CHEMBIO DIAGNOSTICS, INC.
Form 424B3
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PROSPECTUS

CHEMBIO DIAGNOSTICS, INC.

40,466,304 SHARES OF COMMON STOCK

This prospectus relates to the sale by certain stockholders of Chembio Diagnostics, Inc. of up to 40,466,304 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, upon the conversion of shares of our 9% series B 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 May 19, 2005 the closing bid and ask prices for one share of our common stock were $.68 and $.71, 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 5 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 May 23, 2005

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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 inception we have been involved in developing, manufacturing, selling and distributing medical diagnostic 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 Chembio Diagnostics, Inc., formerly known as Trading Solutions.com, Inc. ("Chembio" or the "Company"). As a result of this transaction, the management and business of Chembio Diagnostic Systems Inc. became the management and business of the Company.

Our Business

We are a developer and manufacturer of rapid diagnostic tests that aid in the detection of infectious diseases; until recently, we also manufactured pregnancy tests. Our revenues until 2004 were primarily from private label over-the-counter pregnancy tests. In 2004 we sold substantially all of the business related to our private label pregnancy test. We are currently focused on obtaining FDA regulatory approval for, and increasing revenues from, our HIV rapid test products. During 2004 we experienced a significant increase in sales of our HIV rapid test products as a result of a contract we entered into with an organization affiliated with the Brazilian government. 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; HIV 1/2 Stat Pak Dipstick). Rapid Tests for detection of antibodies to HIV 1 and 2 in finger-stick whole blood, venous whole blood, serum and plasma	In December 2004 we completed clinical trials for Sure Check™ and HIV 1/2 Stat-Pak in the U.S. for FDA approval for sales in the U.S. with results that we believe will exceed the performance requirements for U.S. FDA approval. We are pursuing U.S. FDA approval for these products and on February 17, 2005 we submitted our Pre-Marketing Approval application to the FDA. 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. We have also just recently qualified for procurements by the United States Agency for International Development under the President's Emergency Plan for AIDS Relief and the World Health Organization's Bulk Procurement Scheme.	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	Product has been evaluated for approval in	We are waiting for Prionics AG to	Subject to obtaining European Union approval

Spongeiform Encephalopathy in cattle	the European Union and approval is pending.	complete the transfer of production specifications in order to begin production scale-up, validation, and regulatory submission. There is a significant risk that Prionics AG will be unable to transfer product specifications.	and completing the technology transfer, Prionics AG, Zurich, Switzerland has contracted with Chembio to provide manufacturing services. Additionally, Prionics AG will exclusively market product directly and through its designated distributors.

Existing or Proposed Product	Regulatory Status	Development Status	Partners Involved in the Development or Marketing of the Products
Dental Bacteria Test	Regulatory submissions in the European Union will be made in 2005 if product development is satisfactorily completed in accordance with development timetable.	Discussing revised development plan with marketing partner Ivoclar Vivadent, AG due to technical issues.	If a new development plan is agreed upon, Ivoclar Vivadent AG, Schaan, Liechtenstein will exclusively market the product and is the exclusive licensee of patented antibodies being incorporated by Chembio in product development.
Cerebral Spinal Fluid (CSF) Leak Rapid Test	Not yet submitted for approval.	Initial development work being supported with matching funds from the State of New York.	The State University of New York at Stony Brook (SUNY) is developing antibodies against this marker. SUNY has applied for a patent for the antibodies and the test. Chembio has an exclusive option to license the technology once the patent is issued.
Rapid diagnostic test for the detection of antibodies to active pulmonary tuberculosis in non-human primate whole blood samples	Submitted to United States Department of Agriculture for regulatory approval in the U.S. in March 2005.	Product validation completed.	Sequella Corporation, Rockville, MD and Chembio have entered into an agreement whereby Chembio will have exclusive worldwide marketing and manufacturing rights for the product.
Rapid diagnostic test for the detection of antibodies to active pulmonary tuberculosis in human whole blood samples	Evaluation by World Health Organization to be completed in 2005 to support use in international programs is pending. We do not plan to market this product in the U.S. or Europe and have no plans for seeking regulatory approval in these markets.	Product validation completed.	Public Health Research Institute, Newark, NJ provided initial research collaboration on product development.

Rapid diagnostic test for the detection of antibodies to Chagas Disease	Evaluation by World Health Organization to be completed in 2005 to support use in international programs is pending. We do not plan to market this product in the US or Europe and have no plans for seeking regulatory approval in these markets.	Product validation completed. Studies have been completed that have increased awareness of product. United Nations Development Program began to procure product in 2004.	A consortium of researchers from Latin America collaborated to develop the recombinant antigen incorporated in this product.

Existing or Proposed Product	Regulatory Status	Development Status	Partners Involved in the Development or Marketing of the Products
Private label pregnancy tests	Cleared for marketing by FDA.	Completed	During 2004 we sold substantially all of the business related with this product line for the right to receive participation in future profits, if any, derived from this product line. We have also continued to supply the buyer with certain components for these products.

