

Chembio Diagnostics Inc.  
Form 424B3  
November 09, 2004

**PROSPECTUS**

**CHEMBIO DIAGNOSTICS, INC.**

**21,534,808 SHARES OF COMMON STOCK**

This prospectus relates to the sale by certain stockholders of Chembio Diagnostics, Inc. of up to 21,534,808 shares of our common stock which they own, or which they may at a later date acquire upon the conversion of shares of our 8% series A convertible preferred stock or upon the exercise of warrants and options to purchase shares of our common stock.

Our common stock is quoted on the OTC Bulletin Board under the symbol CEMI. On October 20, 2004 the closing bid and ask prices for one share of our common stock were \$1.25 and \$1.29, respectively, as reported by the OTC Bulletin Board website. These over-the-counter quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

-----

**These securities are speculative and involve a high degree of risk. You should consider carefully the Risk factors beginning on Page 4 of this prospectus before making a decision to purchase our stock.**

-----

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

-----

The date of this prospectus is November 8, 2004

---

## TABLE OF CONTENTS

Prospectus Summary	3
Risk Factors	6
Cautionary Statement Regarding Forward-Looking Statements	10
Use of Proceeds	11
Dilution	11
Selling Security Holders	11
Plan of Distribution	13
Legal Proceedings	14
Directors, Executive Officers and Control Persons	14
Security Ownership of Certain Beneficial Owners and Management	17
Description of Securities	19
Interest of Named Experts and Counsel	19
Disclosure of Commission Position of Indemnification for Securities Act Liabilities	19
Description of Business	19
Management Discussion and Analysis and Plan of Operation	26
Description of Property	30
Certain Relationships and Related Transactions	31
Market for Common Equity and Related Stockholder Matters	31
Executive Compensation	32
Financial Statements	32
Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	33
Additional Information	33

---

## PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. You should read the entire prospectus carefully before making an investment decision.

### Overview

Chembio Diagnostic Systems Inc. was formed in 1985. Since its inception, Chembio Diagnostic Systems Inc. has been involved in developing, manufacturing, selling and distributing tests, including rapid tests, for a number of diseases and for pregnancy. On May 5, 2004, Chembio Diagnostic Systems Inc. completed a merger through which it became a wholly-owned subsidiary of Trading Solutions.com, Inc. and through which the management and business of Chembio Diagnostic Systems Inc. became the management and business of Trading Solutions.com, Inc. Also, as part of this transaction, Trading Solutions.com, Inc. changed its name to Chembio Diagnostics, Inc.

### Our Business

We are a developer and manufacturer of rapid diagnostic tests that aid in the detection of infectious diseases, pregnancy and other conditions. Our revenues to date have been primarily from private label over-the-counter pregnancy tests; however, we are exiting that business due to competitive and other factors and we are focused on obtaining FDA regulatory approval for, and increasing revenues from, our HIV rapid test products. We are engaged in marketing efforts for distribution of our HIV rapid test products in markets outside the United States. We also are focused on efforts to complete development of, and proceed to seek regulatory approval for, other rapid tests in the areas of tuberculosis (human and veterinary), dental bacteria and Mad Cow Disease.

Our main products and products under development are summarized in the following tables:

Existing or Proposed Product	Regulatory Status	Development Status	Partners Involved in the Development or Marketing of the Products
HIV Rapid Tests (Sure Check HIV; HIV 1/2 Stat Pak). Rapid Tests for detection of antibodies to HIV 1 and 2 in whole blood.	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. During the second quarter of 2004 we commenced clinical trials for Sure Check and HIV Stat Pak for FDA approval for sales in the U.S. We expect these trials to be completed during the fourth quarter of 2004. Subject primarily to satisfactory completion of clinical trials and our manufacturing facility inspection in accordance with FDA requirements, we believe that FDA approval can be achieved in 2005.	Completed.	Thirteen-year supply and technology transfer agreement with FIOCRUZ-Bio-Manguinhos, a division 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. We also have been actively seeking to have our tests procured by governmental and non-governmental organizations engaged in HIV prevention programs in numerous locations outside the United States.
Rapid test for detection of Bovine Spongiform Encephalopathy in cattle	Upon completion of product it will be submitted for US and European regulatory approval which we expect will occur in 2005.	Product under development. We are waiting to complete technology transfer with Prionics.	Prionics AG, Zurich, Switzerland has contracted with Chembio to provide manufacturing services. Prionics will exclusively market product directly and through its designated distributors. Prionics provides certain components

Edgar Filing: Chembio Diagnostics Inc. - Form 424B3

			to Chembio
Dental Bacteria Test	Regulatory submission will be made in 2005 if product development is satisfactorily completed and in accordance with development timetable	Currently in Phase 2 (Optimization of Test)-of three phase development project. Timetable is to complete by late 2004/early 2005	Ivoclar-Vivadent, AG, Schaan Liechtenstein will exclusively market product and is the exclusive licensee of patented antibodies being incorporated by Chembio in product development
Rapid diagnostic test for detection of antibodies to active pulmonary tuberculosis in human whole blood samples	No plans for US or EU approval. Evaluations to support use in international public health programs are pending.	Product validation completed.	Public Health Research Institute, Newark, NJ provided initial research collaboration on product development, but will not be involved in the marketing of the product.
Rapid diagnostic test for the detection of antigens for active pulmonary tuberculosis in sputum	Regulatory submission plan and timetable not possible until further progress on product development is made.	Product under development pursuant to grant from the World Health Organization.	None.
Rapid diagnostic test for the detection of antibodies to active pulmonary tuberculosis in non-human primate whole blood samples	Will be submitted for regulatory approvals in the US in 2005.	Product validation completed.	Sequella Corporation, Rockville, Maryland is funding product development and clinical testing costs. Chembio will market this product directly and/or through distributors.
Private Label Pregnancy Tests	Cleared for marketing by FDA.	Completed.	Independent and regional drug store chains and distributors thereto in select markets.

Our historical revenues on a percentage basis are reflected as follows:

	2002	2003	6 months ended June 30, 2004
Pregnancy Tests	45.73%	46.84%	33.31%
HIV Tests	15.46%	18.50%	30.37%
Other Infectious Disease Tests	28.47%	24.88%	14.84%
Research Grants and Contracts	10.34%	9.78%	21.48%
Total	100.00%	100.00	100.00%

All of the tests we currently manufacture as well as those under development employ various formats of lateral flow technology. Lateral flow generally refers to the process of a sample flowing from the point of application on a test strip to provide a test result on a portion of the strip downstream from the point of application. We believe we have expertise and proprietary know-how in the field of lateral flow technology.

We have a history of losses and we continue to incur operating and net losses. We own no patents through we have non-exclusive licenses to lateral flow patents from Abbott Laboratories, Inc. and to reagents that are used in our HIV rapid tests. However, these licenses do not necessarily insulate us from patent challenges by other patent holders.

Our principal executive offices are located at 3661 Horseblock Road, Medford, New York 11763. Our telephone number is (631) 924-1135. Our website address is [www.chembio.com](http://www.chembio.com).

### **The Offering**

By means of this prospectus, a number of our stockholders are offering to sell up to 4,980,113 shares of common stock which they own, up to 6,031,868 shares of common stock which they may at a later date acquire upon the conversion of our series A preferred stock, and up to 10,522,827 shares of common stock which they may at a later date acquire upon the exercise of warrants and/or options. In this prospectus, we refer to these persons as the selling security holders.

As of June 1, 2004, we had 6,417,908 shares of common stock issued and outstanding, which includes shares offered by this prospectus. The number of outstanding shares of common stock does not give effect to common stock which may be issued pursuant to the conversion of our series A preferred stock and the exercise of options and/or warrants previously issued by Chembio Diagnostics, Inc.

We will not receive any proceeds from the sale of common stock by the selling security holders pursuant to this prospectus.

### **Summary Financial Data**

The following table presents summary historical and pro forma financial information for the six months ended June 30, 2004 and for the fiscal year ended December 31, 2003. The pro forma information illustrates the effects of the acquisition of Chembio Diagnostic Systems Inc., as if the merger transaction between Chembio Diagnostics, Inc. and Chembio Diagnostic Systems Inc. had occurred at the beginning of the respective periods presented and therefore assumes that proceeds of the financings were expended in the periods presented, and that costs and expense associated with the merger and associated financings were incurred in the periods presented, all as set forth in the notes to our unaudited pro forma financial statements. The unaudited pro forma financial statements and our audited financial statements are set forth on page F-1 of this prospectus, and you should read this information for a more complete understanding of the presentation of this information.

	<b>Historical</b>		<b>Pro Forma</b>	
	<b>Six Months Ended June 30, 2004</b>	<b>Year Ended December 31, 2003</b>	<b>Six Months Ended June 30, 2004</b>	<b>Year Ended December 31, 2003</b>
Revenue	1,580,377	2,818,351	1,580,377	2,818,351
Operating Expenses	1,693,107	1,516,076	1,769,694	1,693,199
Net Loss	(1,203,999)	(1,059,074)	(1,393,562)	(1,498,686)
Current Assets	2,491,310	772,680	n/a	n/a
<b>Total Assets</b>	<b>2,746,276</b>	<b>1,086,745</b>	<b>n/a</b>	<b>n/a</b>
Current Liabilities	952,374	1,503,418	n/a	n/a
<b>Total Liabilities</b>	<b>1,715,862</b>	<b>3,544,186</b>	<b>n/a</b>	<b>n/a</b>
<b>Redeemable Preferred</b>	<b>2,499,604</b>	<b>-</b>	<b>n/a</b>	<b>n/a</b>
<b>Stockholders Equity</b>	<b>(1,469,190)</b>	<b>(2,457,441)</b>	<b>n/a</b>	<b>n/a</b>



## **RISK FACTORS**

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

### **Risks related to our industry, business and strategy**

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

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

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

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

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

For example, the European Union and other jurisdictions have recently established a requirement that diagnostic medical devices used to test human biological specimens must receive regulatory approval known as a CE mark, or be registered under the ISO 13.485 medical device directive. The letters "CE" are the abbreviation of the French phrase "Conforme Européenne" which means "European conformity." ISO (International Organization for Standardization) is the world's largest developer of standards with 148 member countries. As such, export to the European and other jurisdictions without the CE or ISO 13.485 mark is not possible. Although we are not currently selling products to countries requiring CE marking, we expect that we will do so in the near future in order to grow our business. We are in the process of implementing quality and documentary procedures in order to obtain CE and ISO 13.485 registration, and we are not aware of any material reason why such approvals will not be granted. However, if for any reason CE or ISO 13.485 registration is not granted, our ability to export our products could be adversely impacted.

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

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

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

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

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

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

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

Introducing and achieving market acceptance for our rapid HIV tests and other new products will require substantial marketing efforts and will require us or our contract partners to make significant expenditures. We have no history upon which to base market or customer acceptance of these products. In some instances we will be totally reliant on the marketing efforts and expenditures of our contract partners. If they do not have the expertise and resources to effectively market the products that we manufacture, our operating results will be materially harmed.

**If we lose our funding from research and development grants, we may not be able to fund future research and development and implement technological improvements, which would materially harm our operating results.**

We received \$275,730 or 9.78% of our revenues in 2003 and \$339,457 or 21.48% of our revenues for the six months ended June 30, 2004 from grant and contract development work in connection with grants from the United States National Institute of Health, as well as from universities and commercial companies related to product development efforts for our tuberculosis, mad cow, and dental bacteria rapid test development work. These revenues have funded some of our personnel and other research and developmental costs and expenses for us. As a result of new grants and development contracts awarded to collaborative partners by the National Institute of Health and to us by the World Health Organization and other entities, revenue from funding grants is anticipated to increase in 2004. However, if these awards are not funded in their entirety or if new grants and contracts are not awarded in the future, our ability to fund future research and development and implement technological improvements would be jeopardized which would negatively impact our ability to compete in our industry.

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

We believe that our current cash balances, together with cash generated from operations, will be sufficient to fund operations through December 2004. This estimate is primarily based upon the assumption that we will receive orders from Bio-Manguinhos in 2004 and 2005 in accordance with contractual commitments. However, we also may face additional unanticipated expenses. We anticipate that we will be required to obtain additional capital through the sale of additional equity or debt securities or through additional credit facilities by the end of 2004. Any additional equity financing will result in dilution to existing shareholders. If we are unable to obtain financing on satisfactory terms, we will not be able to effectively carry out our business plan.

The amount of additional capital we need and our ability to obtain it will depend on a number of factors. These factors primarily include (1) receipt of orders from Bio-Manguinhos in 2004 in accordance with contractual commitments; (2) whether we can generally achieve revenue growth for our HIV rapid tests and the extent, if any, to which that revenue growth improves operating cash flows; (3) our investments in research and development, facilities, marketing, regulatory approvals, and other investments we may determine to make; (4) the availability and cost of raising additional capital and potential dilution to shareholders; and (5) the extent, if any, to which any of the Company's

outstanding options or warrants are exercised for cash.

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

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

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

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

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

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

We seek to protect our proprietary products under trade secret and copyright laws, enter into license agreements for various materials and methods employed in our products, and enter into strategic relationships for distribution of the products. These strategies afford only limited protection. We currently have no U.S. or foreign patents, although we have several license agreements for reagents. Our Sure Check trademark has been registered in the United States.

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

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

**In order to sell our rapid HIV tests and generate expected revenue from these tests, we will need to arrange for a license to patents for detection of the HIV-2 virus, and we may not be able to do so.**

Although the current licensor of the peptides used in our HIV tests claims an HIV-2 patent, other companies have also claimed such patents. Even though HIV-2 is a type of the HIV virus estimated to represent only a small fraction of the known HIV cases worldwide, it is still considered to be an important component in the testing regimen for HIV in many markets. HIV-2 patents are in force in most of the countries of North America and Western Europe, as well as in Japan, Korea, South Africa, and Australia. Access to a license for one or more HIV-2 patents may be necessary to sell HIV-2 tests in countries where such patents are in force, or to manufacture in countries where such patents are in force and then sell into non-patent markets. Since HIV-2 patents are in force in the United States, we may be restricted from manufacturing a rapid HIV-2 test in the United States and selling into other countries, even if there were no HIV-2 patents in those other countries. The license agreement that we have in effect for the use and sale of the Adaltis HIV 1 and 2 peptides that are used in our HIV rapid test does not necessarily insulate us from claims by other parties that we need to obtain a license to other HIV-1 and/or HIV-2 patents. Although we have discussed additional HIV-2 licenses that would be advantageous for some markets, if we are unable to successfully continue these discussions our business and operating results would be materially harmed.

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

Our success will depend to a large extent upon the contributions of our executive officers, management, and sales, marketing, operations and scientific staff. Although we have not experienced unusual retention and/or recruitment problems to date, we may not be able to attract or retain qualified employees in the future due to the intense competition for qualified personnel among medical products businesses.

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

We have entered into employment contracts with our President, Lawrence Siebert, our Director of R&D, Javan Esfandiari, and our Director of Sales & Marketing, Avi Pelossof. Due to the specific knowledge and experience of these executives regarding the industry, technology and market, the loss of the services of any one of them would likely have a material adverse effect on the Company. The contract with Mr. Siebert has a term of two years ending May 2006, and those with Messrs. Esfandiari and Pelossof have a term of three years ending May 2007. We have obtained key man insurance policies for Messrs. Esfandiari and Pelossof.

