Company for products and services other than those described above.

**Audit Committee Pre-Approval Policies**

The Company currently does not have an audit committee. The Company's Board of Directors currently approves in advance all audit and non-audit related services performed by the Company's principal accountants.

**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 31, 2005

By: /s/ Lawrence A. Siebert

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Lawrence A. Siebert  
President, Chief Executive Officer and Chairman of the Board

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

Signatures	Title	Date
/s/ Lawrence A. Siebert Lawrence A. Siebert	Chief Executive Officer, President and Chairman Of The Board (Principal Executive Officer)	March 31, 2005
/s/ Richard J. Larkin Richard J. Larkin	Secretary, Chief Financial Officer (Principal Financial & Accounting Officer)	March 31, 2005
/s/ Mark L. Baum Mark L. Baum	Director	March 31, 2005
/s/ Gary Meller Dr. Gary Meller	Director	March 31, 2005
/s/ Gerald A. Eppner Gerald A. Eppner	Director	March 31, 2005

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**

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**REPORT OF REGISTERED INDEPENDENT PUBLIC ACCOUNTANTING FIRM**

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

We have audited the consolidated balance sheet of Chembio Diagnostics Inc. and Subsidiary (the "Company") as of December 31, 2004 and the consolidated statements of operations, stockholders' equity and cash flows for the two years in the period ended December 31, 2004. 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 audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits 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 Diagnostic Systems Inc. and Subsidiary as of December 31, 2004, and the consolidated results of its operations and its cash flows for the two years in the period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States of America.

/s/ Lazar Levine & Felix LLP

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**LAZAR LEVINE & FELIX LLP**

New York, New York  
February 24, 2005

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**CONSOLIDATED BALANCE SHEET**  
**AS OF DECEMBER 31, 2004**

—ASSETS—

**CURRENT ASSETS:**

Cash	\$	34,837
Restricted cash		250,000
Accounts receivable, net of allowance for doubtful accounts of \$16,367		165,056
Inventories		538,647
Prepaid expenses		222,520

**TOTAL CURRENT ASSETS** **1,211,060**

**FIXED ASSETS**, net of accumulated depreciation of \$460,720 **188,399**

**OTHER ASSETS:**

Deposits 26,990

\$ **1,426,449**

**- LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT) -**

**CURRENT LIABILITIES:**

Working capital loan	\$	45,000
Accounts payable and accrued liabilities		1,102,428
Current portion of obligations under capital leases		51,029
Accrued contingency		60,264
Current accrued interest payable		120,000
Payable to related parties		284,475
<b>TOTAL CURRENT LIABILITIES</b>		<b>1,663,196</b>

**OTHER LIABILITIES:**

Obligations under capital leases - net of current portion	74,267
Accrued interest , net of current portion	212,950
<b>TOTAL LIABILITIES</b>	<b>1,950,413</b>

**COMMITMENTS AND CONTINGENCIES**

**PREFERRED STOCK** -Series A 8% Convertible - \$.01 par value; 10,000,000 shares authorized: 162.37241 shares issued and outstanding. (Liquidation preference-please see note 11) **2,427,030**

**STOCKHOLDERS' EQUITY (DEFICIT):**

Common stock - \$.01 par value; 50,000,000 shares authorized: 6,907,143 shares issued and outstanding.	69,071
Additional paid-in capital	9,079,341
Accumulated deficit	(12,099,406)
	<b>(2,950,994)</b>

\$ 1,426,449

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

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**FOR THE YEARS ENDED DECEMBER 31, 2004 AND 2003**

	2004	2003
<b>REVENUES:</b>		
Net sales	\$ 2,749,143	\$ 2,542,621
Research grants and development income	556,789	275,730
	<b>3,305,932</b>	<b>2,818,351</b>
Cost of sales	<b>2,485,593</b>	<b>2,153,454</b>
<b>GROSS PROFIT</b>	<b>820,339</b>	<b>664,897</b>
<b>OVERHEAD COSTS:</b>		
Research and development expenses	1,433,403	313,891
Selling, general and administrative expenses	2,490,298	1,202,185
<b>LOSS FROM OPERATIONS</b>	<b>(3,103,362)</b>	<b>(851,179)</b>
<b>OTHER INCOME (EXPENSES):</b>		
Forgiveness of debt	209,372	-
Loss on retirement of fixed assets	(22,469)	-
Interest income	8,126	7
Interest (expense)	(190,558)	(208,532)
<b>LOSS BEFORE INCOME TAXES</b>	<b>(3,098,891)</b>	<b>(1,059,704)</b>
Income taxes	-	-
<b>NET LOSS</b>	<b>(3,098,891)</b>	<b>(1,059,704)</b>
Dividends paid to preferred stockholders in common stock	240,001	-
Dividend accreted to preferred stock for associated costs and a beneficial conversion feature	1,703,072	-
<b>NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS</b>	<b>(\$5,041,964)</b>	<b>(\$1,059,704)</b>
Basic and diluted loss per share	(\$0.85)	(\$0.22)
Weighted number of shares outstanding	5,966,769	4,919,191

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

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF CHANGES IN PREFERRED STOCK AND STOCKHOLDERS'**  
**EQUITY (DEFICIT)**  
**FOR THE YEARS ENDED DECEMBER 31, 2004 AND 2003**