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

	2004	2003
Pregnancy Tests	25.93%	46.84%
HIV Tests	37.58%	18.50%
Other Infectious Disease Tests	19.65%	24.88%
Research Grants and Contracts	16.84%	9.78%
Total	100.00%	100.00%

We manufacture all of the products we sell. All of these products, as well as those that are 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 though we have non-exclusive licenses to lateral flow patents from Abbott Laboratories, Inc. and to reagents including those 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.

The Offering

By means of this prospectus, a number of our stockholders are offering to sell up to 6,288,238 shares of common stock which they own, up to 14,783,600 shares of common stock which they may at a later date acquire upon the conversion of our series A and/or series B preferred stock, and up to 19,394,466 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 May 12, 2005, we had 7,108,086 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 and B preferred stocks 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 financial information for the fiscal quarter ended March 31, 2005, as well as the fiscal years ended December 31, 2004 and 2003. The financial statements are set forth beginning on page F-1 of this prospectus, and you should read this information for a more complete understanding of the presentation of this information. As described in the audited financial statements, on January 28, 2005 the Company substantially improved its balance sheets with the completion of the $5,047,500 Series B Private Placement financing. The Series B Private Placement financing is reflected in the financial statements for the three months ended March 31, 2005.

	Three Months Ended March 31, 2005 (Unaudited)	Year Ended December 31, 2004	Year Ended December 31, 2003
Revenue	731,885	3,305,932	2,818,351
Operating Expenses	890,811	3,923,701	1,516,076
Net Loss	(619,986)	(3,098,891)	(1,059,074)
Current Assets	4,766,750	1,211,060	772,680
Total Assets	5,135,090	1,426,449	1,086,745
Current Liabilities	1,278,191	1,663,196	1,503,418
Total Liabilities	1,525,926	1,950,413	3,544,186
Convertible Redeemable Preferred	5,783,793	2,427,030	-
Stockholders' Deficit	(2,174,629)	(2,950,994)	(2,457,441)

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 testing, manufacturing and control procedures. If we are required to devote resources to develop such new procedures, we may not have sufficient

resources to devote to research and development, marketing, or other activities that are critical to our business.

For example, the European Union and other jurisdictions have 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 Européene" which means "European conformity." ISO ("International Organization for Standardization") is the world's largest developer of standards with 148 member countries. As such, export to the European and other jurisdictions without the CE or ISO 13.485 mark is not possible. 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 or commit 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 $556,789 or 16.84% of our revenues in 2004 and $275,730 or 9.7% of our revenues in 2003 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. During the first quarter of 2005, we entered into a license and technology transfer agreement for certain rapid test technology. These revenues have funded some of our personnel and other research and developmental costs and expenses for us. 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 diminished which could 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.

As a result of the completion of the $5,047,500 Series B Private Placement on January 28, 2005, we believe that our current cash balances, together with cash generated from operations, will be sufficient to fund operations at least through the third quarter of 2005. We anticipate this based upon our recently completed operating budget which assumes significant new expenditures this year that are intended to help us increase revenues and cash flow, and to achieve a variety of other corporate objectives that are aimed to increase shareholder value. The Company is considering alternatives to provide for its capital requirements for late 2005 and beyond. There are no assurances that it will be successful in raising sufficient capital. Any additional equity financing will result in dilution to existing shareholders. If we are unable to obtain any such additional equity 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) 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; (2) our investments in research and development, facilities, marketing, regulatory approvals, and other investments we may determine to make; (3) the availability and cost of raising additional capital and potential dilution to shareholders; and (4) 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 requirements and customs regulations;
- cultural and political differences;
- foreign exchange rates, currency fluctuations and tariffs;
- dependence on and difficulties in managing international distributors or representatives;
- the creditworthiness of foreign entities;

- difficulties in foreign accounts receivable collection; and
- economic conditions and the absence of available funding sources.

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

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

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

We seek to protect our proprietary products under trade secret and copyright laws, enter into license agreements for various materials and methods employed in our products, and enter into strategic relationships for distribution of the products. These strategies afford only limited protection. We currently have no 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 often are found 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 complete these discussions successfully our business and operating results could 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 skills and experience 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 the contracts with Messrs. Esfandiari and Pelossof have terms 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 participants 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. If we are unsuccessful in our efforts to participate in these programs, our operating results could be materially harmed.

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

Since the inception of Chembio Diagnostic Systems, Inc. in 1985 and through the period ended December 31, 2004, we have incurred net losses. As of December 31, 2004, we have an accumulated deficit of $(12,099,406). We incurred net losses of $(3,098,891), and $(1,059,704) in 2004 and 2003, respectively.

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 Securities Exchange Act of 1934,

as amended (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 13,000 shares per day over the three months ended February 28, 2005. 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 certificates of designation creating our series A and series B preferred stock contain 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.

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 40,798,309. 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.