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

We believe it to be in our best interest to meaningfully participate in the Presidential Emergency Plan for Aids Relief Program, UN Global Fund initiatives and other programs funded by large donors. We have initiated several strategies to participate in these programs. Participation in these programs requires alignment with the many other players in these programs including the World Health Organization, U.S. Center for Disease Control, U.S. Agency for International Development, non-governmental organizations, and HIV service organizations. By participating in these programs, we believe we will gain favorable market recognition with industry peers, and increase our chances of participating in these programs. If we are unsuccessful in our efforts to participate in these programs, our operating results could be materially harmed.

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

Since the inception of Chembio Diagnostic Systems, Inc. in 1985 and through the period ended June 30, 2004, we have incurred net losses. As of June 30, 2004, we have an accumulated deficit of \$8,182,341. We incurred net losses of \$(988,971) and \$(1,059,704) in 2002 and 2003, respectively, and of \$(1,181,710) for the six months ended June 30, 2004.

We expect to continue to make substantial expenditures for sales and marketing, regulatory submissions, product development and other purposes. Our ability to achieve profitability in the future will primarily depend on our ability to increase sales of our products, reduce production and other costs and successfully introduce new products and enhanced versions of our existing products into the marketplace. If we are unable to increase our revenues at a rate that is sufficient to achieve profitability, our operating results would be materially harmed.

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

**materially harmed.**

We may be held liable if any of our products, or any product which is made with the use or incorporation of any of the technologies belonging to us, causes injury of any type or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or usage. Although we have obtained product liability insurance, this insurance may not fully cover our potential liabilities. In addition, as we attempt to bring new products to market, we may need to increase our product liability coverage which would be a significant additional expense that we may not be able to afford. If we are unable to obtain sufficient insurance coverage at an acceptable cost to protect us, we may be forced to abandon efforts to commercialize our products or those of our strategic partners, which would reduce our revenues.

**Risks related to our common stock**

**Our common stock is classified as penny stock and is extremely illiquid, so investors may not be able to sell as much stock as they want at prevailing market prices.**

Our common stock is classified as penny stock. Penny stocks generally are equity securities with a price of less than \$5.00 and trade on the over-the-counter market. As a result, an investor may find it more difficult to dispose of or obtain accurate quotations as to the price of the shares of the common stock being registered in this registration statement. In addition, the penny stock rules adopted by the Commission under the Exchange Act subject the sale of the shares of the common stock to regulations which impose sales practice requirements on broker-dealers, causing many broker-dealers to not trade penny stocks or to only offer the stocks to sophisticated investors that meet specified net worth or net income criteria identified by the Commission. These regulations contribute to the lack of liquidity of penny stocks.

The average daily trading volume of our common stock on the over-the-counter market was less than 1,000 shares per day over the three months ended June 30, 2004. If limited trading in our stock continues, it may be difficult for investors to sell their shares in the public market at any given time at prevailing prices. Since the certificate of designation creating our series A preferred stock contains restrictions on our ability to declare and pay dividends on our common stock, the lack of liquidity of our common stock could negatively impact the rate of return on your investment.

**Sales of a substantial number of shares of our common stock into the public market by the selling stockholders may result in significant downward pressure on the price of our common stock and could affect the ability of our stockholders to realize the current trading price of our common stock.**

Although our stock is illiquid, at the time of effectiveness of the registration statement, the number of shares of our common stock eligible to be immediately sold in the market will increase approximately from 180,000 to 21,715,636. If the selling stockholders sell significant amounts of our stock, our stock price could drop. Even a perception by the market that selling stockholders will sell in large amounts after the registration statement is effective could place significant downward pressure on our stock price.



**As of July 1, 2004, 6,237,080 shares of our total outstanding shares are restricted from immediate resale, but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.**

5,155,060 shares of common stock, including those underlying our convertible securities, that are not being registered in the registration statement are restricted securities as that term is defined under the Securities Act. Though not currently registered, these restricted securities may be sold in compliance with Rule 144 of the Securities Act or pursuant to a future registration statement. Rule 144 provides that a person holding restricted securities for a period of one year or more may, sell those securities in accordance with the volume limitations and other conditions of the rule. Sales made pursuant to Rule 144 or 144(k), or pursuant to a registration statement filed under the Securities Act, could result in significant downward pressure on the market price for our common stock.

**You will experience substantial dilution upon the conversion of the shares of preferred stock and the exercise of warrants that we issued in a private placement and the warrants and options that were assumed in connection with the merger.**

On May 5, 2004, we completed three separate private placements in which we issued 151,579.84 shares of our series A preferred stock and warrants to acquire 9,904,801 shares of our common stock at an exercise price of \$.90 per share. The shares of series A preferred stock are convertible into 7,578,985 shares of our common stock. We also issued warrants to purchase 425,000 shares of our common stock at an exercise price of \$0.72 per share and warrants to purchase 510,000 shares of common stock at an exercise price of \$1.08 per share to designees of our placement agents. We also issued warrants pursuant to an employment agreement with Mark L. Baum, our former president and a current member of our board of directors, to purchase 425,000 shares and 425,000 shares of our common stock, respectively, at exercise prices of \$0.60 and \$0.90 per share respectively. In connection with the acquisition of Chembio Diagnostics Diagnostic Systems, Inc., we assumed warrants to purchase an aggregate of 690,000 shares of our common stock, at exercise prices ranging from \$0.45 to \$4.00 per shares and we adopted the stock option plan of Chembio Diagnostics Diagnostic Systems, Inc. and assumed all outstanding options. As of May 31, 2004, there were 704,000 options issued and outstanding under the stock option plan and 796,000 options available for issuance under the stock option plan. As a result, the conversion of the outstanding preferred stock and the exercise of the outstanding warrants and options will result in substantial dilution to the holders of our common stock.

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

As of July 1, 2004, our named executive officers, directors and 5% stockholders beneficially own approximately 48.16% of our voting power. For the foreseeable future, to the extent that our current stockholders vote similarly, they will be able to exercise control over many matters requiring approval by the board of directors or our stockholders. As a result, they will be able to:

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

### **CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus and the materials incorporated herein by reference contain forward-looking statements that involve substantial risks and uncertainties. You can identify these statements by forward-looking words such as *may*, *will*, *expect*, *intend*, *anticipate*, *believe*, *estimate*, *continue* and other similar words. You should read statements with these words carefully because they discuss our future expectations, make projections of our future results of operations or of our financial condition or state other forward-looking information. We believe that it is important to communicate our future expectations to our investors. However, there may be events in the future that we are not able to accurately predict or control. Our actual results could differ materially from the expectations we describe in our forward-looking statements as a result of certain factors, as more fully described in the *Risk Factors* section of this prospectus and elsewhere in the documents we file with the SEC that are incorporated herein.

## USE OF PROCEEDS

We will not receive proceeds from the sale of shares under this prospectus by the selling security holders.

## DILUTION

We are not selling any common stock in this offering. The selling security holders are current stockholders of Chembio Diagnostics, Inc. As such, there is no dilution resulting from the common stock to be sold in this offering.

## SELLING SECURITY HOLDERS

The securities are being offered by the named selling security holders below. The selling security holders may from time to time offer and sell pursuant to this prospectus up to an aggregate of 4,980,113 shares of our common shares now owned by them, 6,031,868 shares issuable to them upon the conversion of series A preferred stock that they hold, 9,438,827 shares issuable to them upon the exercise of warrants that they hold and 1,084,000 shares issuable to them upon the exercise of options that they hold. The selling security holders may, from time to time, offer and sell any or all of the shares that are registered under this prospectus.

Certain of the individuals listed below received the shares offered hereby in connection with the merger described under the caption Prospectus summary Our business. In connection with the merger, we agreed to prepare and file at our expense, as promptly as practical, and in any event, by June 4, 2004, a registration statement with the Securities and Exchange Commission covering the resale of the shares received in the merger by the individuals listed below. The list of selling security holders also includes Mark L. Baum, who acquired, or has the right to acquire, the shares and warrants indicated next to his name pursuant to an employment agreement dated May 5, 2004 with Chembio Diagnostics, Inc. Also named as selling security holders are designees of H.C. Wainwright & Co., Inc. and WellFleet Partners, Inc., each of which received common stock and warrants to purchase the indicated number of shares of common stock in connection with serving as placement agents in connection with our May 5, 2004 private placement of series A preferred stock, and Patton Boggs LLP, which received 37,319 shares as payment for a past obligation of \$27,989, that we owed. Also included are a total of 25,000 shares and options to acquire 225,000 shares that we issued to non-employee third parties for services performed, together with 375,000 options to purchase shares issued to employees and directors.

The remainder of the entities or individuals listed below acquired the shares offered hereby in connection with our May 5, 2004 private placement of series A preferred stock. Pursuant to this private placement, we received \$2.2 million in cash as payment for 73.3333 shares of preferred stock that are convertible into 3,666,664 shares of common stock. We also received warrants to acquire 4.4 million shares of common stock at an exercise price of \$.90 per share. Based on the \$2.2 million paid, the purchase price per common share is \$.60, without allocating any portion of the purchase price to the warrants. At the same time as this transaction, a conversion of \$1,009,803 face amount and accrued interest of convertible notes that had been issued in February 2004 occurred. Of this conversion, \$330,696 face amount and interest was converted into 826,741 shares of common for a conversion price, based on the face amount of the notes, of \$.40 per share; and \$679,107 face amount and interest was converted into 33.83682 shares of our series A preferred, together with warrants to purchase 2,030,217 shares of common stock at \$.90 per share. The 33.83682 shares of series A preferred are convertible into 1,691,835 shares of our common stock, which based on the face amount of the notes, represents a purchase price of \$.40 per share of common stock, without allocating any portion of the purchase price to the warrants. Also simultaneously with the other two private placement transactions, we issued 44.40972 shares of our series A preferred stock, convertible into 2,220,486 shares of our common stock, together with warrants to purchase 2,664,584 shares of our common stock at an exercise price of \$.90 per share, in

exchange for \$1,332,292 face amount of our debt obligations. Based on the face amount of these obligations, the price per common share is \$.60 per share, without allocating any portion of the purchase price to the warrants. Also in connection with these three private placements, we agreed to prepare and file at our expense, as promptly as practical, and in any event, by June 4, 2004, a registration statement with the Securities and Exchange Commission covering the resale of the shares of common stock issuable upon conversion of the series A preferred stock and the shares of common stock issuable upon exercise of the warrants.

The following table sets forth, with respect to the selling security holders:

- the number of shares of common stock beneficially owned as of May 31, 2004 and prior to the offering contemplated hereby,
- the number of shares of common stock eligible for resale and to be offered by each selling security holder pursuant to this prospectus,
- the number of shares owned by each selling security holder after the offering contemplated hereby assuming that all shares eligible for resale pursuant to this prospectus actually are sold,
- the percentage of shares of common stock beneficially owned by each selling security holder after the offering contemplated hereby, and
- in notes to the table, any relationships, excluding non-executive employee and other non-material relationships, that a selling security holder had during the past three years with the registrant or any of its predecessors or affiliates.

	Number of Shares of Common Stock Owned Before Offering(A)	Number of Shares To Be Offered (B)	Number of Shares Owned After Offering	Percentage of Shares of Common Stock Owned After Offering
Selling security holders(C)				
Alan Perlmutter	60,000	60,000		0.00%
Alchemy, LLC	40,471	40,471		0.00%
Alex Shapiro	112,412	112,412		0.00%
Ami Dabush	494,694	494,694		0.00%
Andrew Merz Hanson1	117,530	117,530		0.00%
Anne Ross	63,236	63,236		0.00%
Ari Fuchs2	49,058	49,058		0.00%
Avi Pelossof	570,282	570,282		0.00%
Bill Ledowitz	7,118	7,118		0.00%
Bio-Equity Partners, Inc.3	175,000	175,000		0.00%
Bruce J. Ide4	496,539	496,539		0.00%
Christopher & Lynn Eckert5	183,333	183,333		0.00%
Chris Phillips	40,471	40,471		0.00%
Claudio Beller	143,063	143,063		0.00%
Colin Lawrence	7,115	7,115		0.00%
Colin Poole	138,579	138,579		0.00%
Daniel Gressel6	472,501	472,501		0.00%
David Hunt	100,000	100,000		0.00%
Elior Pelossof	83,148	83,148		0.00%
Eduardo Haim	7,115	7,115		0.00%
Edwin McGusty	125,000	125,000		0.00%
Elaine Klaus	17,242	17,242		0.00%
Ellen Siebert Best	42,936	42,936		0.00%
Eric Schwartz	5,496	5,496		0.00%
Felicia Lew	31,250	31,250		0.00%
Frank J. Guzikowski	178,114	178,114		0.00%
Gilbert Raker	83,148	83,148		0.00%
Gunther Weiss	28,334	28,334		0.00%
Hanka Lew	31,250	31,250		0.00%
H.C. Wainwright & Co., Inc.	390,867	390,867		0.00%
J & S Sandler	8,287	8,287		0.00%
J.G. Poole	68,365	68,365		0.00%
J.P. Turner	41,250	41,250		0.00%
Javan Esfandiari	167,080	167,080		0.00%
Jean-Paul Calamaro	304,542	304,542		0.00%
Jeff Dashefsky	12,500	12,500		0.00%
Jeffrey Goldberg7	52,875	52,875		0.00%
John R. Clarke8	158,400	158,400		0.00%
John Tyson9	30,000	30,000		0.00%
Joshua Lifshitz	133,037	133,037		0.00%
Kaare Kolstad Jr.	50,589	50,589		0.00%
Karen Keskinen	31,579	31,579		0.00%

Edgar Filing: Chembio Diagnostics Inc. - Form 424B3

KNB Communications LLC <sup>10</sup>	45,000	45,000		0.00%
Konstantin Lyashchenko	10,500	10,500		0.00%
Kurzman Partners, LP <sup>19</sup>	73,333	73,333		0.00%
Kurt Haendler	250,955	250,955		0.00%
Lawrence Siebert	5,305,060	500,000	4,805,060	46.58%
Alpha Capital AG	1,210,000	1,210,000		0.00%
Lon E. Bell	277,159	277,159		0.00%
Marc Glass	20,708	20,708		0.00%
Mark Baum	1,788,333	1,438,333	350,000	4.66%
Mark & Lori Sandler	183,333	183,333		0.00%
Mark Wachs	27,716	27,716		0.00%
Total M.I.S., Inc.	550,000	550,000		0.00%
Metasequoia LLC	36,666	36,666		0.00%
Michael McCarthy	4,145	4,145		0.00%
Mike Ginsberg	2,375	2,375		0.00%
Mike Mayer-Wolf	18,379	18,379		0.00%
MSAS Trust	733,333	733,333		0.00%
Patton Boggs LLP	37,319	37,319		0.00%
Paul & Ellen Knasin	149,788	149,788		0.00%
Phil Greenblatt	10,347	10,347		0.00%
R. Edward Spilka <sup>11</sup>	309,805	309,805		0.00%
R. Lankenau	102,835	102,835		0.00%
R. Siderow <sup>20</sup>	85,874	85,874		0.00%
Renata Haendler	44,829	44,829		0.00%
Richard A. Jacoby	462,675	462,675		0.00%
Richard Bruce	75,500	75,500		0.00%
Richard Larkin	108,182	108,182		0.00%
Robin Smith <sup>12</sup>	119,883	119,883		0.00%
Russ Colby	12,500	12,500		0.00%
Sam Engel	4,118	4,118		0.00%
Sam Jacob	10,000	10,000		0.00%
Sandy Speer	65,468	65,468		0.00%
Scott F. Koch <sup>13</sup>	158,400	158,400		0.00%
Scott W. Phillips	50,589	50,589		0.00%
Victus Capital <sup>14</sup>	5,500,000	5,500,000		0.00%
Sive Paget & Reisel	2,055	2,055		0.00%
Spencer Reibman	18,780	18,780		0.00%
Stanley Seren	8,287	8,287		0.00%
Starobin Partners <sup>15</sup>	110,000	110,000		0.00%
Stephen Feldman	2,055	2,055		0.00%
Steve Chrust	127,656	127,656		0.00%
Steve Schnipper	199,554	199,554		0.00%
Little Gem Life Sciences Fund LLC	91,666	91,666		0.00%
Straightline Capital Opp. Fund, LLC	737,117	737,117		0.00%
Ted Breitbart <sup>16</sup>	18,208	18,208		0.00%
Alan Talesnick <sup>17</sup>	238,194	238,194		0.00%
Thunderbird Global Corporation	1,011,672	1,011,672		0.00%
Tomas Haendler <sup>18</sup>	698,933	698,933		0.00%

Edgar Filing: Chembio Diagnostics Inc. - Form 424B3

Truman Bassett	42,526	42,526	0.00%
Wendy Joffe	36,847	36,847	0.00%
Westbury Diagnostics	141,905	141,905	0.00%
Zilma Rojas	5,500	5,500	0.00%
<b>TOTALS</b>	<b>26,689,868</b>	<b>21,534,808</b>	<b>5,155,060</b>

(A) Includes shares underlying series A preferred stock into which the series A preferred stock is convertible, and shares underlying warrants and/or options held by the selling security holder that are covered by this prospectus, including any convertible securities that, due to contractual restrictions, may not be exercisable within 60 days of the date of this prospectus.