	Preferred stock		Common stock		Additional	Accumulated	Total
	Shares	Amount	Shares	Amount	paid in capital	Deficit	
Balance at January 1, 2003	-	\$ -	38,395	\$ 39	\$ 4,599,962	\$ (5,997,738)	\$ (1,397,737)
<b><u>Restate for merger with TSLU -100</u></b>							
for 1 and par from .001 to .01	-	-	3,801,032	\$ 38,355	(38,355)	-	-
TSLU shares at December 31, 2003 after giving affect of 1:17 reverse split	-	-	1,063,181	10,632	(10,632)	-	-
Net loss - December 31, 2003				-	-	(1,059,704)	(1,059,704)
<b>Balance at December 31, 2003</b>	-	-	<b>4,902,608</b>	<b>49,026</b>	<b>4,550,975</b>	<b>(7,057,442)</b>	<b>(2,457,441)</b>
<b>Preferred stock issued</b>							
For cash	<b>73.33330</b>	<b>352,000</b>	-	-	<b>1,758,460</b>	-	<b>1,758,460</b>
Conversion of long-term debt	<b>90.29853</b>	<b>665,080</b>	-	-	<b>1,707,878</b>	-	<b>1,707,878</b>
<b>Accretion of preferred dividend</b>	-	<b>58,114</b>	-	-	-	-	-
<b>Accretion of beneficial conversion</b>	-	<b>1,373,750</b>	-	-	-	-	-
<b>Common stock issued</b>							
Common issued pre-merger to employees	-	-	<b>160,573</b>	<b>1,606</b>	<b>62,623</b>	-	<b>64,229</b>
Common issued during merger							
Bridge conversion	-	-	<b>826,741</b>	<b>8,267</b>	<b>322,430</b>	-	<b>330,697</b>
Employment contract	-	-	<b>400,000</b>	<b>4,000</b>	<b>236,000</b>	-	<b>240,000</b>
For financing fees, valued \$39,400	-	-	<b>65,667</b>	<b>657</b>	<b>(657)</b>	-	-
Common issued for services	-	-	<b>118,569</b>	<b>1,185</b>	<b>59,831</b>	-	<b>61,016</b>



Common converted from preferred	(1,259,420)	(21,914)	62,971	630	21,284	-	21,914
Payment of preferred dividend			303,145	3,031	178,856	-	181,887
<b>Warrants and options issued to</b>							
Employees	-	-	-	-	969	-	969
Marketing consultants	-	-	-	-	90,620	-	90,620
Existing Debt Holders (pre-merger)	-	-	-	-	60,650	-	60,650
<b>Warrants exercised</b>	-	-	66,869	669	29,422	-	30,091
<b>Net loss to December 31, 2004</b>	-	-	-	-	-	(5,041,964)	(5,041,964)
<b>Balance at December 31, 2004</b>	162,372,411	\$ 2,427,030	6,907,143	\$ 69,071	\$ 9,079,341	\$ (12,099,406)	\$ (2,950,994)

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

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**FOR THE YEARS ENDED DECEMBER 31, 2004 AND 2003**

	2004	2003
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (3,098,891)	\$ (1,059,704)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	109,965	134,357
Loss on retirement of fixed assets	22,469	-
Provision for doubtful accounts	(1,136)	20,953
Stock issued as compensation	304,229	-
Stock issued as payment for fees	37,391	-
Options issued as compensation	969	-
Options -expensed to consultants	48,383	-
Warrants issued as interest for debt	60,650	-
Changes in:		
Accounts receivable	118,814	(150,988)
Restricted cash	(250,000)	-
Inventories	(72,149)	127,441
Prepaid expenses and other current assets	(63,219)	(17,318)
Other assets and deposits	37,828	(2,905)
Accounts payable and accrued expenses	(86,896)	523,668
Increase in accrued interest not paid	93,918	-
Payables to a related party	42,252	-
Accrued contingency	60,264	-
Grant and other current liabilities	(12,648)	549
<b>Net cash used in operating activities</b>	<b>(2,647,807)</b>	<b>(423,947)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Acquisition of fixed assets	(60,552)	-
<b>Net cash used in investing activities</b>	<b>(60,552)</b>	<b>-</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Changes in obligations to bank	(67,434)	67,434
Payment of capital lease obligation	(55,410)	(36,931)
Proceeds from warrant exercise	30,091	-
Proceeds from shareholder loans	-	365,273
Proceeds from working capital loan	295,000	-
Payment of working capital loan	(250,000)	-
Proceeds from bridge loan and converted interest, net the cost of financing of \$83,770	926,035	-
Sale of Series A Preferred Stock, net the cost of financing of \$335,086	1,864,914	-
<b>Net cash provided by financing activities</b>	<b>2,743,196</b>	<b>395,776</b>
<b>NET INCREASE (DECREASE) IN CASH</b>	<b>34,837</b>	<b>(28,171)</b>
Cash - beginning of the period	-	28,171
<b>CASH - end of the period</b>	<b>\$ 34,837</b>	<b>\$ -</b>

**Supplemental disclosure of cash flow information:**

Cash paid during the period for interest	\$	1,985	\$	-
Cash paid during the period for corporate taxes		1,693		1,040

**Supplemental disclosures for non-cash investing and financing activities:**

Fixed assets acquired under capital leases	\$	11,032	\$	107,020
Stock issued as payment for financing fees		39,400		-
Options issued as payment for consulting services		42,237		-
Warrants issued as payment for financing fees		337,973		-
Warrants issued for Chembio Diagnostics Systems, Inc. shareholder consent		144,643		-
Bridge debt and converted interest into Common Stock		330,698		-
Bridge debt and converted interest into Series A Preferred Stock		679,107		-
Long Term debt converted to Preferred Series A Preferred Stock		1,693,851		-
Preferred dividend paid in common stock		181,887		-
Accredited dividend to preferred stock		1,373,750		-

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

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS**  
**DECEMBER 31, 2004 AND 2003**

**NOTE                    1                    —                    DESCRIPTION OF BUSINESS/OPERATIONS:**

Chembio Diagnostics, Inc. (“the Company”) was formerly known as Trading Solutions.com, Inc. (see “Merger and Other Related Transactions” below). The historical information presented prior to the merger is based on the wholly owned subsidiary of the Company, Chembio Diagnostic Systems, Inc. prior to the merger, as discussed below. The earnings per share presented in the statement of operations for 2003 have been restated to reflect the shares outstanding as if the merger had taken place as of January 1, 2003, the earliest period presented.

On May 5<sup>th</sup> 2004 Chembio Diagnostics, Inc. issued 4,000,000 shares of its common stock to acquire all the outstanding common stock of Chembio Diagnostic Systems, Inc. and assumed all outstanding options and warrants. For accounting purposes the acquisition has been treated as a recapitalization of Chembio Diagnostics, Inc. with Chembio Diagnostic Systems, Inc. as the accounting acquirer (reverse acquisition).

Trading Solutions.com, Inc. had no assets, liabilities or transactions (other than a 1:17 reverse split of its common stock) in the current fiscal year prior to the merger. Prior to the merger Trading Solutions.com, Inc. had a fiscal year ending September 30. After the merger Chembio Diagnostics, Inc. fiscal year was changed to December 31, which was the fiscal year end of Chembio Diagnostic Systems, Inc.