You will experience substantial dilution upon the conversion of the shares of preferred stock and the exercise of warrants that we issued in two private placements 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 151.57984 shares of our series A preferred stock and warrants to acquire 9,094,801 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 Diagnostic Systems, Inc., we assumed the obligation to issue 690,000 shares of our common stock upon the exercise of warrants, which warrants are exercisable at prices ranging from $0.45 to $4.00 per share. We also adopted the stock option plan of Chembio Diagnostic Systems, Inc. and assumed all of the obligation to issue 704,000 common shares upon the exercise of the options outstanding as of the merger date. On January 28, 2005, we completed a private placement in which we issued 100 shares of our 9% Series B Convertible Preferred Stock, which we refer to as the “Series B Stock,” together with warrants to purchase 7,786,960 shares of our common stock. For each $.61 invested in this private placement, an investor received (a) $.61 of face amount of Series B Stock, which is convertible into one share of our common stock, and (b) a five-year warrant to acquire .95 of a share of our common stock. Each full share of the Series B Stock was purchased for $50,000, with fractional shares of Series B Stock being purchased by investments of less than $50,000. In connection with the January 28, 2005 offering, we also issued to the placement agent Series B Stock in an aggregate amount equal to 5% of the amount of cash proceeds from the private placement, together with accompanying warrants to purchase our common stock. We also issued to the placement agent warrants to purchase 737,712 shares of our common stock. As of May 19, 2005, there were 1,169,000 options issued and outstanding under the stock option plan and 331,000 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 December 31, 2004, our named executive officers, directors and 5% stockholders beneficially owned approximately 47.81% 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.

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. 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 hold one or more of the following securities which are described in section “Description of Securities”: Common stock, Series A preferred stock which is convertible into common stock at $.60 per share, Series B preferred stock which is convertible into common stock at $.61 per share, options to purchase common stock at prices ranging from $0.45 per share to $4.00 per share, or warrants to purchase common stock exercisable at prices ranging from $0.45 per share to $4.00 per share. However, the table below assumes the immediate conversion by all Series A and B preferred stock into common stock and the immediate exercise of all options and warrants to purchase commons stock, without regard to other factors which may determine whether such rights of conversion or purchase are exercised. These factors include but are not limited to the other rights associated with remaining a preferred stockholder, the terms of these agreements, and the specific conversion or exercise price of the securities held by such selling security holder and its relation to the market price. The selling security holders may from time to time offer and sell pursuant to this prospectus up to an aggregate of 6,288,238 shares of our common shares now owned by them, 6,067,218 shares issuable to them upon the conversion of series A preferred stock that they hold, 8,716,382 shares issuable to them upon the conversion of series B preferred stock that they hold, 18,594,216 shares issuable to them upon the exercise of warrants that they hold and 800,250 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, although they are not obligated to do so.

Certain of the individuals listed below received the shares offered hereby in connection with the merger described under the caption “Description of Business - Merger.” 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 166,250 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.

Certain 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 issued to the investors in the series A preferred stock 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 March 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. On December 29, 2004 the Company converted $361,560 of additional debt into 12.05199 shares of series A preferred stock and associated warrants to purchase 723,120 shares of common stock. 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.

Certain of the entities or individuals listed below acquired the shares offered hereby in connection with our January 28, 2005 private placement of series B preferred stock. Pursuant to this private placement, we received $5 million in cash as payment for (a) 100 shares of preferred stock that are convertible into 8,196,800 shares of common stock, and (b) warrants to acquire 7,786,960 shares of common stock at an exercise price of $.61 per share. Based on the $5 million paid, the purchase price per common share is $.61, without allocating any portion of the purchase price to the warrants. Also in connection with these private placements, we agreed to prepare and file at our expense, as promptly as practical, and in any event, on or before 60 days after January 26, 2005, a registration statement with the Securities and Exchange Commission covering the resale of the shares of common stock issuable upon conversion of the series B preferred stock and the shares of common stock issuable upon exercise of the warrants. In connection with the private placement, the Company issued to the placement agent, Midtown Partners & Co., LLC, or its designees, 4.98 shares of series B preferred stock that are convertible into 409,012 shares of common stock, together with warrants to acquire 388,588 shares of common stock at an exercise price of $.61 per share. The Company also issued to Midtown Partners & Co., LLC, or its designees, warrants to purchase 737,712 shares of the Company's common stock at an exercise price of $.80 per share.

In connection with the series B private placement, three of the investors in the series A preferred stock collectively acquired a .95 share of series B preferred stock, convertible into 77,868 shares of common stock, together with warrants to acquire 73,972 shares of common stock. In addition, one investor in our series A preferred stock converted all of his interests in the series A preferred stock for a .4 share of series B preferred stock, convertible into 32,786 shares of common stock, together with warrants to acquire 38,933 shares of common stock.

The remaining entity listed below acquired the shares offered hereby pursuant to an investor relations contract with the Company. The entity acquired 56,250 shares of common stock on December 9, 2004, and an additional 20,000 shares of common stock on March 9, 2005.

The following table sets forth, to the Company's best knowledge and belief, with respect to the selling security holders:

- the number of shares of common stock beneficially owned as of March 18, 2005 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, additional information concerning the selling security holders including any NASD affiliations and 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.