(B) The number of shares of common stock to be sold assumes that the selling security holder elects to sell all of the shares of common stock held by the selling security holder that are covered by this prospectus.

(C) It is our understanding that any selling security holder that is an affiliate of a broker-dealer purchased in the ordinary course of business and, at the time of the purchase, had no agreements or understanding to distribute the securities.

1 Assisted company in fundraising.

2 Affiliated with HC Wainwright, investment banking services.

3 Provides marketing consulting services to company.

4 Former Director of CDS.

5 Christopher Eckert is an employee of Smith Barney.

6 Former Director of CDS.

7 Affiliated with Wellfleet Partners and Starobin Partners, investment banking services.

8 Affiliated with HC Wainwright, investment banking services.

9 Provides marketing consulting services.

10 Provides public relations services.

19 Affiliated with Needham & Company, investment banking services.

11 Stockholder of Lehman Brothers.

12 Provided marketing consulting services; affiliated with Wellfleet Partners and Starobin Partners.

13 Affiliated with HC Wainwright, investment banking services.

14 Affiliated with HC Wainwright, investment banking services.

15 Affiliated with Wellfleet Partners.

16 Affiliated with Wellfleet Partners.

17 Partner of Patton Boggs LLP, our legal counsel.

18 Former President of CDS and Director.

20 Registered sales representative with RBC Dain Rauscher.

## PLAN OF DISTRIBUTION

The selling security holders and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices.

The selling security holders also may sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus. The selling security holders may engage in short sales against the box, puts and calls and other transactions in our securities or derivatives of our securities, and may sell or deliver shares in connection with these trades. The selling security holders may pledge their shares to their brokers under the margin provisions of customer agreements. If a selling security holder defaults on a margin loan, the broker may, from time to time, offer and sell the pledged shares.

Broker-dealers engaged by the selling security holders may arrange for other broker-dealers to participate in sales. Broker-dealers may receive commissions or discounts from either the selling security holders or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser, in amounts to be negotiated. The selling security holders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved.



The selling security holders and any broker-dealers or agents that are involved in selling the shares may be deemed to be underwriters within the meaning of the Securities Act in connection with those sales. In that event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act.

We are required to pay all fees and expenses incident to the registration of the shares being registered herein, including fees and disbursements of counsel to the selling security holders up to a maximum of \$7,500. We are not required to pay commissions and other selling expenses. We have agreed to indemnify the selling security holders against losses, claims, damages and liabilities, including liabilities under the Securities Act arising out of or based upon any untrue or alleged untrue statement of a material fact contained in the registration statement, any prospectus or any form of prospectus or in any amendment or supplement thereto or in any preliminary prospectus, or arising out of or based upon any omission or alleged omission of a material fact necessary to make the statements therein not misleading.

## 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. A pretrial scheduling conference was held on September 8, 2004. The scheduling conference set March 15, 2005 as the date for the close of all discovery on liability issues and stipulated that a pre-motion conference or summary judgment motion must be requested by April 1, 2005.

## DIRECTORS, EXECUTIVE OFFICERS AND CONTROL PERSONS

**Lawrence A. Siebert (47)**, 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 Pelosof (42)**, Vice President Sales, Marketing and Business Development. Mr. Pelosof 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. Pelosof 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 in 1993. 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)**, Director of Operations. Mr. Bruce has been Director of Operations since April 2000. In this capacity, he directs our production, maintenance, inventory, shipping and receiving, and warehouse operations. Prior to joining Chembio Diagnostic Systems Inc. he held director level positions at American Home Products from 1984 to 1993. From 1998 to 2000, he held a management position at V.I. Technologies. From 1993 to 1998, he held various management positions at Biomerieux. 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 (31)**, Director. Mr. Baum was elected to our Board of Directors on December 11, 2003. Mr. Baum has more than 10 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, and various asset acquisitions and divestitures. Mr. Baum is a licensed attorney in the State of California and the principal attorney for The Baum Law Firm. Mr. Baum's law practice focuses on securities laws and related issues for small-cap and micro-cap publicly reporting companies.

**SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

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 June 1, 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	1,801,402	26.44%
Mark Baum <sup>(2)</sup> 249 Highway 101, Suite 432 Solana Beach, CA 92075	1,550,000	21.33%
Avi Pelosof <sup>(3)</sup> 51A Edgewood Road Port Washington, NY 11050	398,109	6.04%
Richard Bruce <sup>(4)</sup> 17 Amalia Lane Comack, NY 11725	40,500	0.63%
All officers and directors as a group <sup>(5)</sup>	3,790,011	48.16%
Tomas Haendler <sup>(6)</sup> 31 Cogswell Lane Stamford, CT 06902	521,154	7.97%
Thunderbird Global Corporation <sup>(7)</sup> c/o The Baum Law Firm 820 Second Street, Suite 102 Encinitas, CA 92024	457,353	7.13%
Daniel Gressel <sup>(8)</sup> 460 E. 79 <sup>th</sup> Street, Apt. 17B New York, NY 10021	467,501	7.23%
H.C. Wainwright & Co., Inc. <sup>(9)</sup> 245 Park Avenue, 44 <sup>th</sup> Floor New York, NY 10167	390,867	5.74%

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 2003.

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, a holder of series A preferred stock may not convert greater than twenty percent (20%) of the holder's shares of series A preferred stock until the earlier of six (6) months following the effective date of this registration statement or March 4, 2005. Additionally, at no time may a holder of shares of series A preferred stock convert shares of the series A 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 would like to waive this restriction.

- (1) Includes 120,000 shares issuable upon exercise of options exercisable within 60 days and 274,435 warrants. Does not include 100,000 shares issuable upon exercise of options that are not exercisable within the next 60 days, 1,547,117 shares issuable upon conversion of series A preferred stock and 1,856,541 shares issuable upon exercise of warrants because at no time may a holder of shares of series A preferred stock or a holder of warrants issued in connection with the series A preferred stock convert the shares of series A preferred stock or exercise the warrants if the number of shares to be issued pursuant to the conversion or exercise would exceed, when aggregated with all other shares of common stock of that holder at that time, the number of shares of common stock 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, unless the holder waives this restriction upon 61 days' notice to the Company.
- (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 at no time may a holder of shares of series A preferred stock or a holder of warrants issued in connection with the series A preferred stock convert the shares of series A preferred stock or exercise the warrants if the number of shares to be issued pursuant to the conversion or exercise would exceed, when aggregated with all other shares of common stock of that holder at that time, the number of shares of common stock 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, unless the holder waives this restriction upon 61 days' notice to the Company.
- (3) Includes 150,000 shares issuable upon exercise of options exercisable within 60 days and 22,555 shares issuable upon exercise of warrants. Does not include 150,000 shares issuable upon exercise of options that are not exercisable within the next 60 days, 10,078 shares issuable upon conversion of series A preferred stock and 12,095 shares issuable upon exercise of warrants because at no time may a holder of shares of series A preferred stock or a holder of warrants issued in connection with the series A preferred stock convert the shares of series A preferred stock or exercise the warrants if the number of shares to be issued pursuant to the conversion or exercise would exceed, when aggregated with all other shares of common stock of that holder at that time, the number of shares of common stock 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, unless the holder waives this restriction upon 61 days' notice to the Company.
- (4) Includes 35,000 shares issuable upon exercise of options exercisable within 60 days and 500 shares issuable upon exercise of warrants. Does not include 35,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.

(5)

Includes footnotes (1)-(4).

- (6) Includes 80,000 shares issuable upon exercise of options exercisable within 60 days and 38,197 shares issuable upon exercise of warrants. Does not include 80,000 shares issuable upon exercise of options that are not exercisable within the next 60 days, 44,450 shares issuable upon conversion of series A preferred stock and 53,334 shares issuable upon the exercise of warrants because at no time may a holder of shares of series A preferred stock or a holder of warrants issued in connection with the series A preferred stock convert the shares of series A preferred stock or exercise the warrants if the number of shares to be issued pursuant to the conversion or exercise would exceed, when aggregated with all other shares of common stock of that holder at that time, the number of shares of common stock 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, unless the holder waives this restriction upon 61 days' notice to the Company.
- (7) Does not include 251,963 shares issuable upon conversion of series A preferred stock and 302,356 shares issuable upon exercise of warrants because at no time may a holder of shares of series A preferred stock or a holder of warrants issued in connection with the series A preferred stock convert the shares of series A preferred stock or exercise the warrants if the number of shares to be issued pursuant to the conversion or exercise would exceed, when aggregated with all other shares of common stock of that holder at that time, the number of shares of common stock 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, unless the holder waives this restriction upon 61 days' notice to the Company. Gustavo Montilla may be deemed to have voting or investment control over the shares held by Thunderbird Global Corporation.
- (8) Includes 5,000 shares issuable upon exercise of options exercisable within 60 days and 42,065 shares issuable upon exercise of warrants. Does not include 5,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
- (9) 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.

## DESCRIPTION OF SECURITIES

Pursuant to our articles of incorporation, as amended, we are authorized to issue 50,000,000 shares of common stock, par value \$0.01 per share and 10,000,000 shares of preferred stock, par value \$0.01 per share. Below is a description of our common stock, shares of which are being offered in this prospectus and a description of our preferred stock.

### Common stock

Holders of the common stock are entitled to one vote for each share held by them of record on our books in all matters to be voted on by the stockholders. Holders of common stock are entitled to receive dividends as may be legally declared from time to time by the board of directors, and in the event of our liquidation, dissolution or winding up, to share ratably in all assets remaining after payment of liabilities. Declaration of dividends on common stock is subject to the discretion of the board of directors and will depend upon a number of factors, including our future earnings, capital requirements and financial condition. We have not declared dividends on our common stock in the past and we currently anticipate that retained earnings, if any, in the future will be applied to our expansion and development rather than the payment of dividends. Additionally, pursuant to the certificate of designation authorizing and creating the series A preferred stock, we are restricted from paying dividends on the common stock without the approval of holders of at least three-fourths of the then outstanding shares of our series A preferred stock.

The holders of common stock have no preemptive or conversion rights and are not subject to further calls or assessments. There are no redemption or sinking fund provisions applicable to the common stock. Our articles of incorporation require the approval of the holders of a majority of our outstanding common stock for the election of directors and for other fundamental corporate actions, such as mergers and sales of substantial assets, or for an amendment to our articles of incorporation. There exists no provision in our articles of incorporation or our bylaws that would delay, defer or prevent a change in control of Chembio Diagnostics, Inc.

Action Stock Transfer acts as our transfer agent and registrar

## Preferred Stock

*Dividends.* Holders of series A preferred stock are entitled to an 8% per annum dividend per share. The dividend accrues and is payable semi-annually at our option either in cash, in shares of series A preferred stock or in shares of common stock. Accrued but unpaid dividends are also payable upon the conversion or redemption of the shares of series A preferred stock and upon our liquidation, dissolution or winding up.

*Voting Rights.* As long as any shares of series A preferred stock are outstanding, we cannot take any of the following actions without the separate class vote or written consent of at least three-fourths of the then outstanding shares of our series A preferred stock:

- amend, alter or repeal the provisions of the series A preferred stock so as to adversely affect any right, preference, privilege or voting power of the series A preferred stock;
- repurchase, redeem or pay dividends on shares of common stock or any other shares of our equity securities that by their terms do not rank senior to the series A preferred stock, other than de minimus repurchases from our employees in certain circumstances;
- amend our articles of incorporation or bylaws so as to affect materially and adversely any right, preference, privilege or voting power of the series A preferred stock;
- effect any distribution with respect to any equity securities that by their terms do not rank senior to the series A preferred stock;
- reclassify our outstanding securities;
- voluntarily file for bankruptcy, liquidate our assets or make an assignment for the benefit of our creditors; or
- change the nature of our business.

In addition, as long as at least \$1,000,000 of series A preferred stock is outstanding, we cannot, without the affirmative vote or consent of the holders of at least three-fourths of the shares of the series A preferred stock outstanding at the time, authorize, create, issue or increase the authorized or issued amount of any class or series of stock, except for the issuance of shares of series A preferred stock with respect to the payment of dividends on the outstanding shares of series A preferred stock.

Except with respect to items set forth above upon which the series A preferred stock shall be entitled to vote separately as a class and except as otherwise required by Nevada law, the series A preferred stock does not have any voting rights. The common stock into which the series A preferred stock is convertible will have, upon issuance, all the same voting rights as other issued and outstanding shares of our common stock.

*Conversion.* The series A preferred stock is convertible, at the option of the holders, into shares of common stock at an initial conversion price of \$.60 per share. Based on its original purchase price of \$30,000.00 per share, each share of series A preferred stock is initially convertible into 50,000 shares of common stock. The series A preferred stock is issuable in fractional shares. The series A preferred stock contains adjustment provisions upon the occurrence of stock splits, stock dividends, combinations, reclassifications or similar events of our capital stock.

A holder of series A preferred stock cannot convert more than twenty percent (20%) of the shares of series A preferred stock that the holder owns into shares of common stock until the earlier to occur of six (6) months following the



effective date of this registration statement or March 5, 2005.

Each share of the series A preferred stock will automatically convert into common stock on the date that the closing bid price for the common stock exceeds \$1.50 for a period of ten (10) consecutive trading days, if the following conditions are satisfied:

- such date is at least one hundred eighty (180) days following the effective date of this registration statement, and
- this registration statement has been effective, without lapse or suspension of any kind, for a period of sixty (60) days (or the common stock into which the series A preferred stock is convertible can be freely traded pursuant to Rule 144(k) under the Securities Act).