Chembio Diagnostic Systems, Inc., which was originally incorporated in New York on December 15, 1985 and re-incorporated in Delaware on November 5, 1991, develops, manufactures, and markets rapid point of care medical diagnostic tests. These tests are ultimately sold in the U.S. and/or internationally to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and/or retail establishments. Sales are primarily through distributors and are made under the label of Chembio Diagnostic Systems, Inc. and/or the private labels of its distributors or their customers. The products aid in the diagnosis of infectious diseases and other conditions in humans and animals.

On April 8, 2004 we approved: a) An amendment to our articles of incorporation to increase the authorized number of shares of common stock from 20,000,000 to 50,000,000; b) Authorization of 10,000,000 shares of undesignated preferred stock, par value \$0.01 per share; and c) Change of our name to Chembio Diagnostics, Inc.

**MERGER AND OTHER RELATED TRANSACTIONS:**

On May 5, 2004, pursuant to the Agreement and Plan of Merger (the “Merger Agreement”), dated as of March 3, 2004, as amended on May 3, 2004 by and among privately-held Chembio Diagnostic Systems Inc. (“Chembio Diagnostic Systems”), a Delaware corporation, Chembio Diagnostics, Inc. (formerly, Trading Solutions.com, Inc.), a publicly traded Nevada corporation (“the Company”) and New Trading Solutions, Inc., a wholly owned subsidiary of the Company (“Merger Sub”), the Merger Sub merged with and into Chembio Diagnostic Systems, with Chembio Diagnostic Systems remaining as the surviving corporation (the “Merger”). Pursuant to the Merger, the Company issued 4,000,000 shares of its restricted common stock, as well as 704,000 options and warrants to purchase 690,000 shares of its common stock to the stockholders of Chembio Diagnostic Systems in exchange for 100% of their common stock in Chembio Diagnostic Systems and 100% of their options and warrants to purchase Chembio Diagnostic Systems’ common stock. The Company relied on Regulation D promulgated under Section 4(2) of the Act and on Section 4(2) of the Act as the basis for its exemption from registration of this offering. 44 accredited and only 3 non-accredited investors received securities of the Company in the Merger. All of the stockholders of Chembio Diagnostic Systems, including the non-accredited investors, were provided with an information statement meeting the informational requirements of Rule 502 (b)(2) of the Securities Act.



**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS**  
**DECEMBER 31, 2004 AND 2003**

At or about the time of the Merger, the Company consummated three private placements of its 8% Series A Convertible Preferred Stock as follows: (i) shares of series A preferred and warrants were sold for cash (the "Cash Offering"); (ii) shares of series A preferred and warrants were exchanged, as described herein, for conversion of the Bridge Notes described below (the "Bridge Conversion Offering"), and (iii) shares of series A Preferred and warrants were exchanged, as described herein, for conversion of the Existing Debt (as defined below) of Chembio Diagnostic Systems (the "Existing Debt Exchange Offering"). These placements are described below:

- a) The Cash Offering. A total of 73.33330 shares of series A preferred stock and warrants to acquire 4,400,000 shares of common stock at \$.90 per share were issued pursuant to the Cash Offering in May 2005 for total consideration of \$2,200,000.
- b) The Bridge Conversion Offering. On March 22, 2004, Chembio Diagnostic Systems completed a private placement (the "Bridge Financing") of \$1,000,000 in face amount of Convertible Notes (the "Bridge Notes"). The Bridge Financing provided for the Bridge Note holders to elect upon merger whether to convert the Bridge Notes into shares of the Company's series A preferred stock (together with warrants to acquire shares of the Company's common stock) or into shares of the Company's common stock at the effective time of the Merger. As a result, \$672,000 in principal amount of the Bridge Notes, together with accrued and unpaid interest, was converted into 33.83682 shares of the Company's series A preferred stock (together with warrants to acquire an additional 2,030,217 shares of the Company's common stock at \$.90 per share). The balance of the Bridge Financing, or \$328,000, was converted into 826,741 shares of the Company's common stock.
- c) The Existing Debt Exchange Offering. Per the merger agreement a minimum of \$1,300,000 of existing debt of Chembio Diagnostic Systems, Inc. was required to be converted to series A preferred stock, Any balances not converted were to be, if not paid by December 31, 2004, automatically converted to series A preferred stock as of December 31, 2004. Pursuant to this offering, which was consummated at the effective time of the Merger, the Company issued 44.40972 shares of series A preferred stock and warrants to acquire 2,664,584 shares of common stock at \$.90 per share in exchange for the conversion of \$1,332,292 of Chembio Diagnostic Systems' debt existing on its balance sheet as of the date of merger.

On May 5, 2004 the Company issued warrants to designees of H.C. Wainright & Co., Inc. to purchase 751,667 shares of our common stock and to designees of Wellfleet Partners, Inc. to purchase 183,333 shares of our common stock, our placement agents in the series A preferred stock private placement, at exercise prices of \$0.72 and \$1.08. In addition, designees of Wellfleet Partners received 59,000 shares of common stock and an individual finder received 6,667 shares of common stock.

**RECENT DEVELOPMENTS:**

On January 28, 2005, subsequent to the balance sheet date, we completed a private placement offering which raised \$5,047,500 before costs in new capital in the form of 9% Convertible Series B Preferred Stock and associated warrants ("Series B Offering") (see note 17). The proceeds from the Series B Offering will be used primarily for general corporate purposes including sales and marketing, research and development, and intellectual property, and also for working capital, investor relations, and capital expenditures.

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS**  
**DECEMBER 31, 2004 AND 2003**

We anticipate that the funds from the Series B offering will be enough to fund our needs through the end of 2006 by which time we expect to be profitable; however this depends on several factors. These factors primarily include (1) whether we can generally achieve revenue growth and the extent to which, if any, that revenue growth improves operating cash flows; (2) our investments in research and development, facilities, marketing, regulatory approvals, and other investments we may determine to make, and (3) the investment in capital equipment and the extent to which it improves cash flow.

Our cash requirements depend on numerous factors, including product development activities, penetration of the direct sales market, market acceptance of new products, and effective management of inventory levels in response to sales forecasts. We expect to devote capital resources to improve our sales and marketing efforts, continue our product development, expand manufacturing capacity and continue research and development activities. We will examine other growth opportunities, including strategic alliances, and we expect any such activities will be funded from existing cash and cash equivalents, as well as utilization of the funds provided from the Series B offering. We believe that our current cash balances, and cash generated from future operations, will be sufficient to fund operations through the end of 2006.