Selling security holders [C]	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
Alchemy, LLC [1]	40,471	40,471	—	0.00%
Alpha Capital AG [2] [3]	1,232,000	1,232,000	—	0.00%
Bassett, Truman [1]	42,526	42,526	—	0.00%
Baum, Mark L. [2]	1,792,666	1,792,666	—	0.00%
Bell, Lon E. [2]	282,198	282,198	—	0.00%
Beller, Claudio [2]	145,582	145,582	—	0.00%
BioEquity Partners, Inc. [1,4]	175,000	175,000	—	0.00%
Breitbart, Ted [1,5]	18,208	18,208	—	0.00%
Bruce, Richard [1]	75,500	75,500	—	0.00%
Calamaro, Jean—Paul [2]	309,581	309,581	—	0.00%
CEOcast, Inc.	76,250	76,250	—	0.00%
Chrust, Steve [1]	127,656	127,656	—	0.00%
Clarke, John R.[1,6]	158,400	158,400	—	0.00%
Colby, Russ [1]	12,500	12,500	—	0.00%
Crestview Capital Master, LLC [7]	9,590,162	9,590,162	—	0.00%
Dabush, Ami [2]	569,718	569,718	—	0.00%
Daedalus Consulting, Inc.[8]	35,963	35,963	—	0.00%
Dashefsky, Jeff [1]	12,500	12,500	—	0.00%
Diamond Deecembra [8]	143,853	143,853	—	0.00%
DKR Soundshore Oasis Holding Fund, Ltd.[9]	1,198,770	1,198,770	—	0.00%

[A] Includes shares underlying series A and series B preferred stock into which the series A and series B 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 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 the securities offered hereunder in the ordinary course of business, and at the time of the purchase, had no agreements or understanding to distribute the securities.

[1] The sale of all of these shares is currently registered under Chembio's Registration Statement on Form SB-2 that became effective with the SEC on November 4, 2004. The sale of these shares also is included in this Prospectus so that Chembio can make any future amendments for the Registration Statement of which this Prospectus is a part, together with amendments of the 2004 Registration Statement in a single joint prospectus.

[2] The sale of all of these shares, except for less than 235,000 that represent dividend shares, currently is registered under Chembio's Registration Statement on Form SB-2 that became effective with the SEC on November 4, 2004. The sale of these shares also is included in this Prospectus so that Chembio can make any future amendments for the Registration Statement of which this Prospectus is a part, together with amendments of the 2004 Registration Statement, in a single joint prospectus.

[3] Konrad Ackerman has ultimate control over Alpha Capital AG and the shares held by Alpha Capital AG.

4 Provides marketing consulting services to the Company.
5 Affiliated with Wellfleet Partners.
6 Affiliated with HC Wainwright, investment banking services.
7 Affiliated with Dillion Capital, a NASD member. Robert Hoyt has ultimate control over Crestview Capital Master, LLC and the shares held by Crestview Capital Master, LLC.
8 Affiliated with Midtown Partners & Co., LLC, investment banking services.

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Selling security holders [C]	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
Eckert, Christopher & Lynn [2,10]	186,666	186,666	—	0.00%
Engel, Sam [1]	4,118	4,118	—	0.00%
Esfandiari, Javan [1]	167,080	167,080	—	0.00%
Falvo, Pete [2]	40,000	40,000	—	0.00%
FAMALOM, LLC [8]	179,817	179,817	—	0.00%
Feldman, Stephen [1]	2,055	2,055	—	0.00%
Fuchs, Ari [2,6]	49,058	49,058	—	0.00%
Ginsberg, Mike [1]	2,375	2,375	—	0.00%
Glass, Marc [1]	20,708	20,708	—	0.00%
Goldberg, Jeffrey [1,11]	52,875	52,875	—	0.00%
Greenblatt, Phil [1]	10,347	10,347	—	0.00%
Gregoretti, Gordan	79,916	79,916	—	0.00%
Gressel, Daniel [1,12]	462,501	462,501	—	0.00%
Guzikowski, Frank J.[1]	178,114	178,114	—	0.00%
H.C. Wainwright & Co. [1,13]	390,867	390,867	—	0.00%
Haendler, Kurt [1]	434,288	434,288	—	0.00%
Haendler, Renata [1]	138,211	138,211	—	0.00%
Haendler, Tomas [2,14]	540,710	540,710	—	0.00%
Haim, Eduardo [1]	7,115	7,115	—	0.00%
Hamblett, Michael [15]	498,714	498,714	—	0.00%
Hanson, Andrew Merz [2,16]	119,545	119,545	—	0.00%
Hunt, David [1]	60,000	60,000	—	0.00%
Ide, Bruce J.[2,17]	491,062	491,062	—	0.00%
Jacob, Sam [1]	10,000	10,000	—	0.00%
Jacoby, Richard A.[2]	469,545	469,545	—	0.00%
Joffe, Wendy [2]	37,222	37,222	—	0.00%
Jordan, Bruce [18]	67,931	67,931	—	0.00%

[9] DKR SoundShore Oasis Holding Fund Ltd. (the "Fund") is a master fund in a master-feeder structure. The Fund's investment manager is DKR Oasis Management Company LP (the "Investment Manager"). Pursuant to an investment management agreement among the Fund, the feeder funds and the Investment Manager, the Investment Manager has the authority to do any and all acts on behalf of the Fund, including voting any shares held by the Fund. Mr. Seth Fischer is the managing partner of Oasis Management Holdings LLC, one of the general partners of the Investment Manager. Mr. Fischer has ultimate responsibility for trading with respect to the Fund. Mr. Fischer disclaims beneficial ownership of the shares.