*Redemption.* In the event of:

- a consolidation, merger, or other business combination involving Chembio Diagnostics, Inc.,  
the sale of more than 50% of our assets, or
- the closing of a purchase, tender or exchange offer made to and accepted by holders of more than 50% of our outstanding shares of common stock,

each holder of series A preferred stock has the right to require us to redeem all or a portion of such holder's shares of series A preferred stock at a price per share of series A preferred stock equal to 100% of the then current liquidation preference amount for the series A preferred stock, plus any accrued and unpaid dividends; provided that we will have the sole option to pay the redemption price in cash or shares of common stock. If we elect to pay the redemption price in shares of common stock, the price per share will be based upon the lesser of the conversion price for the series A preferred stock or the closing bid price for the common stock, in each case measured on the day preceding the date of delivery of the notice of redemption by such holder. In the event we elect to pay the redemption price in shares of common stock, demand registration rights will be granted on those additional shares.

Upon the occurrence of any of the following events:

- the lapse or unavailability of the registration statement,
- the suspension from listing of the common stock for a period of seven (7) consecutive days,
- our failure or inability to comply with a conversion request from a holder of series A preferred stock, or
- our material breach of any of its representations or warranties contained in the series A preferred stock documentation that continues uncured for a period of ten (10) days,

each holder of series A preferred stock has the right to require us to redeem all or a portion of that holder's shares of series A preferred stock at a price per share of series A preferred stock equal to 120% of the then current liquidation preference amount for the series A preferred stock, plus any accrued and unpaid dividends; provided that with respect to some of the triggering events referenced above, we will have the sole option to pay the redemption price in cash or shares of common stock. If we elect to pay the redemption price in shares of common stock, the price per share will be based upon the lesser of the conversion price for the series A preferred stock and the closing bid price for the common stock, in each case measured on the day preceding the date of delivery of the notice of redemption by such holder. In the event we elect to pay the redemption price in shares of common stock, demand registration rights will be granted on those additional shares.

*Rank; Liquidation Preference.* The holders of our series A preferred stock rank prior to the holders of our common stock and, unless otherwise consented to by the holders of series A preferred stock, prior to all other classes of capital stock that we may establish, with respect to the distribution of its assets upon a bankruptcy, liquidation or other similar event. The liquidation preference for the series A preferred stock is an amount equal to \$30,000.00 per share plus any accrued and unpaid dividends.

#### **INTEREST OF NAMED EXPERTS AND COUNSEL**

Lazar, Levine & Felix LLP, independent auditors, have audited our financial statements of as of and for the years ended December 31, 2003 and 2002, as set forth in their report. The financial statements are included in reliance on such reports given upon the authority of Lazar, Levine & Felix LLP as experts in accounting and auditing. Lazar, Levine & Felix LLP does not have any ownership interest in us.

The validity of the issuance of the shares of common stock offered hereby and other legal matters in connection herewith have been passed upon for us by Patton Boggs LLP. A partner of Patton Boggs LLP owns 69,787 shares of common stock, 1,447 shares of series A preferred stock (which are convertible into 72,350 shares of common stock) and a warrant to purchase 96,023 shares of our common stock. The sale of the common stock, the sale of the common stock, and the shares of common stock into which the preferred stock and the warrants are convertible, are being registered as part of this registration statement. Patton Boggs LLP owns 37,319 shares of common stock, the sale of which is being registered as part of this registration statement.

#### **DISCLOSURE OF COMMISSION POSITION OF INDEMNIFICATION FOR SECURITIES ACT LIABILITIES**

Our directors and officers are indemnified by our bylaws against amounts actually and necessarily incurred by them in connection with the defense of any action, suit or proceeding in which they are a party by reason of being or having been directors or officers of Chembio Diagnostics, Inc. or of our subsidiary. Our articles of incorporation provide that none of our directors or officers shall be personally liable for damages for breach of any fiduciary duty as a director or officer involving any act or omission of any such director or officer. Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, may be permitted to such directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the Securities and

Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

In the event that a claim for indemnification against such liabilities, other than the payment by Chembio Diagnostics, Inc. of expenses incurred or paid by such director, officer or controlling person in the successful defense of any action, suit or proceeding, is asserted by such director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

## **DESCRIPTION OF BUSINESS**

### **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.

## Our business following the merger

### 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 two HIV Rapid Tests (Sure Check HIV and HIV 1/2 Stat Pak).

<b>HIV Rapid Tests Commercially Available</b>	<b>Regulatory Status</b>	<b>Partners Involved in the Product</b>
HIV Rapid Tests (Sure Check HIV; HIV 1/2 Stat Pak). Rapid Tests for detection of antibodies to HIV 1 and 2 in finger-stick whole blood, venous whole blood, serum and plasma	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 addition, we have commenced clinical trials for Sure Check and HIV Stat Pak in US for FDA approval for sales in the U.S.	Thirteen-year supply and technology transfer agreement with FIOCRUZ-Bio-Manguinhos, a division 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.

A majority of our revenues historically and in 2004 have been 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 are endeavoring to transfer this product line to a third party manufacturer and maintain a profit share derived from these products by the third party. We believe that this will result in a substantial reduction of our revenues from these products during the balance of 2004 and beyond. The timing of this transfer and the extent to which we will derive a benefit from it are difficult to estimate because of uncertainties in regulatory changes, product pricing and manufacturing cost changes, and patent litigation.

As described below, we also have other commercially available products, such as rapid tests for lyme disease and parvo virus, 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. 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 clinical trials and 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, like other competitive rapid HIV tests, requires 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. Both 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.

## Lateral Flow Technology

All our 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 20 minutes), safe (minimizes handling of specimens potentially infected), non-invasive (requires 5-20 micro liters of serum or whole blood easily obtained with a finger prick), stable (18 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, as is the objective in our dental bacteria test for bacterial levels under development. We can also develop tests for multiple conditions, using different colored lines as is the case in our prototype HIV/tuberculosis test. We have developed proprietary techniques that enable us to achieve high levels of sensitivity and specificity 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 finger-tip 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 of this prospectus entitled Legal Proceedings for a discussion of the legal issues we face with regard to Sure Check .*

## 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 infection clinics, maternal and child health clinics, and health care settings where HIV is prevalent. Last year 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 used where AIDS prevalence is high 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.

**Other Products Under Development.** Our products under development with partners in the areas of mad cow disease, dental bacteria and non-human primate tuberculosis 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 and human tuberculosis markets, which are primarily donor-funded markets. We do not have an expertise in assessing the markets in each of these new product undertakings, and in each case we 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.

In February of this year 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 ½ 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 150,000 tests have been purchased through June 30, 2004, and we anticipate receiving orders for an additional 300,000 units in 2004.

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. Our efforts to have our tests evaluated and used in these programs were recently facilitated through our attendance and exhibition at the World Aids Conference in Bangkok, Thailand from July 11-15, 2004.

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:

- 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 will 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 compete 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), detection of early cases, time to reading result, and product shelf life. We believe that our HIV 1/2 Stat Pak and SureCheck 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 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 US 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 burden 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: Bovine Spongiform Encephalopathy, which is also known as mad cow disease, dental bacteria, tuberculosis, and HIV.

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 we signed a contract to be one of two contract manufacturers of this product following their 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 expect that the technology transfer and European regulatory approval can be completed this year, and that initial sales will 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. 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 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. 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. Although our contract with Ivoclar-Vivadent contemplated that product development will be completed this year, and that regulatory approvals and products launch will be in 2005, 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, 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 now involved in one evaluation in Uganda, and we are discussing several other evaluations, some of which we believe could take place in 2004. However, the timing and results of these evaluations 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.

Edgar Filing: Chembio Diagnostics Inc. - Form 424B3

We have also begun work on a \$100,000 grant we received beginning in March, 2004 from the World Health Organization to develop a simple and rapid lateral flow test for antigen detection in tuberculosis. We also have developed a prototype of a combination lateral flow rapid test for detecting antibodies to HIV and active pulmonary tuberculosis using separate test lines of different colors on a single test strip. Given the developmental stage of this research, there is no expectation of revenues from this product in the foreseeable future.

We have also expended efforts related to the detection of active pulmonary tuberculosis in animals and are currently seeking a collaboration partner. We do not anticipate any sales from this product line in 2004 and most of 2005.

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 sales from this product line in 2004 and most of 2005.

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 Satens Serum Institute
TBD rapid diagnostic test for the detection of antigens for active pulmonary tuberculosis in sputum	Not yet submitted for approval	Product under development pursuant to grant from the World Health Organization	World Health Organization- Special Program for Research and Training in Tropical Diseases
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	Not yet submitted for	Initial Prototype	None

active pulmonary tuberculosis and HIV in human whole blood samples using different color latex test lines	approval		
New Generation HIV Test	Not yet submitted for approval	Initial Prototype	None

During 2003 and 2002, approximately \$313,891 and \$378,089 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>2002</b>	<b>2003</b>
Human Tuberculosis	\$ 265,118	\$ 59,491
Veterinary Tuberculosis	39,169	116,239
HIV, Dental, Mad Cow	20,000	100,000
Other	53,802	48,161
Totals	\$ 378,089	\$ 313,891

### **Employees**

At May 31, 2004, we employed 51 employees, including 48 full-time employees. At the time of closing of the merger, we entered into employment agreements with Lawrence Siebert, President and Chairman, Avi Pelossof, VP Sales, Marketing and Business Development, and Javan Esfandiari, Director of research and development. 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 Stat Pak rapid tests and is currently beginning clinical trials as the initial step toward FDA approval of these products.

## **Environmental Laws**

To date, we have not encountered any costs relating to the 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 own no patents covering lateral flow technology, we have obtained a 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 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 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.



## **MANAGEMENT'S DISCUSSION AND ANALYSIS AND PLAN OF OPERATION**

### **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 Diagnostic Systems, Inc., 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 Diagnostic Systems, Inc. We are now de-emphasizing the manufacturing of private label pregnancy tests and 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.

The de-emphases of the private label pregnancy tests will not impair any assets of Chembio Diagnostic Systems, Inc. This is primarily due to the gradual nature of this move. Chembio Diagnostic Systems, Inc. will continue to produce component parts, while transferring technology to another manufacturer.

### **RESULTS OF OPERATIONS FOR THE SIX MONTHS ENDED JUNE 30, 2004 AS COMPARED WITH THE SIX MONTHS ENDED JUNE 30, 2003**

Revenues were \$1,580,377 for the six months ended June 30, 2004 as compared with \$1,538,698 for the six months ended June 30, 2003, representing an increase of \$41,679, or 2.7%. The increase in sales is primarily attributable to increased income from contracts and grants (\$241,287 increase) as well as increased sales of our HIV product (\$166,421 increase). The increases were partially offset by reduced pregnancy test kit sales (\$272,661 decrease). A substantial portion of the grant-related income will recur for the balance of 2004 and in 2005.

Cost of goods sold for the six months ended June 30, 2004 was \$1,091,010, or 87.9% of net sales, as compared with \$1,174,808, or 81.6% of net sales, for the six months ended June 30, 2003. The resulting decrease in gross margin is primarily attributable to underutilization of manufacturing capacity. We also had increased costs in our quality department to improve our product. In addition, the initial order with Bio-Manguinhos for HIV related product resulted in additional overtime costs to meet shipping deadlines.

Research and development expenses for the six months ended June 30, 2004 were \$499,446, or 31.6% of revenues, compared with \$161,560, or 10.5% of revenues, for the six months ended June 30, 2003. Clinical & Regulatory Affairs, which totaled \$229,635 for the six months ended June 30, 2004, accounted for most of this increase. This cost category includes costs incurred for regulatory approvals, clinical studies, product evaluations and registrations. These costs are expected to increase in the 3<sup>rd</sup> quarter of 2004 when the bulk of the HIV rapid test clinical studies will be completed and then return to substantially reduced levels in the fourth quarter. 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 June 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.

Selling, general and administrative expense increased \$618,744 to \$1,193,661 for the first six months of 2004 compared with the same period in 2003. This increase is primarily attributable to \$304,229 of non-cash expenses reflecting the fair value of common stock issued to key employees and \$27,688 of non-cash expenses reflecting the

amortized fair value of options to purchase common stock that were issued to consultants. Also driving this increase were \$25,500 in cash salary increases to key employees, and increased legal and accounting expenses of \$63,100 relating to the merger. The balance of the increase, or \$198,227, is primarily attributable to increased travel costs related to HIV rapid test marketing efforts, increased costs for marketing consultants, and increased commissions relating to the Bio-Manguinhos contract.

In addition, \$210,000 attributable to settlements of old outstanding payables due that were settled during the six months ended June 30, 2004 are reflected in Other income as forgiveness of debt..

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
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	During the balance of 2004, we expect to complete Phase 2 of the Project Plan (Optimization of Test) and move into Phase 3 (Scale Up of Production and validation).
Nature, timing and estimated costs of the efforts necessary to complete	In April 2004, Chembio received 80% of the Phase 2 project cost of \$65,000, or \$52,000 and this reflects the estimate of the costs anticipated to be incurred to complete Phase 2 during a three to five month period. We expect to complete Phase 2 in September. Upon completion of Phase 2 we will provide a report to Ivoclar-Vivadent. If the report is acceptable, we will receive the \$13,000 balance from Phase 2 and 80% of the Phase III project cost, also \$65,000. Phase 3 is also estimated to take three to five months to complete
Anticipated completion date	Assuming the project plan is achieved, the anticipated completion date of the product is first quarter 2005. It is not known at this time how long it will take to 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 has 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	Not known
Anticipated completion date	Not known
Risks and uncertainties associated with completing development on	The requirements for clinical testing and the outcomes of such clinical testing can not be known at this time, and this information

schedule, and the consequences to operations, financial position and liquidity if not completed timely	poses substantial risk and uncertainty as to whether or when this product will contribute to the operations, financial position and liquidity.
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.

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 2004 and 2005 from any of these products.

## **RESULTS OF OPERATIONS FOR THE TWELVE MONTHS ENDED DECEMBER 31, 2003 AS COMPARED WITH THE TWELVE MONTHS ENDED DECEMBER 31, 2002**

Revenues were \$2.818 million for the twelve months ended December 31, 2003 as compared with \$3.135 million for the twelve months ended December 31, 2002, representing a decrease of \$316,788 or 10.1%. The decrease in sales is attributable to HIV unit pricing decreases of approximately \$58,000 and to reduced sales of our midstream pregnancy tests of approximately \$77,000 to our distributor in Japan and approximately \$182,000 in other reduced unit sales. Unit pricing decreases were necessary in order to maintain competitive pricing of HIV tests in certain developing country markets. Reduced sales of pregnancy tests occurred due to correspondence the Japanese distributor received from a representative of Unipath regarding the alleged infringement by the distributor of the patent Unipath had been issued in Japan and our eventual decision to not pursue or contest the claim of infringement due to the relatively low volume of the business and, more importantly, our plan of de-emphasizing the pregnancy test business.