Beyond 2006, it is expected that our cash flow from operations, along with anticipated exercise of outstanding warrants and options (due to the improving operation picture) will be sufficient to fund our expected growth.

**NOTE**                    **2**                    **—**                    **SIGNIFICANT ACCOUNTING POLICIES:**

*(a) Principles of Consolidation:*

The consolidated financial statements include the accounts of the Company, Chembio Diagnostics, Inc. and its wholly owned subsidiary, Chembio Diagnostic Systems, Inc. All material 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.



**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS**  
**DECEMBER 31, 2004 AND 2003**

***(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 related interpretations. The Company has adopted the disclosure-only provisions of SFAS No. 123, as amended, "Accounting for Stock-Based Compensation."

***(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. Some grants are funded up front; these funds are then deferred until earned.

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

In 1998, the Company adopted Financial Accounting Standards Boards 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 quality financial institutions and, at times, may maintain balances in excess of the \$100,000 FDIC Insurance limit. The Company monitors the credit ratings of its financial institutions to mitigate this risk. Concentrations of credit risk with respect to trade receivables are principally mitigated by the Company's large customer base and their customers' national and international locations.

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

Fair values of cash, accounts receivable, accounts payable and working capital loan reflected in these financial statements approximate carrying value.



**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS**  
**DECEMBER 31, 2004 AND 2003**

*(m) Recent Accounting Pronouncements:*

In March 2004, the FASB reached a consensus on Emerging Issues Task Force (EITF) Issue No. 03-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments," which provides guidance to determine the meaning of other-than-temporary impairment and its application to investments classified as either available-for-sale or held-to-maturity (including individual securities and investments in mutual funds), and investments accounted for under the cost method or the equity method. The guidance for evaluating whether an investment is other-than-temporarily impaired should be applied in other-than-temporary impairment evaluations made in reporting periods beginning after June 15, 2004. The adoption of Issue No. 03-1 has not had any impact on the Company's financial statements and results of operations.

In December 2004, the FASB issued a revision of SFAS No. 123 "Share-Based Payment" 123(R). The 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 incurs liabilities in exchange for goods or services that are based on the fair value of the entity's equity instruments or that may be settled by the issuance of those 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 a liability instrument based on its current fair value; the fair value of that award will be re-measured 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 with periods beginning after December 15, 2005.

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs, an amendment of APB No. 43, Chapter 4" ("SFAS 151") which clarifies the types of costs that should be expensed rather than capitalized as inventory. This statement also clarifies the circumstances under which fixed overhead costs associated with operating facilities involved in inventory processing should be capitalized. The provisions of SFAS No. 151 are effective for fiscal years beginning on or after June 15, 2005. The Company has not determined the impact, if any, that this statement will have on its consolidated financial position or results of operations.

In November 2004, the Financial Accounting Standards Board ratified the Emerging Issues Task Force's Statement No. 04-08, "The Effect of Contingently Convertible Debt on Diluted Earnings per Share" ("EITF 04-08"). EITF 04-08 addresses the issue of when the dilutive effects of contingently convertible debt instruments should be included in diluted earnings per share. This statement concludes that contingently convertible debt instruments should be included in diluted earnings per share regardless of whether any of the conversion criteria has been met. In addition, prior period earnings per share amounts presented for comparative purposes should be restated. EITF 04-08 is effective for reporting periods ending after December 15, 2004. Accordingly, the Company has included the dilutive effect from the assumed conversion of 8% series A preferred stock in the computation of diluted earnings per share for the year ended December 31, 2004 and has recalculated the diluted earnings per share for the year ending December 31, 2003, however the effect of such calculations were anti-dilutive and as such were not included in the diluted earnings per

share. The common stock equivalents for these preferred shares were shown as part of Note 2 (q).

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
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*(n) Shipping and Handling Charges:*

The Company includes shipping and handling charges in its cost of goods sold section. The costs recorded for shipping and handling totaled \$73,868, and \$60,672 for the years ended December 21, 2004 and 2003, respectively.

*(o) Geographic Information:*

In June 1997, FASB issued SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information". SFAS 131 establishes standards for the way that business enterprises report information about operating segments in annual financial statements and requires that those enterprises report certain selected information. It also establishes standards for related disclosures about product and services, geographic areas, and major customers.

SFAS 131 further states that enterprises report "Information about Products and Service". Chembio Diagnostic Systems, Inc. produces only one group of similar products known collectively as "rapid medical tests". We do not produce any further breakdown in our general-purpose statements and it would be impracticable for us to do so.

Accordingly, Chembio Diagnostics Systems, Inc. believes that they operate in a single business segment, however, attributes revenues to different geographic areas on the basis of the location of the customer. Net sales by geographic area which are all transacted in U.S. dollars, are as follows:

	<b>Year Ended December 31,</b>	
	<b>2004</b>	<b>2003</b>
Brazil	\$ 1,071,111	\$ 3,930
USA	577,451	655,964
Canada	367,841	445,412
Costa Rica	143,994	126,063
Japan	105,290	116,111
Israel	72,830	37,864
Saudi Arabia	64,137	50,577
Austria	49,096	72,684
Honduras	45,269	4,200
Switzerland	37,651	15,734
India	34,009	79,052
Puerto Rico	33,398	28,237
France	30,752	50,166
Korea	30,372	104,434
Italy	900	294,676
Mexico	1,425	186,130
Others	83,617	271,387
	\$ 2,749,143	\$ 2,542,621

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*(p) Accounts payable and accrued liabilities*

The following tables detail the component parts of accounts payable and accrued liabilities as of December 31, 2004:

Accounts payable - suppliers	\$ 453,839
Accrued payroll	49,888
Accrued commissions and royalties	383,630
Accrued payroll and other taxes	30,540
Accrued legal and accounting	81,005
Accrued expenses - other	103,526
<b>TOTAL</b>	<b>\$ 1,102,428</b>

*(q) 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, 2004</b>	<b>December 31, 2003</b>
<b>Basic</b>	5,966,769	4,919,191
<b>Diluted</b>	5,966,769	4,919,191

*Computation of per share loss*

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, 2004 and 2003 are the same as basic loss per share, since the effects of the calculation using common stock equivalents 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>Year Ended December 31,</b>	
	<b>2004</b>	<b>2003</b>
Stock Options	1,300,250	365,000
Warrants	12,226,054	140,000
Preferred stock	8,118,611	-

In January subsequent to the balance sheet date the Company completed a private placement offering (see Note 17(a)). Although anti-dilutive it will add 8,716,382 equivalent common shares for preferred stock and 9,018,262 equivalent common shares for warrants.