[10] Christopher Eckert is an employee of Smith Barney.

[11] Affiliated with Wellfleet Partners and Starobin Partners, investment banking services.

[12] Former Director of CDS.

[13] NASD member.

[14] Former President of CDS and Director.

[15] Employee of Starboard Capital Markets, LLC, investment banking services.

16		Assisted the Company in fundraising.
17		Form Director of CDS.
18		Employee of Midtown Partners & Co., LLC, investment banking services.

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Selling security holders [C]	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
JP Turner [1,5]	41,250	41,250	—	0.00%
Keskinen, Karen [1]	1,579	1,579	—	0.00%
Klaus, Elaine [1]	2,242	2,242	—	0.00%
Knasin, Paul and Ellen [2]	152,307	152,307	—	0.00%
Koch, Scott F.[1,6]	158,400	158,400	—	0.00%
Kolstad Jr., Kaare [1]	50,589	50,589	—	0.00%
Kreger, Richard [18]	453,435	453,435	—	0.00%
Krumholz, Jacob & Arlene	66,869	66,869	—	0.00%
Kurzman Partners, LP [19]	65,265	65,265	—	0.00%
Lankenau, Robert [1]	226,585	226,585	—	0.00%
Lanouette, Kevin P.	31,966	31,966	—	0.00%
Larkin, Richard [2]	109,189	109,189	—	0.00%
Lawrence, Colin [1]	7,115	7,115	—	0.00%
Ledowitz, Bill [1]	7,118	7,118	—	0.00%
Lew, Felicia [1]	31,250	31,250	—	0.00%
Lew, Hanka [1]	31,250	31,250	—	0.00%
Lifshitz, Joshua [20]	98,959	98,959	—	0.00%
Little Gem Life Sciences Fund LLC [21]	173,248	173,248	—	0.00%
Lyashchenko, Konstantin [1]	10,500	10,500	—	0.00%
Maloney & Company, LLC	79,916	79,916	—	0.00%
Mayer-Wolf, Mike [1]	18,379	18,379	—	0.00%
McCarthy, Michael [1]	4,145	4,145	—	0.00%
McGusty, Edwin [1]	125,000	125,000	—	0.00%
Metasequoia, LLC [2]	37,332	37,332	—	0.00%
Midtown Partners & Co., LLC [22]	116,639	116,639	—	0.00%
Millennium 3 Opportunity Fund, LLC [23]	3,196,720	3,196,720	—	0.00%
Moran, Sean	47,950	47,950	—	0.00%

[19] Affiliated with Needham & Company, investment banking services.

[20] Except for 26,393 shares, the sale of these shares is registered under Chembio's Registration Statement on Form SB-2 that became effective with the SEC on November 4, 2004. The sale of these shares also is included in this Prospectus so that Chembio can make any future amendments for the Registration Statement of which this Prospectus is a part, together with amendments of the 2004 Registration Statement, in a single joint prospectus.

[21] Except for 81,582 shares, the sale of these shares is registered under Chembio's Registration Statement on Form SB-2 that became effective with the SEC on November 4, 2004. The sale of these shares also is included in this Prospectus so that Chembio can make any future amendments for the Registration Statement of which this Prospectus is a part, together with amendments of the 2004 Registration Statement, in a single joint prospectus.

[22] NASD member, assisted the Company in fundraising.

[23] Fred Fraenkel and Udi Toledano have ultimate control over Millennium 3 Opportunity Fund and the shares held by Millennium 3 Opportunity Fund.

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Selling security holders [C]	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
MSAS Trust [2]	742,666	742,666	—	0.00%
Nite Capital, LP	719,261	719,261	—	0.00%
Patton Boggs LLP [1]	37,319	37,319	—	0.00%
Pelossof, Avi [2]	570,685	570,685	—	0.00%
Pelossof, Elior [2]	84,659	84,659	—	0.00%
Perlmutter, Alan [1]	60,000	60,000	—	0.00%
Phillips, Chris [8]	86,264	86,264	—	0.00%
Phillips, Scott W.[1]	50,589	50,589	—	0.00%
Poole, Colin [2]	141,098	141,098	—	0.00%
Poole, John G.[1]	68,365	68,365	—	0.00%
Raker, Gilbert [2]	84,659	84,659	—	0.00%
Reibman, Spencer [1]	18,780	18,780	—	0.00%
Rohan, J. Rory [18]	453,435	453,435	—	0.00%
Rojas, Zilma [1]	5,500	5,500	—	0.00%
Ross, Anne [1]	63,236	63,236	—	0.00%
Sandler, J & S [1]	8,287	8,287	—	0.00%
Sandler, Mark and Lori [2]	186,666	186,666	—	0.00%
Schnipper, Steve [24]	160,426	160,426	—	0.00%
Schwartz, Eric [1]	5,496	5,496	—	0.00%
Seren, Stanley [1]	8,287	8,287	—	0.00%
Shapiro, Alex [1]	112,412	112,412	—	0.00%
Siderowf, Richard [2,25]	86,624	86,624	—	0.00%
Siebert Best, Ellen [2]	43,311	43,311	—	0.00%
Siebert, Lawrence [26]	6,318,138	1,163,078	5,155,060	43.33%
Sive Paget & Reisel [1]	2,055	2,055	—	0.00%
Smith, Robin [1,27]	119,883	119,883	—	0.00%
Spatacco, Jr., Anthony J. [28]	89,520	89,520	—	0.00%
Speer, Sandy [1]	65,468	65,468	—	0.00%
Spilka, R. Edward [2,29]	313,138	313,138	—	0.00%
Starboard Capital Markets, LLC [30]	9,604	9,604	—	0.00%