Cost of goods sold for the twelve months ended December 31, 2003 was \$2.153 million, or 84.7% of net sales, as compared with \$2.458 million, or 87.5% of net sales, for the twelve months ended December 31, 2002. Although costs of raw materials, labor and overhead associated with manufacturing remained level during the twelve months ended December 31, 2003, improved material usage due to the implementation of an inventory purchasing and production control (known as Material Requirements Planning or MRP ) system in January 2003, as well as other production and quality controls implemented during 2003, began to show an effect in 2003.

Research and development expenses for the twelve months ended December 31, 2003 were \$313,891, or 11.1% of revenues, compared with \$378,089, or 12.1% of revenues, for the twelve months ended December 31, 2002. The decrease is due primarily to sub-contractor grant expense in 2002 that did not recur in 2003 and certain pre-clinical evaluations in 2002 that did not recur in 2003.

Selling, general and administrative expenses increased 4.1% to \$1.202 million, which was 42.7% of revenues, for the twelve months ended December 31, 2003 compared to \$1.155 million, or 36.8% of revenues, for the twelve months ended December 31, 2002. A decrease in officer salaries of \$(64,198), attributable to the consolidation of the Chairman and President position during the second half of 2002, was offset by increased insurance, bank, legal and accounting charges.

Interest expense increased 57.2% to \$208,525, or 7.4% of revenues, for the twelve months ended December 31, 2003 compared to \$132,626, or 4.2% of revenues, for the twelve months ended December 31, 2002. The increase is due to increased amounts outstanding under a 12% line of credit.

Net Loss increased 7.2% to \$1,060,000 from \$989,000 for the twelve months ended December 31, 2002.

## **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 with Trading Solutions.com. 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 to 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 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) since December 31, 2003.

During the six months ended June 30, 2004, we used \$1,174,415 cash in operations, \$47,337 to acquire fixed assets, \$29,887 to fund capital lease payments, and \$67,434 to fund the bank overdraft 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 \$210,000, the sale of \$2,200,000 of series A preferred stock and the funding of \$305,198 of compensation expense by the issuance of common stock and options to some of our key employees.

Accordingly, we had a working capital deficiency of \$730,738 at December 31, 2003 and a working capital surplus of \$1,538,936 at June 30, 2004. This increase in working capital is due to the completion of the convertible note offering as well as the completion of the series A offering and the capitalization of employee stock and options being amortized. Our current assets increased 222.4% to \$2,491,310 at June 30, 2004 from \$772,680 at December 31, 2003. This increase is also primarily attributable to the completion of the convertible note offering in March, the series A preferred offering in May.

Compared with corresponding balances at December 31, 2003, current liabilities as of June 30, 2004 decreased 36.7% to \$952,374, long-term liabilities decreased 62.6% to \$763,488, and total liabilities decreased 51.6% to \$1,715,862. The decrease in long-term liabilities is attributable to the completion of the merger where \$1,332,292 of debt was converted into series A preferred offering.

We anticipate that we will have additional capital requirements in near future. The amount of additional capital we may need to raise will depend on a number of factors. These factors primarily include (1) receipt of orders from Bio-Manguinhos in 2004 and 2005 in accordance with contractual commitments; (2) whether we can generally achieve revenue growth and the extent to which if any that revenue growth improves operating cash flows; (3) our investments in research and development, facilities, marketing, regulatory approvals, and other investments we may determine to make, and (4) the availability and cost of raising additional capital and potential dilution to shareholders.

The following table lists the future payments required on our debt and any other contractual obligations as of June 30, 2004:

<b>OBLIGATIONS</b>	<b>Total</b>	<b>Less than 1 Year</b>	<b>1-3 Years</b>	<b>4-5 Years</b>	<b>Greater than 5 Years</b>
Long-Term Debt <sup>(1)</sup>	\$ 673,351	-	-	-	\$ 673,351
Capital Leases <sup>(2)</sup>	\$ 139,787	\$ 49,650	\$ 74,764	\$ 15,373	-
Operating Leases	\$ 76,016	\$ 76,016	-	-	-
Other Long-Term Obligations <sup>(3)</sup>	\$ 45,000	\$ 12,000	\$ 33,000	-	-
<b>Total Obligations</b>	<b>\$ 934,154</b>	<b>\$ 137,666</b>	<b>\$ 107,764</b>	<b>\$ 15,373</b>	<b>\$ 673,351</b>

(1) This represents existing debt and accrued interest which if not paid by the end of 2004 must convert into series A preferred. It is currently expected that the company will not be able to repay this debt and it will be converted.

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

(3) This represents contractual obligations for licenses.

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

Clinical trials for our HIV rapid tests have begun, and we believe that they will be completed during the fourth quarter. The trials will be used to support a pre-marketing approval application to the FDA. Simultaneous with this regulatory approval process, we are actively involved in increasing distribution of our HIV rapid tests through a variety of distribution channels and partners. We have engaged Bio-Equity Partners, a company that specializes in helping small biotech firms in the HIV field, to assist in these efforts. Several other marketing and business development efforts are ongoing that are 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 is being used to obtain US regulatory approval of our HIV rapid tests and to provide the marketing and business development resources 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 will 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 2004. We therefore expect that we will be required to sell additional equity or obtain additional credit facilities in the near term. We further expect that cash generated from operations will not be sufficient to satisfy our working capital and capital expenditure requirements over the next twelve months, so we expect that we will be required to sell additional equity or obtain additional credit facilities during that period. We cannot be certain that this financing will be available or that we will be able to complete financing on satisfactory terms, if at all.

Beyond twelve months out, it is likely that we will have additional financing requirements to finance our expected growth and/or to fund continuing operating deficits. 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 expected additional financing requirements.

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 complete the clinical testing portion related to our HIV rapid test FDA submission in the fourth quarter of this year (2004), and we believe that if the results of these tests are at the level required for FDA approval, these results will provide strong evidence of our progress. We also have other important international evaluations pending of our HIV rapid tests which, if favorable, would result in additional independent proof of the quality of our products and the accretion of long-term value to our shareholders. 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. Based upon our agreement with Bio-Manguinhos alone, we expect to receive orders for our HIV rapid tests that will more than offset the net cash flow that we will no longer have from the private label manufacturing of pregnancy tests.

Our attendance at the XVth World AIDS Conference recently in Bangkok, Thailand has generated potential new revenue opportunities for our HIV rapid tests.



Progress in our other major product groups, particularly those for the mad cow disease and dental bacteria test, as well as the non-human primate tuberculosis test, are also likely to lend credibility to our plan to become profitable. In this regard, we have hired a director of regulatory affairs who will be directing the regulatory activities related to the veterinary products (e.g., mad cow and non-human primate tuberculosis) as well as the dental bacteria test, provided that each of the projects progresses to the point where a regulatory submission is appropriate. This individual will eventually absorb some of the responsibilities that have been performed by our outside regulatory consultant. We have also added one person to our solutions manufacturing group and have hired an assembly supervisor. These three positions will add at least \$250,000 in annual costs. We have not decided at this juncture whether to add to our research and development team, though it is under consideration. If such a position is added, the annual cost would be at least \$100,000.

If we are not successful in obtaining additional financing, then we would not be able to pursue our current plan of operation.

### **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.

#### *Research & Development Costs -*

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

#### *Valuation of Inventories -*

Inventories are stated at the lower of cost or market, using the first-in, first-out method (FIFO) to determine cost. Our policy is to periodically evaluate the market value of the inventory and the stage of product life cycle, and record a reserve for any inventory considered slow moving or obsolete.

#### *Valuation of Long-Lived Assets -*

We assess the realizable value of long-lived assets for potential impairment at least annually or when events and circumstances warrant such a review. The carrying value of a long-lived asset is considered impaired when the anticipated fair value is less than its carrying value. In assessing the recoverability of our long-lived assets, we must

make assumptions regarding estimated future cash flows and other factors to determine the fair value of the respective assets. In addition, we must make assumptions regarding the useful lives of these assets. As of December 31, 2003, we evaluated our long-lived assets for potential impairment. Based on our evaluation, no impairment charge was recognized.

*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.

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.

**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 approximately \$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 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.

## **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 will 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. 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. Prior to the merger, Mr. Baum was the sole director and officer of Chembio Diagnostics, Inc.

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, holds 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. Approximately \$234,062 of the debt held by Mr. Siebert was not so exchanged and continues to accrue interest. Approximately \$214,241 of accrued interest on the converted and unconverted portions of the debt is also due to Mr. Siebert, but is not accruing interest. The debt and accrued interest are required to be repaid by Chembio Diagnostics, Inc. on or before December 31, 2004 or, at the option of Chembio Diagnostics, Inc., converted into shares of its series A preferred stock as of December 31, 2004.

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.

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.

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.

**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 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 series in this table have been adjusted to reflect this split.

	<b>High Bid</b>	<b>Low Bid</b>
<b>Fiscal Year 2004</b>		
First Quarter	\$3.00	\$0.34
Second Quarter	\$2.00	\$1.00
Third Quarter	\$1.54	\$1.01
<b>Fiscal Year 2003</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
<b>Fiscal Year 2002</b>		
First Quarter	\$5.10	\$0.16
Second Quarter	\$2.72	\$0.02
Third Quarter	\$2.04	\$0.17
Fourth Quarter	\$0.17	\$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 May 31, 2004, there were approximately 97 record owners of Chembio Diagnostics, Inc.'s 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 certificate of designation authorizing our series A preferred stock also prohibits us from making any distribution with respect to any equity securities that by their terms do not rank senior to the series A preferred stock.

## **EXECUTIVE COMPENSATION**

The following table summarizes the annual compensation paid to Chembio Diagnostics, Inc.'s named executive officers for the two years ended December 31, 2003, 2002 and 2001:

	Long-Term Compensation Awards Securities Underlying
Annual Comp	

<b>Name and Position</b>	<b>Year</b>	<b>Salary</b>	<b>Stock Options</b>
Lawrence A. Siebert, President, CEO, Chairman of Board of Chembio Diagnostic Systems Inc. <sup>(1)</sup>	2003	103,846	
	2002	63,000	
	2001	\$ 50,462	10,000
Rick Bruce, Vice President of Chembio Diagnostic Systems Inc. <sup>(2)</sup>	2003	110,326	
	2002	106,240	
	2001	101,500	15,000
Mark L. Baum, President, Secretary and Director of Chembio Diagnostics, Inc. <sup>(3)</sup>	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.

(2) Mr. Bruce 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.

(3) Mr. Baum currently is a director and the Secretary of Chembio Diagnostics, Inc. The compensation information represents compensation earned while employed by Chembio Diagnostics, Inc.

There were no option grants to the named executive officers, and no options were exercised by the named executive officers in the last fiscal year.

## FINANCIAL STATEMENTS

See the Consolidated Financial Statements beginning on page F-1, Index to Consolidated Financial Statements.

## **CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

On June 1, 2004, our Board of Directors voted to replace Madsen & Associates, CPAs, Inc., certified public accountants and to retain Lazar, Levine & Felix LLP as our principal accountant. Lazar, Levine & Felix LLP had been the principal accountant of Chembio Diagnostic Systems Inc. since 2000. There were no disagreements between us and Madsen, whether resolved or not resolved, on any matter of accounting principles or practices, financial statement disclosure or auditing, scope or procedure which, if not resolved, would have caused them to make reference to the subject matter of the disagreement in connection with their reports. During its tenure, Madsen's audit opinion on our financial statements did not contain an adverse opinion or a disclaimer of opinion, nor was it modified as to audit scope or accounting principles. Madsen's reports did include an explanatory paragraph where they expressed substantial doubt about our ability to continue as a going concern.

Prior to retaining Lazar, Levine & Felix, LLP, management did not consult Lazar, Levine & Felix LLP regarding the application of accounting principles to a specific completed or contemplated transaction or the type of audit opinion that might be rendered, nor concerning any matter that was the subject of any disagreement or event.

## **ADDITIONAL INFORMATION**

We have filed with the SEC a registration statement on Form SB-2 under the Securities Act for the common stock offered by this prospectus. This prospectus, which is a part of the registration statement, does not contain all of the information in the registration statement and the exhibits filed with it, portions of which have been omitted as permitted by SEC rules and regulations. For further information concerning us and the securities offered by this prospectus, please refer to the registration statement and to the exhibits filed with it. Statements contained in this prospectus as to the content of any contract or other document referred to are not necessarily complete. In each instance, we refer you to the copy of the contracts and/or other documents filed as exhibits to the registration statement and these statements are qualified in their entirety by reference to the contract or document.

The registration statement, including all exhibits, may be inspected without charge at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549, and at the SEC's regional offices located at the Woolworth Building, 233 Broadway, New York, New York 10279 and Citicorp Center, 500 West Madison Street, Suite 1400, Chicago, Illinois 60661. Copies of these materials may also be obtained from the SEC's Public Reference at 450 Fifth Street, N.W., Room 1024, Washington D.C. 20549, upon the payment of prescribed fees. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The registration statement, including all exhibits and schedules and amendments, has been filed with the SEC through the Electronic Data Gathering, Analysis and Retrieval system, and is publicly available through the SEC's Website located at <http://www.sec.gov>.

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**Index to Consolidated Financial Statements.**

**INDEX**

	<b>Page(s)</b>
Report of Independent Accountants	F-1
Financial Statements:	
Consolidated Balance Sheets	
June 30, 2004 (unaudited) and December 31, 2003	F-2
Consolidated Statements of Operations	
Six months ended June 30, 2004 (unaudited) and June 30, 2003 (unaudited)	F-3
The years ended December 31, 2003 and 2002	F-4
Consolidated Statements of Changes in Stockholders' Equity	F-5
Consolidated Statements of Cash Flows	
Six months ended June 30, 2004 (unaudited) and June 30, 2003 (unaudited)	F-6
The years ended December 31, 2003 and 2002	F-7
Notes to Financial Statements	F-8 - F-19
Unaudited Pro forma Financial Statements:	
Introduction	F-20
Condensed Consolidated Pro Forma Statements Of Operations	
Six months ended June 30, 2004	F-21
The year ended December 31, 2003	F-22
Notes to Unaudited Pro Forma Condensed Consolidated Financial Statements	F-23



**INDEPENDENT ACCOUNTANTS REPORT**

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

We have audited the consolidated balance sheet of Chembio Diagnostic Systems Inc. and Subsidiary (the Company) as of December 31, 2003 and the consolidated statements of operations, stockholders' equity and cash flows for the two years in the period ended December 31, 2003. 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes 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, 2003, and the consolidated results of its operations and its cash flows for the two years in the period ended December 31, 2003 in conformity with accounting principles generally accepted in the United States of America.