**NOTE 3 — EMPLOYEE STOCK OPTION PLAN:**

As part of the merger, the Company adopted the 1999 Stock Option Plan (the "Plan") of Chembio Diagnostic Systems, Inc. Under the terms of this plan, the Company's option committee is authorized to grant incentive options to key

employees and to grant non-qualified options to key employees and key individuals. The option committee has been authorized to grant options to purchase up to 1,500,000 shares of common stock. The options become exercisable at such times and under such conditions as determined by the option committee. The Company has assumed 704,000 options outstanding from Chembio Diagnostic Systems, Inc.

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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 earnings and earnings per share would have been adjusted to the pro forma amounts indicated below. The Company also adopted Statement of Financial Accounting Standards No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure - an amendment of FASB Statement No. 123" as of January 1, 2003, which amended SFAS 123. The effect of the fair value method allowed under SFAS 123 is shown below.

	<b>2004</b>	<b>2003</b>
Net Income (loss) applicable to common stockholders, as reported	\$ (5,041,964)	\$ (1,059,704)
Add: Stock-based compensation included in reported net loss	969	-
Deduct: Total stock based employee compensation expense determined under the fair value based method for all awards, net of tax	(490,348)	-
Pro forma net income (loss)	\$ (5,531,343)	\$ (1,059,704)
<b>Income (loss) per share:</b>		
Basic and diluted (loss) per share - as reported	\$ (0.85)	\$ (0.22)
Basic and diluted (loss) per share - pro forma	\$ (0.93)	\$ (0.22)

The fair value of each option grant for 2004 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, 2004: expected volatility of 82.6%; risk-free interest rate of 3.31%; and expected lives of 4 to 7 years for all periods presented.

The fair value of option grants for 2003 was estimated on the date of grant using a Black-Scholes option-pricing model with weighted average assumptions for the year ended December 31, 2003: risk free interest rate of 3.23% volatility of 0.01%; and expected life of 3½ years, respectively. Pro forma information for the year ended December 31, 2003 is not presented since compensation expenses calculated using the Black-Scholes option pricing model are immaterial.

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



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Stock incentive plan activity is summarized as follows:

	Number of shares	Weighted Average Exercise Price
Options outstanding at December 31, 2002	315,000	3.12
Granted	50,000	.45
Canceled	-	-
Exercised	-	-
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
Options exercisable at:		
December 31, 2003	197,500	
December 31, 2004	805,000	

Range of Exercise Prices	Options Outstanding at 12/31/04	Weighted Average Remaining Life	Weighted Average Exercise Price	Options Exercisable at 12/31/04	Weighted Average Exercise Price
\$2.17 — 4.00	315,000	3.07	\$ 3.12	315,000	\$ 3.12
\$0.60 — 1.50	740,000	6.42	\$ 0.95	440,000	\$ 0.75
\$0.45	50,000	5.71	\$ 0.45	50,000	\$ 0.45

The Company issued additional options to consultants that were not part of this plan. Some of these options have been forfeited. The net amount of options issued for the year ended December 31, 2004 was 195,250 (see note 12(b)) of which 52,500 were exercisable as December 31, 2004.

**NOTE****4**

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**RELATED PARTIES:**

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 additional interest. The accrued interest is being paid out

according to the terms of Chembio Diagnostics, Inc.'s private placement of its series B preferred stock on January 28, 2005, which permits the payment of \$10,000 per month to the holders thereof. 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 at a price of \$0.61 per share.





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**NOTE 7 — LONG-TERM DEBT AND WORKING CAPITAL LINE OF CREDIT:**

**a) Long-term debt:**

Prior to the merger Chembio Diagnostic Systems, Inc. had \$707,914 of Senior Notes bearing interest at 11% and a line of credit agreement dated April 2001, with the President who is also a major shareholder, agreeing to advance the Company up to a maximum principal amount of \$1,200,000, of which \$985,937 was advanced.

As a result of the merger (see Note 1), \$1,332,292 of debt (\$580,417 of senior notes and \$751,875 of the line of credit) was converted into series A preferred stock. As per the terms of the merger agreement the total debt remaining as of December 29, 2004 which totaled \$361,559 was converted into series A preferred stock as of that date.

There is an additional amount due of \$332,950 which represents interest on the entirety of the debt prior to the conversion. Per the terms of the Series B offering (see note 17 (a)) it was agreed to allow this interest to be paid at the rate of \$10,000 per month. The holders of this accrued interest agreed to be subordinated to the redemption rights of the Series B preferred stockholders. Accordingly this \$332,950 has been reflected based upon repayment terms of \$120,000 short term and \$212,950 long term.

**b) Working Capital Loan and Restricted Cash:**

During 2004, the Company opened a \$250,000 certificate of deposit with HSBC Bank USA which was used as collateral for a working capital line of credit. The line of credit provides for advances of up to \$250,000 at the banks prime rate, which was 5.25% at December 31, 2004. The agreement expires on June 30, 2005, with an option to renew for another year. An addendum modified the interest rate for the first six months to 0.9% per annum, which expired on December 10, 2004. The Company expanded the allowable advances under this line in the fourth quarter of 2004 by \$80,000 which was guaranteed by the president of Chembio Diagnostics, Inc. The Company had a balance outstanding of \$45,000 as of December 31, 2004.

As part of the requirements of the Series B Offering (see note 17 (a)) this line of credit was repaid and closed in February of 2005, subsequent to the balance sheet date.

**NOTE 8 — 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, 2004 were as follows:

Year ending December 31,

2005	\$ 62,510
2006	42,688
2007	35,928
2008	4,470
	145,596
Less: imputed interest	20,300
Present value of future minimum lease payments	125,296

Less: current maturities	51,029
	\$ 74,267

These leases have interest rates ranging from 7% - 15%.

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**NOTE 9 — RESEARCH GRANTS AND DEVELOPMENT CONTRACTS:**

In 2004 and 2003 the Company received research grants and development contracts in the amount of \$556,789 and \$275,730 respectively. A substantial portion of the revenues realized in 2004 will recur in 2005.