[24] Except for 51,578 shares, the sale of these shares is registered under Chembio's Registration Statement on Form SB-2 that became effective with the SEC on November 4, 2004. The sale of these shares also is included in this Prospectus so that Chembio can make any future amendments for the Registration Statement of which this Prospectus is a part, together with amendments of the 2004 Registration Statement, in a single joint prospectus.

[25] Registered sales representative with RBC Dain Rauscher.

[26] Except for 663,078 shares, the sale of these shares is registered under Chembio's Registration Statement on Form SB-2 that became effective with the SEC on November 4, 2004. The sale of these shares also is included in this Prospectus so that Chembio can make any future amendments for the Registration Statement of which this Prospectus is a part, together with amendments of the 2004 Registration Statement, in a single joint prospectus.

[27] Provided marketing consulting services; affiliated with Wellfleet Partners and Starobin Partners.

28	Assisted the Company in fundraising; employee of Starboard Capital Markets LLC.
29	Stockholder of Lehman Brothers.
30	NASD member.

Selling security holders [C]	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
Starobin Partners [1,5]	110,000	110,000	—	0.00%
Straightline Capital Opportunities Fund I, LLC [2]	750,195	750,195	—	0.00%
Talesnick, Alan L. [2,31]	241,088	241,088	—	0.00%
TCMP3 Partners	319,671	319,671	—	0.00%
Thunderbird Global Corporation [2,32]	1,021,750	1,021,750	—	0.00%
Total M.I.S., Inc. [2]	560,000	560,000	—	0.00%
Tyson, John [2,33]	16,250	16,250	—	0.00%
Vicis Capital Master Fund [2,34]	5,600,000	5,600,000	—	0.00%
Wachs, Mark [2]	28,219	28,219	—	0.00%
Weiss, Gunther [1]	28,334	28,334	—	0.00%
Westbury Diagnostics, Inc. [2]	144,485	144,485	—	0.00%
TOTALS	**45,621,364**	**40,466,304**	**5,155,060**	

PLAN OF DISTRIBUTION

· Each selling stockholder (the "Selling Stockholders") of the common stock (the "Common Stock") of the Company 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. A Selling Stockholder may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the date of this prospectus;
- broker-dealers may agree with the Selling Stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale;

[31] Partner at Patton Boggs LLP, our legal counsel.

[32] WSITE International Foundation ("WSITE") is the ultimate beneficiary of Thunderbird Global Corporation. Gustavo Montilla is the Chairman of WSITE International Foundation and controls the daily affairs of WSITE.

[33] Provides marketing consulting services.

[34] Vicis Capital Master Fund's investment manager is Vicis Capital, LLC. Shad Stastney, John Succo, and Sky Lucas have the ultimate control over the shares held by Vicis Capital Master Fund.

- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise; or

- any other method permitted pursuant to applicable law.

The Selling Stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the Selling Stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with NASDR Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with NASDR IM-2440.

In connection with the sale of the Common Stock or interests therein, the Selling Stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the Common Stock in the course of hedging the positions they assume. The Selling Stockholders may also sell shares of the Common Stock short and deliver these securities to close out their short positions, or loan or pledge the Common Stock to broker-dealers that in turn may sell these securities. The Selling Stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The Selling Stockholders 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 such sales. In such 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. Each Selling Stockholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the Common Stock. In no event shall any broker-dealer receive fees, commissions and markups which, in the aggregate, would exceed eight percent (8%).

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the shares. The Company has agreed to indemnify the Selling Stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

Because Selling Stockholders may be deemed to be "underwriters" within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. Each Selling Stockholder has advised us that they have not entered into any written or oral agreements, understandings or arrangements with any underwriter or broker-dealer regarding the sale of the resale shares. There is no underwriter or coordinating broker acting in connection with the proposed sale of the resale shares by the Selling Stockholders.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the shares may be resold by the Selling Stockholders without registration and without regard to any volume limitations by reason of Rule 144(e) under the Securities Act or any other rule of similar effect or (ii) all of the shares have been sold pursuant to the prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale shares may not be sold unless they have been registered or qualified for sale in the applicable state or an

exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to the Common Stock for a period of two business days prior to the commencement of the distribution. In addition, the Selling Stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of the Common Stock by the Selling Stockholders or any other person. We will make copies of this prospectus available to the Selling Stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale.