/s/ Lazar Levine & Felix LLP  
**LAZAR LEVINE & FELIX LLP**

New York, New York  
February 27, 2004, except  
for the first paragraph of Note 1,  
the date of which is May 5, 2004

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

**ASSETS (Note 5)**

**June 30, 2004**

**Dec. 31, 2003**

**CURRENT ASSETS:**

Cash	\$ 1,471,876	\$
Accounts receivable, net of allowance for doubtful accounts of \$33,534 and \$15,231 for June 30, 2004 and December 31, 2003, respectively (Note 12)	299,093	282,734
Inventories (Note 3)	585,835	466,498
Prepaid expenses and other current assets	134,506	23,448

<b>TOTAL CURRENT ASSETS</b>	<b>2,491,310</b>	<b>772,680</b>
-----------------------------	------------------	----------------

<b>FIXED ASSETS</b> (Notes 4 and 6)	<b>222,028</b>	<b>249,247</b>
-------------------------------------	----------------	----------------

**OTHER ASSETS:**

Deposits	32,938	55,723
Other assets		9,095

	\$ 2,746,276	\$ 1,086,745
--	--------------	--------------

**LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIENCY)**

**CURRENT LIABILITIES:**

Bank overdraft	\$	\$ 67,434
Accounts payable and accrued liabilities (Note 2(p) and Note 12)	902,724	1,361,547
Current portion of obligations under capital leases (Note 6)	49,650	61,789
Other current liabilities		12,648

<b>TOTAL CURRENT LIABILITIES</b>	<b>952,374</b>	<b>1,503,418</b>
----------------------------------	----------------	------------------

**OTHER LIABILITIES:**

Notes payable net of current portion (Note 1 and 5)	361,559	1,693,851
Obligations under capital leases net of current portion (Note 6)	90,137	107,885
Accrued interest (Note 5)	311,792	239,032
<b>TOTAL LIABILITIES</b>	<b>1,715,862</b>	<b>3,544,186</b>

**COMMITMENTS AND CONTINGENCIES (NOTES 2(n) AND 11)**

**CONDITIONALLY REDEEMABLE**

**CONVERTIBLE PREFERRED STOCK (Note 9)**

Series A 8% Convertible - \$.01 par value; 10,000,000 shares authorized: 151.57984 and 0 shares issued and outstanding as of June 30, 2004 and December 31, 2003, respectively.	2,499,604
--	-----------

Liquidation preference - please see note 9.

**STOCKHOLDERS EQUITY (DEFICIENCY) (NOTES 1, 10 AND 11):**

Common stock - \$.01 par value; 50,000,000 shares  
authorized: 6,417,908 and 4,902,608 shares issued  
and outstanding as of June 30, 2004 and December

31, 2003, respectively	<b>64,179</b>	<b>49,026</b>
Common stock warrants	<b>2,311,871</b>	
Additional paid-in capital	<b>4,416,200</b>	<b>4,550,975</b>
Accumulated deficit	<b>(8,261,440)</b>	<b>(7,057,442)</b>
	<b>(1,469,190)</b>	<b>(2,457,441)</b>

	<b>\$ 2,746,276</b>	<b>\$ 1,086,745</b>
--	---------------------	---------------------

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

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**FOR THE PERIODS ENDED:**  
**(UNAUDITED)**

	Six months ended	
	June 30, 2004	June 30, 2003
<b>REVENUES:</b>		
Net sales	\$ 1,240,920	\$ 1,440,528
Research grants and development income	339,457	98,170
	1,580,377	1,538,698
Cost of sales	1,091,010	1,174,808
<b>GROSS PROFIT</b>	<b>489,367</b>	<b>363,890</b>
<b>OVERHEAD COSTS:</b>		
Research and development expenses	499,446	161,560
Selling, general and administrative expenses	1,193,661	574,917
<b>LOSS FROM OPERATIONS</b>	<b>(1,203,740)</b>	<b>(372,587)</b>
<b>OTHER INCOME (EXPENSES):</b>		
Forgiveness of Debt	209,372	
Interest income	2,697	
Interest (expense)	(155,518)	(98,766)
<b>LOSS BEFORE INCOME TAXES</b>	<b>(1,147,189)</b>	<b>(471,353)</b>
Income taxes		
<b>NET LOSS BEFORE DIVIDENDS</b>	<b>\$ (1,147,189)</b>	<b>\$ (471,353)</b>
Preferred Dividend	56,810	
<b>NET LOSS AVAILABLE TO COMMON SHAREHOLDERS</b>	<b>\$ (1,203,999)</b>	<b>\$ (471,353)</b>
<b>Basic and diluted (loss) per share</b>	<b>(\$0.22)</b>	<b>(0.10)</b>
<b>Weighted average number of shares outstanding, basic and diluted</b>	<b>5,361,729</b>	<b>4,929,118</b>

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, 2003 AND 2002:**

	2003	2002
<b>REVENUES:</b>		
Net sales (Notes 2(n) and 12)	\$ 2,542,621	\$ 2,810,852
Research grants and development income (Note 7)	275,730	324,287
	<b>2,818,351</b>	<b>3,135,139</b>
Cost of sales (Note 12)	2,153,454	2,458,596
<b>GROSS PROFIT</b>	<b>664,897</b>	<b>676,543</b>
<b>OVERHEAD COSTS:</b>		
Research and development expenses	313,891	378,089
Selling, general and administrative expenses	1,202,185	1,154,799
<b>LOSS FROM OPERATIONS</b>	<b>(851,179)</b>	<b>(856,345)</b>
<b>OTHER INCOME (EXPENSES):</b>		
Interest income (expense) - net of interest income of \$7 and \$175 for years ended 12/31/03 and 12/31/02 respectively	(208,525)	(132,626)
<b>LOSS BEFORE INCOME TAXES</b>	<b>(1,059,704)</b>	<b>(988,971)</b>
Income taxes (Note 8)	-	-
<b>NET LOSS AVAILABLE TO COMMON SHAREHOLDERS</b>	<b>\$ (1,059,704)</b>	<b>\$ (988,971)</b>
<b>Pro forma basic and diluted loss per share</b> (Note 2(q))	<b>(0.22)</b>	<b>(0.20)</b>
<b>Weighted number of shares outstanding</b> (Note 2(q))	<b>4,919,191</b>	<b>4,929,118</b>

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

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND**  
**STOCKHOLDERS' EQUITY (DEFICIT)**  
**FOR THE SIX MONTHS ENDED JUNE 30, 2004 (Unaudited)**  
**AND THE YEAR ENDED DECEMBER 31, 2003**

	Redeemable Convertible Preferred	Common stock Shares	Amount	Warrants	Additional paid in capital	Accumulated Deficit	Total Stockholders Equity
Balance at January 1, 2003	-	38,395	\$ 39	-	\$ 4,599,962	(5,997,738)	(1,397,737)
Restate for merger with TSLU -100 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 - Dec. 31, 2003	-	-	-	-	-	(1,059,704)	(1,059,704)
<b>Balance at December 31, 2003</b>	<b>-</b>	<b>4,902,608</b>	<b>49,026</b>	<b>-</b>	<b>4,550,975</b>	<b>(7,057,442)</b>	<b>(2,457,441)</b>
<b>Common stock issued</b>							
Common issued pre-merger to employees	-	160,573	1,606	-	62,623	-	64,229
Common issued during merger							
Bridge conversion	-	826,741	8,267	-	322,430	-	330,697
Employment contract	-	400,000	4,000	-	236,000	-	240,000
For financing fees, valued \$39,400	-	65,667	657	-	(657)	-	-
Common issued for marketing services	-	25,000	250	-	14,750	-	15,000
Common issued for legal services	-	37,319	373	-	22,018	-	22,391
<b>Preferred stock issued</b>							
Cash offering	1,276,000	-	-	924,000	-	-	924,000
Bridge debt conversion	394,065	-	-	285,042	-	-	285,042
Existing debt conversion	772,729	-	-	559,563	-	-	559,563
<b>Accretion of preferred dividend</b>	<b>56,810</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Warrants and options issued to</b>							

Edgar Filing: Chembio Diagnostics Inc. - Form 424B3

Employees	-	-	-	-	969	-	969
For financing fees	-	-	-	337,973	(337,973)	-	-
Marketing consultants	-	-	-	-	108,564	-	108,564
Chembio Diagnostic Systems, Inc. stockholders for consent prior to merger	-	-	-	144,643	(144,643)	-	-
Existing Debt Holders(pre-merger)	-	-	-	60,650	-	-	60,650
<b>Cash expended for financing</b>	-	-	-	-	(418,856)	-	(418,856)
<b>Rounding</b>	-	-	-	-	-	1	1
<b>Net loss to June 30, 2004</b>	-	-	-	-	-	(1,203,999)	(1,203,999)
<b>Balance at June 30, 2004 (Unaudited)</b>	<b>\$ 2,499,604</b>	<b>6,417,908</b>	<b>\$ 64,179</b>	<b>\$ 2,311,871</b>	<b>\$ 4,416,200</b>	<b>\$ (8,261,440)</b>	<b>\$ (1,469,190)</b>

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

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**FOR THE SIX MONTHS ENDED JUNE 30, 2004 AND 2003**  
**(UNAUDITED)**

	2004	2003
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (1,147,189)	\$ (471,353)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	74,556	48,257
Provision for doubtful accounts	9,118	9,200
Increase in accrued interest not paid	72,760	84,302
Stock issued as compensation	304,229	-
Warrants issued to existing debt holders, prior to the merger, recorded as interest expense.	60,650	-
Stock issued as payment for fees	37,391	-
Options issued as compensation	969	-
Options issued as payment for fees	27,688	-
Changes in:		
Accounts receivable	(25,477)	(221,750)
Inventories	(119,337)	88,348
Prepaid expenses and other current assets	(30,182)	(8,270)
Other assets and deposits	31,880	(2,975)
Accounts payable and accrued expenses	(458,823)	66,417
Grant and other current liabilities	(12,648)	648
<b>Net cash used in operating activities</b>	<b>(1,174,415)</b>	<b>(407,176)</b>
<b>CASH FLOWS USED IN INVESTING ACTIVITIES:</b>		
Acquisition of fixed assets	(47,337)	-
<b>Net cash used in investing activities</b>	<b>(47,337)</b>	<b>-</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Bank overdraft	(67,434)	117,563
Change of capital lease obligation	(29,887)	45,240
Proceeds from Shareholder Loans	-	216,202
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>2,693,628</b>	<b>379,005</b>
<b>NET INCREASE (DECREASE) IN CASH</b>	<b>1,471,876</b>	<b>(28,171)</b>
Cash beginning of the period	-	28,171
<b>CASH end of the period</b>	<b>\$ 1,471,876</b>	<b>\$ -</b>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid during the period for interest	\$ 1,976	\$ -



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

Fixed Assets acquired under capital leases	\$	-	\$	31,071
Stock issued as compensation to employees		304,229		-
Stock issued as payment for financing fees		39,400		-
Stock issued as payment for consulting services		37,391		-
Options issued as employee compensation		969		-
Options issued as payment for consulting services		337,973		-
Options issued as payment for financing fees		108,564		-
Warrants issued as interest for existing debt		60,650		-
Warrants issued for Chembio Diagnostic 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 Series A Preferred Stock		1,332,292		-
	\$	3,375,916	\$	31,071

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, 2003 AND 2002**

	2003	2002
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (1,059,704)	\$ (988,971)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	134,357	80,475
Provision for doubtful accounts	20,953	25,440
Changes in:		
Accounts receivable	(150,988)	187,259
Inventories	127,441	95,238
Prepaid expenses and other current assets	(17,318)	12,817
Other assets and deposits	(2,905)	(30,625)
Accounts payable and accrued expenses	523,668	(44,199)
Grant and other current liabilities	549	(142,628)
<b>Net cash used in operating activities</b>	<b>(423,947)</b>	<b>(805,194)</b>
<b>CASH FLOWS USED IN INVESTING ACTIVITIES:</b>		
Acquisition of fixed assets	-	(60,527)
<b>Net cash used in investing activities</b>	<b>-</b>	<b>(60,527)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Net proceeds from sale of common stock	-	535,125
Bank overdraft	67,434	-
Repayment of capital lease obligation	(36,931)	(37,834)
Proceeds from shareholder loans	365,273	385,603
<b>Net cash provided by financing activities</b>	<b>395,776</b>	<b>882,894</b>
<b>NET DECREASE IN CASH</b>	<b>(28,171)</b>	<b>17,173</b>
Cash beginning of the year	28,171	10,998
<b>CASH end of the year</b>	<b>\$ -</b>	<b>\$ 28,171</b>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid during the year for interest	\$ -	\$ 63,491
<b>Supplemental disclosures for non cash investing and financing activities:</b>		
Fixed assets acquired under capital leases	\$ 107,020	\$ 90,455

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



**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS (INFORMATION AS OF AND FOR THE SIX MONTHS**  
**ENDED JUNE 30, 2004 AND 2003 IS UNAUDITED)**

<b>NOTE</b>	<b>1</b>	<b>DESCRIPTION OF BUSINESS/OPERATIONS:</b>
-------------	----------	--

Chembio Diagnostics, Inc. ( the Company ) was formerly known as Trading Solutions.com, Inc. (see Merger and Other Related Transactions below). The historical information presented for 2002 and 2003 is based on the wholly owned subsidiary of the Company, Chembio Diagnostic Systems, Inc. prior to the merger, as discussed below. The equity sections of the balance sheets for 2002 and 2003 as well as the earnings per share presented in the statement of operations for 2002 and 2003 have been restated to reflect the shares outstanding as if the merger had taken place as of the first date of 2002, the earliest period presented. Prior filings of the SB-2 contain the audited balances sheet for both years.

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

Trading Solutions.com, Inc. had no assets, liabilities or transactions (other than the 1:17 reverse split) for the six months ended June 30, 2004. Trading Solutions.com, Inc. had a fiscal year ending September 30, after the merger Chembio Diagnostics, Inc fiscal year was December 31, which was the year end of Chembio Diagnostic Systems, Inc.

Included as part of the SB-2 Amendment 3 are pro forma statement of operations for the six months ended June 30, 2004 and the year ended December 31, 2003. These statements illustrate the effects of the acquisition of Chembio Diagnostic Systems Inc., as if the merger transaction between Chembio Diagnostics, Inc. and Chembio Diagnostic Systems Inc. had occurred at the beginning of the periods presented and therefore assumes that proceeds of the financings were expended in the periods presented, and that costs and expense associated with the merger and associated financings were incurred in the periods presented.

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 Chembio Diagnostic Systems, Inc. s 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, 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.

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 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.

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS (INFORMATION AS OF AND FOR THE SIX MONTHS**  
**ENDED JUNE 30, 2004 AND 2003 IS UNAUDITED)**

c) The Existing Debt Exchange Offering. Per the merger agreement a minimum of \$1,300,000 of existing debt was required to be converted to series A preferred stock, any balances not converted will, if not paid by December 31, 2004, automatically be converted to series A preferred stock as of December 31, 2004. 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 May 5, 2004 the Company issued warrants to designees of H.C. Wainright & Co., Inc. and Wellfleet Partners, Inc., our placement agents in the series A preferred stock private placement, to purchase 751,667 shares and 183,333 shares of our common stock 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.

## **LIQUIDITY AND CAPITAL RESOURCES**

We anticipate that we will have additional capital requirements in the near future. The amount of additional capital we may need to raise will depend on a number of factors. These factors primarily include (1) receipt of orders from Bio-Manguinhos in 2004 and 2005 in accordance with contractual commitments; (2) whether we can generally achieve revenue growth and the extent to which, if any, that revenue growth improves operating cash flows; (3) our investments in research and development, facilities, marketing, regulatory approvals, and other investments we may determine to make, and (4) the availability and cost of raising additional capital and potential dilution to shareholders.

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 2004. We therefore expect that we will be required to sell additional equity or obtain additional credit facilities in the near term. We further expect that cash generated from operations will not be sufficient to satisfy our working capital and capital expenditure requirements over the next twelve months, so we expect that we will be required to sell additional equity or obtain additional credit facilities during that period. We cannot be certain that this financing will be available or that we will be able to complete financing on satisfactory terms, if at all.