**NOTE 10 — INCOME TAXES:**

No provision for Federal income taxes has been made for the years ended December 31, 2004 or 2003, due to the Company's operating losses. At December 31, 2004, the Company has unused net operating loss carryforwards of approximately \$10,800,000 which expire at various dates through 2024. Most of this amount is subject to annual limitations due to "changes in ownership" that have occurred over the past few months. In addition the Company also has a research and development credit carryforward of approximately \$230,000, which have created net deferred tax assets.

As of December 31, 2004 and 2003, the deferred tax assets related to the net operating loss carryforwards have been fully offset by valuation allowances, since the utilization of such amounts is uncertain. This valuation allowance, which increased by \$1,384,800 during 2004 and \$331,000 during 2003, has been provided due to management's uncertainty as to the reliability of these deferred tax assets.

Deferred tax assets consist of the following at:

	<b>December 31, 2004</b>	December 31, 2003
Net operating loss carryforwards	<b>\$ 4,424,000</b>	\$ 3,116,000
Research and development credit	<b>230,000</b>	214,000
Other	<b>73,000</b>	12,200
Gross deferred tax assets	<b>4,727,000</b>	3,342,200
Valuation allowance	<b>(4,727,000)</b>	(3,342,200)
Net deferred tax assets	<b>\$ —</b>	\$ —

**Note 11 - Preferred Stock:**

The Series A preferred stock was issued at a face value of \$30,000 per share and came with detachable warrants. Partial shares can also be issued. The value of the preferred shares was calculated using a fair value allocation between the preferred shares and detachable warrants. The series A preferred stock contains provisions whereby it can be conditionally redeemed outside of the control of management, accordingly per EITF #D-98 it has been classified outside of permanent equity. Some key features include:

- Dividends: Holders are entitled to an 8% per annum dividend accrued monthly and payable semi-annually.

In November the Company's Board of Directors voted to pay the \$181,896 dividend due on the 8% series A preferred stock in the form of Common Stock. The number of shares issued for this transaction was 303,145.

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- Conversion: Series A preferred stock is convertible, at the option of the holders, into shares of common stock at an initial 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 initially convertible into 50,000 shares of common stock.
- Redemption: The holders have the right based on certain events to redeem all or a portion of such holder's shares of series A preferred stock. As the series A preferred is not currently redeemable and there is no certainty that it will be redeemable, no accretion has been made to bring the value up to its redemption value (currently \$30,000 per share plus accrued and unpaid dividends of \$357.90 per share for an aggregate of \$4,929,286). Accrued but unpaid dividends of \$58,114 are included in the preferred stock carrying value as at December 31, 2004.

In connection with the merger described in Note 1, 151.57984 shares of 8% series A preferred stock convertible into 50,000 shares of common stock per preferred share, were issued as follows:

- i) 73.33330 shares were issued in connection with the cash offering of \$2,200,000, along with warrants to purchase 4,400,000 shares of common stock at an exercise price of \$0.90. Cash offering costs associated with this transaction were \$335,086.
- ii) 33.83682 shares were issued upon the conversion of \$672,000 of convertible debt and related interest thereon. Warrants to purchase 2,030,217 shares of common stock at an exercise price of \$0.90 were issued in connection with these shares. Cash offering costs associated with this transaction were \$83,770.
- iii) 44.40972 shares were issued upon the conversion of \$1,332,292 of existing debt, along with warrants to purchase 2,664,584 shares of common stock at an exercise price of \$0.90.

The total amount received or converted into series A preferred stock in connection with the merger was \$4,211,399. This value has been allocated between preferred stock at a value of \$2,442,791 and warrants issued at a value of \$1,768,605.

Per the Series A Offering, until March 5, 2005, holders are permitted to convert up to 20% of the Series A preferred stock into common at which point there are no further restrictions. As of December 31, 2004, 1.25942 shares of 8% Series A preferred were converted into 62,971 shares of Common Stock all of which occurred in the fourth quarter of 2004.

As a requirement of the merger, debt not converted as part of the Series A offering had to be paid or converted into 8% Series A preferred stock by the end of 2004 (see note 7(a)). On December 29, 2004, \$361,559 of debt was converted into 12.05199 shares of 8 % Series A preferred stock along with warrants to purchase 723,120 shares of common stock at an exercise price of \$0.90. This value has been allocated between preferred stock at a value of \$209,704 and warrants issued at a value of \$151,855.

As per EITF 00-27 "Application of Issue 98-5 to Certain Convertible Instruments" the Company evaluated the preferred stock transactions and accordingly found that there was an associated beneficial conversion feature. The cash purchase and existing debt conversions were found to contain a beneficial conversion totaling \$1,635,416 and 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 date 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 was effective. The total amount accreted back to the preferred and charged to dividends was



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\$1,373,750. Likewise, costs associated with the offering were charged to dividends over the same period. This amount totaled \$329,322 for the period ended December 31, 2004.

As of December 31, 2004 there were 162.37241 shares of Series A preferred stock outstanding.

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**NOTE**                      **12**                      **—**                      **STOCKHOLDERS' EQUITY:**

*(a) Common Stock*

i) As of March 1, 2004 Chembio Diagnostic Systems, Inc. issued 160,573 shares of its common stock to employees as compensation prior to the completion of the merger (see note 1) at a price of \$0.40 per share. These shares are included in ii) below.

As a result of the merger;

ii) Stockholders owning 40,000 shares of existing common stock in Chembio Diagnostic Systems, Inc. were issued 4,000,000 shares of common stock in the Company.

iii) Convertible Note holders converted \$328,000 of debt along with interest of \$2,697 into 826,741 shares of common stock of the Company.

iv) An employee was issued 400,000 shares of common stock pursuant to an employment contract. The value of the shares was recorded at \$240,000 and since there was no vesting period the entire value was expensed immediately. In addition this employee received warrants to purchase 850,000 shares of common stock at exercise prices from \$0.60 to \$0.90. These warrants had no intrinsic value.

v) As compensation for the financing of the convertible debt and the series A financing 65,667 shares of common stock were issued. The fair value of these shares were recorded as \$39,400 and ultimately reflected as deferred financing costs in the equity section of the balance sheet.