LEGAL PROCEEDINGS

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. Please refer to the section of this prospectus entitled "Description of business—Our business following the merger—Certain legal and intellectual property issues" for a discussion of some of the legal issues we face. Other than as set forth below, we know of no material, existing or pending legal proceedings against us, nor are we involved as a plaintiff in any material proceeding or pending litigation. There are no proceedings in which any of our directors, officers or affiliates, or any registered or beneficial shareholder, is an adverse party or has a material interest to our interest. The outcome of the open unresolved legal proceeding set forth below is presently indeterminable. We do not believe the potential outcome from this legal proceeding will significantly impact our financial position, operations or cash flows.

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

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

DIRECTORS, EXECUTIVE OFFICERS AND CONTROL PERSONS

Lawrence A. Siebert (48), President and Director. Mr. Siebert was appointed President of Chembio Diagnostics, Inc. and a member of our board of directors upon consummation of the merger. Mr. Siebert has been Chairman of Chembio Diagnostic Systems Inc. for approximately 12 years and its President since May 2002. Mr. Siebert's background is in private equity and venture capital investing. From 1982 to 1991, Mr. Siebert was associated with Stanwich Partners, Inc, which during that period invested in middle market manufacturing and distribution companies. From 1992 to 1999, Mr. Siebert was an investment consultant and business broker with Siebert Capital Corp. and Siebert Associates LLC, and was a principal investor in a privately held test and measurement company which was sold in 2002. Mr. Siebert received a JD from Case Western Reserve University School of Law in 1981 and a BA with Distinction in Economics from the University of Connecticut in 1978.

Richard J. Larkin (48), Chief Financial Officer. Mr. Larkin was appointed as Chief Financial Officer of Chembio Diagnostics, Inc. upon consummation of the merger. Mr. Larkin oversees our financial activities and information systems. Mr. Larkin has been the Chief Financial Officer of Chembio Diagnostic Systems Inc. since September 2003. Prior to joining Chembio Diagnostic Systems Inc., Mr. Larkin served as CFO at Visual Technology Group from May 2000 to September 2003, and also led their consultancy program that provided hands-on expertise in all aspects of financial service, including the initial assessment of client financial reporting requirements within an Enterprise Resource Planning (Manufacturing) environment through training and implementation. Prior to joining VTG, he served as CFO at Protex International Corporation from May 1987 to January 2000. Mr. Larkin holds a BBA in Accounting from Dowling College and is a member of the American Institute of Certified Public Accountants.

Avi Pelossof (42), Vice President Sales, Marketing and Business Development. Mr. Pelossof joined Chembio Diagnostic Systems Inc. in 1996 and has been responsible for developing Chembio Diagnostic System's marketing strategy and collaborations. From 1991 to 1996, he was Managing Director and co-founder of The IMS Group, Inc., which provided strategic marketing advisory services to companies involved in Latin American markets including Chembio Diagnostics, Inc. Prior to IMS he was a Citibank Vice President in the International Corporate Finance Group focused on Latin America. Mr. Pelossof received his MBA in finance and international business from New York University in 1986 and a BA with Distinction in economics from the University of Michigan in 1984.

Javan Esfandiari (38), Director of Research & Development. Mr. Esfandiari co-founded, and became a co-owner of Sinovus Biotech AB where he served as Director of Research and Development concerning lateral flow technology until Chembio Diagnostic Systems Inc. acquired Sinovus Biotech AB in 2000. From 1993 to 1997, Mr. Esfandiari was Director of Research and Development with On-Site Biotech/National Veterinary Institute, Uppsala, Sweden, which was working in collaboration with Sinovus Biotech AB on development of veterinary lateral flow technology. Mr. Esfandiari received his B.Sc. in Clinical Chemistry and his M. Sc. in Molecular Biology from Lund University, Sweden. He has published articles in various veterinary journals and has co-authored articles on tuberculosis serology with Dr. Lyashchenko.

Rick Bruce (50), Vice President, Operations. Mr. Bruce was hired in April 2000 as Director of Operations. He is responsible for production, maintenance, inventory, shipping, receiving, and warehouse operations. Prior to joining Chembio Diagnostic Systems Inc., he held director level positions at Wyeth Laboratories from 1984 to 1993. From 1993 to 1998, he held various management positions in the Operations department at Biomerieux. From 1998 to 2000, he held a management position at V.I. Technologies. Mr. Bruce has over 25 years of operations management experience with Fortune 500 companies in the field of in-vitro diagnostics and blood fractionation. Mr. Bruce received his BS in Management from National Louis University in 1997.