Beyond twelve months out, it is likely that we will have additional financing requirements to finance our expected growth and/or to fund continuing operating deficits. 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 expected additional financing requirements.

**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 double declining balance 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 (INFORMATION AS OF AND FOR THE SIX MONTHS**  
**ENDED JUNE 30, 2004 AND 2003 IS UNAUDITED)**

**(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. 101, Revenue Recognition ( SAB 101 ). Under SAB 101, 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 notes payable reflected in these financial statements approximate carrying value.

**(m) *Recent Accounting Pronouncements:***



On May 1, 2002, the FASB issued SFAS No. 145, Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections. The Company anticipates no impact from this standard on the Company's financial statements.

On July 30, 2002, the FASB issued Statement of Financial Accounting Standards No. 146, Accounting for Costs Associated with Exit or Disposal Activities: ( SFAS 146 ), that is applicable to exit or disposal activities initiated after December 31, 2002. This standard requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of a commitment to an exit or disposal plan.

On December 31, 2002, the FASB issued Statement of Financial Accounting Standards No. 148, Accounting for Stock-Based Compensation-Transition and Disclosure ( SFAS 148 ), that is applicable to financial statements issued for fiscal years ending after December 15, 2002. In addition, interim disclosure provisions are applicable for financial statements issued for interim periods beginning after December 15, 2002. This standard amends SFAS 123 and provides guidance to companies electing to voluntarily change to the fair value method of accounting for stock-based compensation. In addition, this standard amends SFAS 123 to require more prominent and more frequent disclosures in financial statements regarding the effects of stock-based compensation.

In January 2003, FASB Interpretation No. 46 ( FIN No. 46 ), Consolidation of Variable Interest Entities, an interpretation of Accounting Research Bulletin No. 51, was issued. In general, a variable interest entity is a corporation, partnership, trust, or any other legal structure used for business purposes that either (a) does not have equity investors with voting rights or (b) has equity investors that do not provide sufficient financial resources for the entity to support its activities. FIN No. 46 requires a variable interest entity to be consolidated by a company if that company is subject to a majority of the risk of loss from the variable interest entity's activities or is entitled to receive a majority of the entity's residual returns or both. Currently this standard has not had an impact on Chembio Diagnostics, Inc.'s consolidated financial statements.

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS (INFORMATION AS OF AND FOR THE SIX MONTHS**  
**ENDED JUNE 30, 2004 AND 2003 IS UNAUDITED)**

In April 2003, FASB issued Statement of Financial Accounting Standards No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities (SFAS 149). SFAS 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities under FASB Statement No. 133 Accounting for Derivative Instruments and Hedging Activities. SFAS 149 is generally effective for contracts entered into or modified after June 30, 2003. Currently this standard has not had an impact on Chembio Diagnostics, Inc.'s consolidated financial statements.

In May 2003, FASB issued Statement of Financial Accounting Standards No. 150 Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity (SFAS 150). SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS 150 is effective for financial instruments entered into or modified after May 31, 2003. Currently this standard has not had an impact on Chembio Diagnostics, Inc.'s consolidated financial statements.

(n)

***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 selected information. It also establishes standards for related disclosures about product and services, geographic areas, and major customers. SFAS 131 was effective for financial statements for fiscal years beginning after December 15, 1997.

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.

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 are as follows:

	<b>Six Months Ended June 30,</b>		<b>Year Ended December 31,</b>	
	<b>2004</b>	<b>2003</b>	<b>2003</b>	<b>2002</b>
USA	\$ 269,844	\$ 355,542	\$ 655,964	\$ 832,341
Brazil	361,156	-	3,930	16,846
Costa Rica	114,998	85,500	126,063	95,653
Canada	184,555	229,265	445,412	383,109
Saudi Arabia	51,026	29,918	50,577	56,978
Japan	37,000	41,649	116,111	277,637
Venezuela	-	-	55,424	147,552
France	-	-	50,166	38,420
Australia	-	-	25,195	21,773
Austria	20,033	30,739	72,684	82,634
India	34,009	56,711	79,052	84,692
Italy	900	209,197	294,676	138,981
Mexico	-	115,000	186,130	1,887
Korea	27,132	58,059	104,434	111,453
Others	140,267	228,948	276,803	520,896
	\$ 1,240,920	\$ 1,440,528	\$ 2,542,621	\$ 2,810,852

(o)

*Interim Financial data:*

**Basis of Presentation:**

In the opinion of management, the accompanying unaudited Consolidated Financial Statements include all adjustments (consisting of normal recurring accruals or adjustments only) necessary to present fairly the financial position at June 30, 2004, and the results of operations and the cash flows for all periods presented. The results of operations for the interim periods are not necessarily indicative of the results to be obtained in any future interim period or for the entire year.

Trading Solutions.com, Inc. had no assets, liabilities or transactions (other than the 1:17 reverse split) for the six months ended June 30, 2004. Trading Solutions.com, Inc. had a fiscal year ending September 30, after the merger Chembio Diagnostics, Inc fiscal year was December 31.

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS (INFORMATION AS OF AND FOR THE SIX MONTHS**  
**ENDED JUNE 30, 2004 AND 2003 IS UNAUDITED)**

(p) **Accounts payable and accrued liabilities**

The following tables detail the component parts of Accounts payable and accrued liabilities:

	as of	
	June 30, 2004	December 31, 2003
Accounts Payable - Suppliers	\$ 656,163	\$ 1,027,252
Accrued Payroll	59,927	119,236
Accrued Commissions and Royalties	89,289	80,927
Accrued Payroll and other taxes	63,064	41,737
Accrued Legal and Accounting	31,285	81,315
Accrued Expenses - other	2,996	11,080
<b>TOTAL</b>	<b>\$ 902,724</b>	<b>\$ 1,361,547</b>

(q) **Earnings Per Share**

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

	<u>For the six</u>		<u>For the years ended</u>	
	<u>months ended</u>	<u>months ended</u>	<u>December 31,</u>	<u>December 31,</u>
	<u>June 30,</u>	<u>June 30,</u>	<u>December 31,</u>	<u>December 31,</u>
	<u>2004</u>	<u>2003</u>	<u>2003</u>	<u>2002</u>
<b>Basic</b>	5,361,729	4,929,118	4,919,191	4,929,118
<b>Diluted</b>	5,361,729	4,929,118	4,919,191	4,929,118

**Computation of pro forma 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 2003 and 2002 is the same as basic loss per share, since the effects of the calculation were anti-dilutive due to the fact that the Company incurred losses for all periods presented. The following securities, presented on a common share equivalent basis, have been excluded from the per share computations:

	<u>Six Months Ended June</u>	<u>Year Ended December</u>		
	<u>30,</u>	<u>31,</u>		
	<u>2003</u>	<u>2003</u>	<u>2002</u>	
	<u>2004</u>			
Stock Options	1,304,000	389,000	365,000	315,000
Warrants	11,569,803	140,000	140,000	140,000
Preferred stock	7,578,985	-	-	-

(r) **Reclassifications**

Certain reclassifications have been made to the December 31, 2003 balance sheet to conform to the 2004 presentation, including the reclassification as shown on the Consolidated Statement of Redeemable Convertible Preferred Stock and Stockholders' Equity.

F-12

---

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS (INFORMATION AS OF AND FOR THE SIX MONTHS**  
**ENDED JUNE 30, 2004 AND 2003 IS UNAUDITED)**

**NOTE 3 INVENTORY:**

Inventory consists of the following at:

	June 30, 2004	Dec. 31, 2003
Raw materials	\$ 478,030	\$ 379,079
Work-in-progress	50,162	73,319
Finished goods	57,643	14,100
	\$ 585,835	\$ 466,498

**NOTE 4 FIXED ASSETS:**

Fixed assets consist of the following at:

	June 30, 2004	Dec. 31, 2003
Machinery and equipment	\$ 651,869	\$ 637,969
Furniture and fixtures	65,965	53,329
Computer and telephone equipment	91,823	81,678
Leasehold improvements	45,221	34,566
Tooling	41,900	41,900
	896,778	849,442
Less accumulated depreciation and amortization	(674,750)	(600,195)
	\$ 222,028	\$ 249,247

Included in the above fixed assets are \$308,615 of assets under capital leases for June 30, 2004 and December 31, 2003, respectively.

**NOTE 5 LONG-TERM DEBT:**

Long-term debt is comprised of the following:

\$707,914 of Senior Notes bearing interest at 11% were issued in 1999 in connection with a debt restructuring. The Senior Notes are collateralized by a first lien on all of the assets of the Company. Holders of these Notes were also granted warrants to purchase an aggregate of 140,000 shares of common stock at \$1.80 per share. The aggregate fair value of the warrants was \$10,000, of which \$7,000 was related to the debt refinancing and is being amortized over the term of the loan. \$3,000 of the fair value of the warrants are related to the conversion of debt to equity. As of December 31, 2003 the outstanding principal balance of the Senior Notes was \$707,914 with accrued unpaid interest of \$92,379.

Per a waiver agreement dated July 10, 2002, the senior note holders agreed to extend the Company's required first principal payment until July 31, 2003 provided that the Company pay the balance of accrued and unpaid interest on or before August 31, 2002 and remain current on interest payments due during the period from September 1, 2002 through July 31, 2003. Current interest payments were not maintained nor was the first principal payment made when it became due on July 31, 2003. However, no acceleration or event of default has been claimed on these Notes and, as described below, this debt will be converted to equity unless the Board of Directors chooses to refinance or otherwise retire this debt. Accordingly the entire amount of this debt has been classified as long term.

Per a line of credit agreement dated April 2001, a major shareholder agreed to advance the Company up to a maximum principal amount of \$350,000. This amount was later increased to \$1,200,000. The line of credit is collateralized by a subordinated security interest in all of the assets of the Company. In consideration for the above, the Company agreed to repay such borrowed funds on a quarterly basis with accrued interest at 12% per annum, starting September 30, 2003, with a final payment due March 31, 2005, at a maximum quarterly payment of \$43,750. As of December 31, 2003 the principal amount of the advance was \$985,937 with additional accrued interest of \$146,653. Current payments were not being made however, no acceleration or event of default has been claimed on these Notes and as described below, the entire amount of this debt has been classified as long term.

Long-term was originally comprised of \$1,693,851, of which \$707,914 was attributable to senior notes bearing interest at 11% issued in 1999 in connection with a debt restructuring of Chembio Diagnostic Systems, Inc., as described above and \$985,937 of which was attributable to a line of credit bearing interest at 12%, as described above. The senior notes are collateralized by a first lien on all of the assets of the Chembio Diagnostic Systems, Inc. Holders of these notes were also granted warrants to purchase an aggregate of 140,000 shares of common stock at \$1.80 per share. This line of credit is collateralized by a subordinated secured interest in all the assets of Chembio Diagnostic Systems, Inc.

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. The total debt remaining totaled \$361,559.

There is an additional amount due of \$311,792 which represents interest on the entirety of the debt prior to the conversion.

As part of the merger agreement this debt, along with the unpaid interest will either be paid or converted into series A preferred stock by the end of December 2004. The remaining debt and unpaid interest is not expected to be paid before the end of December 2004 and therefore the expectation is it will be converted on December 31, 2004 and accordingly it has been reflected as long-term.

## **NOTE 6 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, 2003 were as follows:

Year ending December 31,	
2004	\$ 79,431
2005	58,093
2006	38,272
2007	32,984
2008	4,470
	213,250
Less: imputed interest	43,576
Present value of future minimum lease payments	169,674
Less: current maturities	61,789
	\$ 107,885

These leases have interest rates ranging from 7% - 21%.





**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS (INFORMATION AS OF AND FOR THE SIX MONTHS**  
**ENDED JUNE 30, 2004 AND 2003 IS UNAUDITED)**

**NOTE                      7                      RESEARCH GRANTS AND DEVELOPMENT CONTRACTS:**

In 2002 and 2003 the Company received funding from third parties in connection with research and development activities as follows:

· In 2002, \$215,118 was received from the US National Institute of Health and \$50,000 was received from a diversified Japanese health care company, both in connection with efforts to develop a rapid test for the detection of antibodies to tuberculosis in human whole blood, serum and plasma. Also in 2002, \$20,000 was received from a major university dental school to conduct a feasibility study on certain reagents related to dental bacteria in order to evaluate a possible future test. Additional amounts received in 2002 for various grant projects totaled \$39,170.

· In 2003 the Company received the following new research and development grants and contracts that are still ongoing for additional amounts in 2004.

- \$40,000 from a leading multinational dental products company in connection with additional product development efforts begun through the abovementioned university partner in 2002.
- \$60,000 from a leading multinational company in the field of bovine spongiform encephalitis (BSE or mad cow disease) for development of a rapid test for BSE.
- \$50,000 for additional development work from the above-mentioned diversified Japanese health care company for further development work on the tuberculosis product for the Japanese market.
- \$89,000 from a research foundation focused on tuberculosis vaccines and diagnostics in connection with the commencement of a Phase II National Institute of Health grant sub-contract awarded in September 2003 for development of a whole blood rapid test for detection of tuberculosis in monkeys primarily for use in pharmaceutical research facilities.
- Approximately \$36,000 in various other funded development for the rapid detection of tuberculosis in humans and animals.
- Additionally, in November 2003, the Company received notice of a \$100,000 grant award from the World Health Organization to develop a tuberculosis antigen detection test. However no funds were received for this award in 2003.

· In the first six months of 2004 the Company received no new research and development grants and contracts. The revenue received for the six months included:

§ \$165,433 from a research foundation focused on tuberculosis vaccines and diagnostics in connection with the commencement of a Phase II National Institute of Health grant sub-contract awarded in September 2003 for development of a whole blood rapid test for detection of tuberculosis in monkeys primarily for use in pharmaceutical research facilities.

§        \$64,506 from the World Health Organization to develop a tuberculosis antigen detection test.

§        \$62,000 from a leading multinational dental products company in connection with additional product development efforts begun through the above-mentioned university partner in 2002.

§

\$25,000 from a leading multinational company in the field of bovine spongiform encephalitis (BSE or mad cow disease) for development of a rapid test for BSE.

§ \$22,518 from various other funded development for the rapid detection of tuberculosis in humans and animals.

F-14

---

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS (INFORMATION AS OF AND FOR THE SIX MONTHS**  
**ENDED JUNE 30, 2004 AND 2003 IS UNAUDITED)**

**NOTE****8****INCOME TAXES:**

At June 30, 2004 and December 31, 2003, the Company has net operating loss carryforwards of approximately \$7,600,000 and \$6,800,000 available to offset future federal taxable income, which expires at various dates through 2024 and a research and development credit carryforward of approximately \$214,000, which have created net deferred tax assets. A full valuation allowance, which increased by \$331,000 during the first six months of 2004 and \$490,600 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:

	June 30, 2004	Dec. 31, 2003
Net operating loss carryforwards	\$ 3,116,000	\$ 2,791,000
Research and development credit	214,000	214,000
Bad debt reserve	12,200	6,200
Gross deferred tax assets	3,342,200	3,011,200
Valuation allowance	(3,342,200)	(3,011,200)
Net deferred tax assets	\$	\$

**NOTE 9 - CONDITIONALLY REDEEMABLE CONVERTIBLE 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 be issued. The value of the preferred 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 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.
- 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 \$374.79 per share). Accrued but unpaid dividends of \$56,810 are included in the preferred stock carrying value.