In addition 25,000 shares of common stock were issued to a consultant; the fair value of these shares was recorded as \$15,000 and reflected as an expense. Payables of \$27,989 to an attorney were paid with 37,319 shares of common stock, valued at \$22,391 and reflected as a reduction of payables and a gain on settlement.

In November, the Company's Board of Directors voted to pay the \$181,887 dividend due on the 8% series A preferred stock in the form of Common Stock. The number of shares issued for this transaction was 303,145.

On December 9, 2004, 56,250 shares of restricted common stock were issued to a consultant. Due to their restriction a discount to market price was used in the calculation of their fair value. The fair value recorded was \$23,625 and is being amortized over the three month contract.

During the fourth quarter of 2004 an aggregate of 1.25942 shares of 8% Series A preferred stock with a value of \$21,914 were converted into 62,971 shares of common stock.

On December 30, 2004 the president of the Company exercised warrants to purchase 66,869 shares of common stock at the exercise price of \$0.45 per share or an aggregate of \$30,091.

This results in 6,907,143 shares of common stock issued and outstanding as of December 31, 2004.

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*(b) Options*

On March 13, 2004 (prior to the merger - see note 1) Chembio Diagnostic Systems, Inc. issued 24,000 options as part of a consulting agreement. The exercise price for these options is \$0.60 per share. These options were part of the assumed options noted below. The fair value of these options was \$11,089 and was expensed.

Prior to the merger (see note 1) Chembio Diagnostic Systems, Inc. issued 315,000 options to existing option holders as part of the employee stock option plan (see note 3). The exercise price for these options ranged from \$0.543 to \$1.00 per share. These options were also part of the assumed options noted below. 32,500 options had an intrinsic value of \$929 and were expensed as they became fully vested at the time of merger. The remaining 282,500 options had no intrinsic value.

The Company assumed options of Chembio Diagnostic Systems, Inc. during the merger. The options assumed were to purchase a total of 704,000 shares of common stock of the Company.

Employee options were issued during the quarter ended June 30, 2004 as per the employee stock option plan (see note 3). Options to purchase an aggregate of 375,000 shares of common stock at exercise prices from \$0.60 to \$1.50 were granted. These options had no intrinsic value.

Options were issued to various consultants during the quarter ended June 30, 2004 to purchase a total of 225,000 shares of common stock at exercise prices from \$0.60 to \$1.50. The original fair values of these options were \$108,564 and are treated as prepaid expense and are being amortized over the life of their contracts. As per EITF 96-18 these options will continually be revalued until the measurement date for each option issuance has been reached. On October 31, 2004, the contract with one of these consultants was cancelled resulting in the forfeiture of 45,000 options valued at \$17,371 as of September 30, 2004. \$11,580 was removed from prepaid expenses and charges of \$5,791 taken through September 30, 2004 were reversed. Also, in November, another consultant's agreement was modified reducing the number of options by 13,750 valued at \$5,632 as of September 30, 2004. \$3,757 was removed from prepaid expenses and charges of \$1,875 taken through September 30, 2004 were reversed. The re-valuation of the remaining options increased their original value by \$4,980.

Options were issued in accordance with the 1999 Stock Option Plan (see note 3) to an employee on December 13, 2004 to purchase 50,000 shares of common stock. 25,000 of these options had an exercise price of \$1.00 and were immediately vested, the remaining 25,000 options had an exercise price of \$1.50 and vest on July 1, 2005. These options had no intrinsic value.

As of December 31, 2004 total options are outstanding to purchase 1,295,250 shares of common stock.

*(c) Warrants*

In May 2004, prior to the merger, Chembio Diagnostic Systems, Inc. issued 140,000 warrants to existing debt holders to compensate them for the valuation of the Company in the merger and issued 400,002 to existing stockholders for their consent to the merger. The warrants issued to debt holders had a fair value of \$60,650 and were expensed. The warrants issued to existing stockholders had a fair value of \$144,643 and were charged to additional paid in capital.

The Company assumed warrants of Chembio Diagnostic Systems, Inc. during the merger. The warrants assumed were to purchase a total of 690,002 shares of common stock of the Company.



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9,094,801 warrants were issued along with the series A preferred stock offering. These warrants were assigned a value of \$1,768,605, (See Note 11).

850,000 warrants were issued in connection with an employment agreement (See Note 12 (a)).

Warrants were issued to placement agents in connection with the series A preferred stock financing to purchase a total of 935,000 shares of common stock at exercise prices from \$0.72 to \$1.80. The fair values of these warrants are \$337,973.

On December 29, 2004, in connection with the debt converted into Series A preferred stock, 723,120 warrants were issued. These warrants were assigned a value of \$151,855, (See Note 11).

As of December 31, 2004 total warrants are outstanding to purchase 12,226,054 shares of common stock.

**NOTE 13 — COMMITMENTS AND CONTINGENCIES:**

***Employment Contracts:***

The Company entered into contracts with three key employees. The contracts call for salaries initially aggregating \$385,000 per year starting May of 2004. Two contracts expire in two years in May of 2006 and one contract expires in three years in May of 2007. The contracts call for a minimum increase in the second year of \$16,000 and a minimum increase of \$10,000 in the third year.

***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, 2004 and 2003 and accordingly no expense has been recorded.

***Obligations Under Operating Leases:***

The Company leases office space at three locations in buildings located at 3661 Horseback Road, Medford, New York. The following is a schedule of future minimum rental commitments as of December 31, 2004:

Year ending December 31,

2005		\$ 28,896
		\$ 28,896

The Company has entered into negotiations on extending the lease. The current proposal from the landlord is for two years with an option for two more. The rental being asked for is \$98,000 per year. If agreed to, the future minimums would be \$86,062 (including the \$28,896 from the table above) for 2005, \$98,000 for 2006 and \$32,667 for 2007.

Rent expense associated with these leases aggregated \$88,385 and \$90,693 for the years ended December 31, 2004 and 2003, respectively.



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***Economic Dependency:***

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 \$1,071,111 and \$308,913, respectively. Accounts receivable from these customers were \$0 and \$0, respectively at December 31, 2004.

The Company had sales to two customers in excess of 10% of total sales in the year ended December 31, 2003. Sales to these customers aggregated approximately \$397,030 and \$292,094, respectively. Accounts receivable from these customers were \$38,334 and \$13,101, respectively at December 31, 2003.

The Company had no purchases from any vendor in excess of 10% of total purchases for the years ended December 31, 2004 and 2003.

***Governmental Regulation:***

All of Chembio's existing and proposed diagnostic products are regulated by the FDA, U.S. Department of Agriculture, 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. All of Chembio's FDA and U.S. Department of Agriculture regulated products require some form of action by that agency before they can be marketed in the United States, and, after approval or clearance, Chembio must continue to comply with other FDA requirements applicable to marketed products. Both before and after approval or clearance, failure to comply with the FDA's requirements can lead to significant penalties.

**NOTE**

**14**

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**LITIGATION:**

Saliva Diagnostic Systems Dispute. An integral part of our business plan is the manufacture and sale of our Sure Check™ HIV rapid test product which incorporates a sample collection method that provides conveniences in terms of ease of use and safety. Until May 2003, Sure Check™ was known as "Hema Strip." Hema Strip was manufactured by Chembio Diagnostic Systems Inc. pursuant to a manufacturing agreement between Chembio Diagnostic Systems Inc. and Saliva Diagnostic Systems, Inc. The contract with Saliva Diagnostic was based upon, among other things, a patent that Saliva Diagnostic owns that was represented by Saliva Diagnostic to cover the sample collection method employed by the Hema Strip and which patent Saliva Diagnostic also represented to be valid and enforceable. Saliva Diagnostic unilaterally terminated the manufacturing agreement and alleged patent infringement by Chembio Diagnostic Systems Inc. We believe that the aforementioned patent did not cover the sample collection method used by the Hema Strip. We also believe that the Saliva Diagnostic patent was not valid due to the existence of previously uncited prior art.

On March 17, 2004, Saliva Diagnostic made further allegations of patent infringement against Chembio Diagnostic Systems Inc. In connection with the foregoing, Chembio Diagnostic Systems Inc. filed a complaint against Saliva Diagnostic in the United States District Court for the Eastern District of New York on March 18, 2004 (Civil Action No. 04-1149-JS-ETB). The complaint asks the court for declaratory and other relief that our Sure Check™ HIV test does not infringe the Saliva Diagnostic patent, that the Saliva Diagnostic patent is invalid, and that the Saliva Diagnostic patent is unenforceable due to inequitable procurement. On April 8, 2004, Saliva Diagnostic filed its answer and counterclaim, alleging that we were infringing on the Saliva Diagnostic Patent. We filed our Reply to Counterclaim on May 3, 2004, denying the allegation of infringement of the Saliva Diagnostic Patent. Briefs regarding the meaning of the claims of the Saliva Diagnostic Patent were filed February 28, 2005, and oppositions to

those briefs were filed March 9, 2005. A ruling on the meaning of the claim terms will then be issued by the court. Fact discovery is due to be completed by March 31, 2005, but may be extended depending on the date the court issues the claim construction ruling.



**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
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**NOTE 15 ~~RECALL~~:**

In October of 2004, the Company issued a voluntary recall of approximately 100,000 pregnancy tests. As a precautionary measure, the recall was expanded on November 3, 2004 to include approximately 215,000 additional pregnancy tests. As of December 31, 2004 the Company has estimated the total impact of this recall to be approximately \$100,000 which includes an accrual of \$60,264 as of December 31, 2004.

**NOTE 16 ~~FORGIVENESS OF DEBT~~:**

The Company negotiated settlements on several old outstanding payables aggregating \$209,372, which are reflected in other income as forgiveness of debt for the year ended December 31, 2004.

**NOTE 17 ~~SUBSEQUENT EVENTS~~:**

*(a) Series B Offering -*

On January 28, 2005 Chembio Diagnostics, Inc. completed a private placement of \$5,047,500 in 9% Series B Convertible Preferred Stock and associated warrants. The purchase price per share was \$50,000 for a total of 100.95 shares and warrants to purchase 7,860,935 shares of common stock. In addition one Series A preferred stockholder exercised it's rights to exchange \$20,000 worth of Series A 8 % Preferred Stock and associated warrants for .40 shares of 9% Series B Preferred Stock and for warrants to purchase 31,147 shares of common stock.

As part of the terms of the Series B purchase Agreement, the accrued but unpaid interest related to long term debt (see note 7) totaling \$332,950 is to be paid out over 34 months at a rate of \$10,000 per month.

Placement Agents were paid a commission in cash of 5% of the gross cash proceeds and received 5% of the gross cash proceeds in the form of 9 % Series B Preferred stock and associated warrants. 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, Crestview Master Capital, LLC, has given notice of its intent to exercise its warrants.

Dividends: The 9% Series B Preferred stock accrues dividends at 9% per annum and is payable on the first of July and January. The dividend is payable in either Series B preferred stock (and warrants) or cash, at the option of the Company; however, the majority investor in the Series B financing, Crestview Capital Master, LLC, has the option as it pertains to their dividend payment in respect of the Series B preferred stock.

Conversion: The Series B Preferred Stock is convertible, at the option of the holders, into shares of Common Stock at an initial conversion price of \$.61 per share. Based on the original purchase price of \$50,000 per share, each share of Series B Stock is initially convertible into 81,968 shares of Common.

Rank; Liquidation Preference: The holders of Series B Stock rank pari passu to the holders of the Registrant's Series A Convertible Preferred Stock (the "Series A Stock") and prior to the holders of the Common Stock and, unless otherwise consented to by the holders of Series B Stock, prior to all other classes of capital stock that the Registrant may establish, with respect to (i) the payment of dividends and (ii) the distribution of its assets upon a bankruptcy, liquidation or other similar event. The liquidation preference for the Series B Stock is an amount equal to \$50,000 per share plus any accrued and unpaid dividends and liquidated damages owing thereon.



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Redemption: The holders have the right based on certain events to redeem all or a portion of such holder's shares of series B preferred stock.

**(b) License and Technology Transfer Agreement -**

On February 14, 2005, Chembio Diagnostic Systems, Inc., a wholly owned subsidiary of Chembio Diagnostics, Inc., entered into a License and Technology Transfer Agreement with Prionics AG, Zurich, Switzerland. This agreement calls for up to \$500,000 in milestone payments to be made upon the completion of various events and up to \$1,500,000 in royalties based upon product sales. The Company has only completed the first milestone and received a non-refundable payment of \$250,000. As of this date the remaining milestones, upon which the remaining \$250,000 in milestone payments and the \$1,500,000 of royalties based upon product sales would be paid, have not been completed.