In connection with the merger, 151.57984 shares of 8% series A preferred stock convertible into 50,000 shares of common stock per preferred share, were issued and outstanding at June 30, 2004 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 and were charged against Additional Paid in Capital.

- ii)

33,836,82 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 and were charged against Additional Paid in Capital.

iii) 44,409,72 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 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.

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS (INFORMATION AS OF AND FOR THE SIX MONTHS**  
**ENDED JUNE 30, 2004 AND 2003 IS UNAUDITED)**

<b>NOTE</b>	<b>10</b>	<b>STOCKHOLDERS EQUITY:</b>
-------------	-----------	-----------------------------

The stockholders equity section on the balance sheet as of December 31, 2003 has been restated to reflect its recapitalization as a result of the consummated merger transaction (see Note 1).

<i>(a)</i>	<i>Common Stock</i>
------------	---------------------

As a result of the merger;

- 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.
- ii) Stockholders of 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 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 intrinsic value of the shares was recorded at \$240,000 and since there was no vesting period it has been expensed in the quarter ended June 30, 2004. 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 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.

This results in 6,417,908 shares of common stock issued and outstanding as of June 30, 2004.

<i>(b)</i>	<b>Options</b>
------------	----------------

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 \$11,089 was expenses.

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 11). The exercise price for these options ranged from \$0.543 to \$1.00 per share. These options were 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 11). 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 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 fair values of these options were \$108,564 and are treated as prepaid expense and are being amortized over the life of their contracts. For the quarter ended June 30, 2004 amortization of these options were \$27,688. As per EITF 96-18 these options will continually be revalued until the measurement date for each options has been reached.

As of June 30, 2004 total options are outstanding to purchase 1,304,000 shares of common stock.

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS (INFORMATION AS OF AND FOR THE SIX MONTHS**  
**ENDED JUNE 30, 2004 AND 2003 IS UNAUDITED)**

(c)

**Warrants**

In May 2004, prior to the merger, Chembio Diagnostic Systems, Inc. issued 140,000 warrants to existing debt holders to compensate for the valuation of the company in the merger and issued 400,002 to existing stockholders in consent of the merger. The warrants issued to debt holders had a fair value of \$60,650 and were expensed for the quarter ended June 30, 2004. 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.

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

850,000 warrants were issued in connection to an employment agreement see Note 10 (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 and reflected as deferred financing costs in the equity section of the balance sheet.

As of June 30, 2004 total warrants are outstanding to purchase 11,569,803 shares of common stock.

**NOTE**

**11**

**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.

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 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.

	Six months ended		Years ended	
	June 30, 2004	June 30, 2003	Dec. 31, 2003	Dec. 31, 2002
Net Income (loss) applicable to common stockholders, as reported	\$ (1,203,999)	\$ (471,353)	\$ (1,059,704)	\$ (988,971)
	969	-	-	-

Add: Stock-based compensation  
included in reported net loss

Deduct: Total stock based employee  
compensation expense determined  
under the fair value based method for  
all awards, net of tax

		453,320		-		-		-
Pro forma net income (loss)	\$	(1,656,350)	\$	(471,353)	\$	(1,059,704)	\$	(988,971)
Income (loss) per share:								
Basic and diluted (loss) per share - as reported	\$	(0.22)	\$	(0.10)	\$	(0.22)	\$	(0.20)
Basic and diluted (loss) per share - pro forma	\$	(0.31)	\$	(0.10)	\$	(0.22)	\$	(0.20)

F-17



**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS (INFORMATION AS OF AND FOR THE SIX MONTHS**  
**ENDED JUNE 30, 2004 AND 2003 IS UNAUDITED)**

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 quarter ended June 30, 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. No options were issued during the year ended December 31, 2002. Proforma information for the years ended December 31, 2003 and 2002 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.

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	690,000	0.93
Canceled		
Exercised		
Options outstanding at June 30, 2004	1,055,000	\$ 1.56
Options exercisable at December 31, 2003	197,500	
Options exercisable at June 30, 2004	780,000	

Range of Exercise Prices	Options Outstanding at 6/30/04	Weighted Average Remaining Life	Weighted Average Exercise Price	Options Exercisable at 6/30/04	Weighted Average Exercise Price
\$2.17 4.00	315,000	3.6	\$3.12	315,000	\$3.12
\$0.60 1.50	690,000	6.9	\$0.93	415,000	\$0.74
\$0.45	50,000	6.2	\$0.45	50,000	\$0.45

The company issued additional options to consultants that were not part of this plan. The total issued for the six months ended June 30, 2004 was 249,000 (see note 10(b)) of which 2,500 were exercisable as of June 30, 2004.

NOTE

12

COMMITMENTS AND CONTINGENCIES:

***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, 2003:

Year ending December 31,	
2004	\$89,792
2005	28,896
	\$118,688

Rent expense associated with these leases for the following periods:

	<u>Six Months Ended March</u>		<u>Year Ended December</u>	
	<u>31,</u>		<u>31,</u>	
	<u>2004</u>	<u>2003</u>	<u>2003</u>	<u>2002</u>
Rent	\$45,397	\$46,763	\$90,693	\$85,949

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS (INFORMATION AS OF AND FOR THE SIX MONTHS**  
**ENDED JUNE 30, 2004 AND 2003 IS UNAUDITED)**

***Economic Dependency:***

The Company had sales to two customers in excess of 10% of total sales in the six months ended June 30, 2004. Sales to these customers aggregated approximately \$361,000 and \$167,800, respectively. Accounts receivable from these customers were \$3,050 and \$48,447, respectively at June 30, 2004.

The Company had sales to two customers in excess of 10% of total sales in the six months ended June 30, 2003. Sales to these customers aggregated approximately \$208,600 and \$206,800, respectively. Accounts receivable from these customers were \$54,220 and \$42,671, respectively at June 30, 2003.

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 \$397,000 and \$292,000, respectively. Accounts receivable from these customers were \$38,334 and \$13,101, respectively at December 31, 2003.

The Company had sales to one customer in excess of 10% of total sales in the year ended December 31, 2002. Sales to this customer aggregated approximately \$305,000. Accounts receivable from this customer at December 31, 2002 was \$0.

The Company had no purchases from any vendor in excess of 10% of total purchases for the six months ended June 30, 2004 or June 30, 2003.

The Company had purchases from one vendor in excess of 10% of total purchases for the year ended December 31, 2003. Purchases from this vendor aggregated approximately \$91,000. The corresponding accounts payable at December 31, 2003 to this vendor was \$5,890.

The Company had purchases from one vendor in excess of 10% of total purchases for the year ended December 31, 2002. Purchases from this vendor aggregated approximately \$200,000. The corresponding accounts payable at December 31, 2002 to this vendor was \$11,700.

**NOTE**

**13**

**OTHER EVENTS:**

***Litigation:***

The Company filed a complaint in the United States District Court for the Eastern District of New York against Saliva Diagnostic Systems, Inc. Saliva Diagnostic is the assignee of patent #5,935,864 ( the 864 patent ) that describes a method for collecting samples. The complaint asks the court for declaratory and other relief that the Company's Sure Check HIV test does not infringe the 864 patent, that the 864 patent is invalid, and that the 864 patent is unenforceable due to inequitable procurement. In 2001 and 2002, pursuant to various agreements it had entered into with Saliva Diagnostic, the Company developed, manufactured and sold an HIV rapid test that Saliva Diagnostic had represented incorporates the sample collection method described in the 864 patent. Saliva Diagnostic also represented that the 864 patent is valid. During 2001-2003, the Company paid royalties to Saliva Diagnostic and took several other actions based upon Saliva Diagnostic's representations. In 2003, Saliva Diagnostic sought to abrogate the agreements between the companies and alleged that the Company was infringing the 864 patent. The Company has received opinions from its patent counsel that the product manufactured by the Company is in fact not covered by this patent, that the patent is invalid, and that the patent was obtained through inequitable procurement.

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. A pretrial scheduling conference was held on September 8, 2004. The scheduling conference set March 15, 2005 as the date for the close of all discovery on liability issues and stipulated that a pre-motion conference or summary judgment motion must be requested by April 1, 2005.

**CHEMBIO DIAGNOSTICS, INC.**

**(f/k/a Trading Solutions.com)**

**INTRODUCTION TO CONDENSED CONSOLIDATED PRO FORMA FINANCIAL STATEMENTS**

**(Unaudited)**

The following unaudited pro forma consolidated statement of operations for the six months ended June 30, 2004 and the twelve months ended December 31, 2003 are based on the historical financial statements of Trading Solutions.Com, Inc. ( TSLU ) and Chembio Diagnostic Systems Inc. and Subsidiary ( Systems ) after giving effect to the merger of Systems into a subsidiary of TSLU formed exclusively for the merger. The result of the combination will have Systems as the continuing operating entity in a reverse merger transaction. See notes to unaudited pro forma financial statements for a detailed description of the events as a result of this reverse merger.

The unaudited pro forma consolidated financial statements should be read with the accompanying unaudited pro forma footnotes as well as the historical financial statements and accompanying notes of Systems included in this registration statement as well as the historical financial statements and accompanying footnotes of TSLU as filed with the Securities & Exchange Commission. The unaudited pro forma consolidated financial statements are not intended to represent or be indicative of the consolidated results of operations or financial condition that would have been reported had the merger been completed as of the dates presented and should not be taken as representative of future consolidated results of operations and financial condition of the merged entity.

**CHEMBIO DIAGNOSTICS, INC.**  
**(formerly Trading Solutions.com)**  
**CONDENSED CONSOLIDATED PRO FORMA STATEMENTS OF OPERATIONS**  
**FOR THE SIX MONTHS ENDED JUNE 30, 2004**  
(Unaudited)

	<b>HISTORICAL</b>		<b>PROFORMA ADJUSTMENTS</b>		
	<b>Trading Solutions.Com, Inc.</b>	<b>Chembio Diagnostic Systems, Inc.</b>	<b>Debit</b>	<b>Credit</b>	<b>Consolidated Pro Forma</b>
<b>REVENUES:</b>					
Net sales	\$	\$ 1,240,920			\$ 1,240,920
Grant income		339,457			339,457
		1,580,377			1,580,377
Cost of sales		1,091,010			1,091,010
<b>GROSS PROFIT</b>		<b>489,367</b>			<b>489,367</b>
<b>OVERHEAD COSTS:</b>					
Research and development expenses		499,446			499,446
Selling, general and administrative expenses	19,920	1,193,661	56,667 (c)		1,270,248
<b>LOSS FROM OPERATIONS</b>	<b>(19,920)</b>	<b>(1,203,740)</b>			<b>(1,280,327)</b>
<b>OTHER INCOME (EXPENSES):</b>					
Forgiveness of Debt		209,372			209,372
Interest (expense) - net		(152,821)	60,650 (d)	72,760 (a)	(140,711)
<b>LOSS BEFORE INCOME TAXES</b>	<b>(19,920)</b>	<b>(1,147,189)</b>			<b>(1,211,666)</b>
Income taxes					
<b>NET LOSS</b>	<b>\$ (19,920)</b>	<b>\$ (1,147,189)</b>			<b>\$ (1,211,666)</b>
<b>PRO FORMA DIVIDEND PAYABLE</b>					
		56,810	125,086(b)		\$ 181,896
<b>NET LOSS AVAILABLE TO COMMON SHAREHOLDERS</b>		<b>\$ (1,203,999)</b>			<b>\$ (1,393,562)</b>
<b>Basic and Diluted Loss per share</b>					
(Shares used for calculation 5,361,729)					
		(\$0.22)			\$ (.26)

**CHEMBIO DIAGNOSTICS, INC.**  
**(formerly Trading Solutions.com)**  
**CONDENSED CONSOLIDATED PRO FORMA STATEMENTS OF OPERATIONS**  
**FOR THE TWELVE MONTHS ENDED DECEMBER 31, 2003**  
**(Unaudited)**

	<b>HISTORICAL</b>		<b>PROFORMA ADJUSTMENTS</b>		
	<b>Trading Solutions.Com, Inc.</b>	<b>Chembio Diagnostic Systems, Inc.</b>	<b>Debit</b>	<b>Credit</b>	<b>Consolidated Pro Forma</b>
<b>REVENUES:</b>					
Net sales	\$	\$ 2,542,621			\$ 2,542,621
Grant income		275,730			275,730
		2,818,351			2,818,351
Cost of sales		2,153,454			2,153,454
<b>GROSS PROFIT</b>		<b>664,897</b>			<b>664,897</b>
<b>OVERHEAD COSTS:</b>					
Research and development expenses		313,891			313,891
Selling, general and administrative expenses			170,000		
	7,123	1,202,185	(c)		1,379,308
<b>LOSS FROM OPERATIONS</b>	<b>(7,123)</b>	<b>(851,179)</b>			<b>(1,028,302)</b>
<b>OTHER INCOME (EXPENSES):</b>					
Gain from debt settlement	8,513				8,513
			60,650	154,070	
Interest (expense) - net		(208,525)	(d)	(a)	(115,105)
<b>LOSS BEFORE INCOME TAXES</b>	<b>1,390</b>	<b>(1,059,704)</b>			<b>(1,134,894)</b>
Income taxes					
<b>NET LOSS</b>	<b>\$ 1,390</b>	<b>\$ (1,059,704)</b>			<b>\$ (1,134,894)</b>
<b>PRO FORMA DIVIDEND PAYABLE</b>			363,792		
			(b)		\$ 363,792
<b>NET LOSS AVAILABLE TO COMMON SHAREHOLDERS</b>					<b>\$ (1,498,686)</b>
<b>Basic and Diluted Loss per share</b>					
(Shares used for calculation 6,417,908)					\$ (.23)





**CHEMBIO DIAGNOSTICS, INC.**

**(formerly Trading Solutions.com)**

**NOTES TO UNAUDITED PRO FORMA CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**JUNE 30, 2004 AND DECEMBER 31, 2003**

**(Unaudited)**

On May 5, 2004, TSLU and Systems closed on a merger agreement, which resulted in Systems being a wholly owned subsidiary of TSLU, with Systems as the operating Company. The pro forma Balance sheet for June 30, 2004 is not shown as there is no continuing impact that is not already reflected on the historical balance sheet as of June 30, 2004. The pro forma Statement of Operations assumes the transaction occurred as of the first day of the earliest period presented. The pro forma adjustments specifically relating to this transaction are reflected below:

- (a) As part of the merger some of the existing debt of Systems was converted into series A preferred stock. Elimination of historical interest expense on this converted debt was \$72,760 for the six months ended June 30, 2004 and \$154,070 for the twelve months ended December 31, 2003.
- (b) The preferred stock pays an 8% dividend. The total number of outstanding shares of preferred stock is 151,580 shares at \$30,000 per share. Dividends therefore would be \$181,896 for the six months ended June 30, 2004 (\$56,810 reflected in historical number) and \$363,792 for the twelve months ended December 31, 2003.
- (c) In connection with the closing of the merger employment agreements were entered into. The expected additional salary expense is \$56,667 for the six months ended June 30, 2004 (note this represents four months of additional salary as the six month historical contains two months at the higher rates) and \$170,000 for the twelve months ended December 31, 2003.
- (d) Prior to the merger 140,000 additional warrants were issued to existing debt holders, the fair value of \$60,650 was categorized as interest expense.