Alan Carus (66), Director. Mr. Carus was elected to our Board of Directors on April 15, 2005. Mr. Carus is a co-founder of LARC Strategic Concepts LLC, a consulting firm dedicated to guiding emerging companies to next stage development. Prior to co-founding LARC Strategic Concepts LLC, Mr. Carus was Senior Vice President of Maritime Overseas Corporation ("MOC") and a senior executive of Overseas Shipholding Group, Inc. ("OSG") from 1981 to 1998, when he retired. MOC was managing agent for OSG, one of the world's largest ship-owners. Mr. Carus was a member of OSG's senior management committee and had senior responsibility in areas relating to administration, accounting, tax, finance, budgets, long-range projections, and human resources. He was involved in numerous acquisitions, debt and equity offerings, complex transaction structuring, and was active in the management of OSG's major investments in the cruise industry and other development stage companies. From 1964 to 1981, Mr. Carus was with Ernst & Young (including predecessors), the last seven years as a partner. Mr. Carus has a B.B.A. from the Baruch School of Business of the City College of New York.

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

Gary Meller MD, MBA (55), Director. Dr. Meller was elected to our Board of Directors on March 15, 2005. Dr. Meller has been the president of CommSense Inc., a healthcare business development company, since 2001. CommSense Inc. works with clients in Europe, Asia, North America, and the Middle East on medical information technology, medical records, pharmaceutical product development and financing, health services operations and strategy, and new product and new market development. From 1999 until 2001 Dr. Meller was the executive vice president, North America, of NextEd Ltd., a leading internet educational services company in the Asia Pacific region. Dr. Meller also is a member of the Advisory Board of Crestview Capital Master LLC, which was the lead investor in our series B preferred stock private placement. Dr. Meller a graduate of the University of New Mexico School of Medicine and has an MBA from the Harvard Business School.

Gerald A. Eppner (65), Director. Mr. Eppner was elected to our Board of Directors on March 15, 2005. Mr. Eppner is a partner at Cadwalader, Wickersham & Taft, a law firm based in New York City, New York. Mr. Eppner has experience in domestic and international corporate and securities law matters. Mr. Eppner has been in private practice

in New York City since 1966. For more than five years prior to 1966, Mr. Eppner was an employee of certain agencies and departments of the United States government.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table summarizes certain information as of April 20, 2005 with respect to the beneficial ownership of our Common Stock by each director, by all named executive officers, and by all officers and directors as a group, and by each other person known by us to be the beneficial owner of more than five percent of our Common Stock. The term "named executive officer" refers to our chief executive officer and each of our other four most highly compensated executive officers serving as of December 31, 2004 (we refer to these five individuals, collectively, as the named executive officers) for the fiscal years ended December 31, 2004, 2003 and 2002. Unless otherwise indicated, the address for each person set forth in the table is the address of the Company, 3661 Horseblock Road, Suite A, Medford, NY 11763.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percent of Class
Lawrence Siebert [1]	1,846,417	24.87%
Avi Pelossof [2]	498,512	6.81%
Javan Esfandiari [3]	117,080	1.64%
Richard Bruce [4]	75,500	1.06%
Konstantin Lyashchenko [5]	10,500	0.15%
Dr. Gary Meller [6]	12,000	0.17%
Gerald A. Eppner [6]	12,000	0.17%
Alan Carus [6]	12,000	0.17%
All officers, directors and director nominees as a group [7]	2,584,009	32.68%
Mark Baum [8] 580 Second Street, Suite 102 Encinitas, California 92024	1,554,333	19.68%
Tomas Haendler [9] 31 Cogswell Lane Stamford, CT 06902	451,820	6.38%
Thunderbird Global Corporation [10] c/o The Baum Law Firm 820 Second Street, Suite 102 Encinitas, CA 92024	467,431	6.63%
Daniel Gressel [11] 460 E. 79th Street, Apt. 17B New York, NY 10021	462,501	6.52%
H.C. Wainwright & Co., Inc. [12] 245 Park Avenue, 44th Floor New York, NY 10167	390,867	5.25%

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.

This table does not include convertible securities which, due to contractual restrictions, are not exercisable within 60 days of the date of this prospectus. Specifically, at no time may a holder of shares of series A or series B preferred stock convert shares of the series A or series B preferred stock, or warrants issued in connection with the purchase of series A or series B preferred stock, if the number of shares of common stock to be issued pursuant to the conversion would exceed, when aggregated with all other shares of common stock owned by that holder at that time, the number of shares of common stock which would result in that 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 that time, unless the holder has provided us with sixty-one (61) days notice that the holder has elected to waive this restriction. This contractual restriction does not apply to warrants not obtained in connection with the purchase of series A or series B preferred stock.

(1) Includes 170,000 shares issuable upon exercise of options exercisable within 60 days and 207,566 shares issuable upon exercise of warrants. Does not include 50,000 shares issuable upon exercise of options that are not exercisable within the next 60 days. Also does not include 1,937,220 shares issuable upon conversion of series A preferred stock, 2,324,666 shares issuable upon exercise of warrants, 81,967 shares issuable upon conversion of series B preferred stock and 77,868 shares issuable upon exercise of warrants because conversion of any of those shares of series A or series B preferred stock or exercise of those warrants would result in the holder beneficially owning in excess of 4.99% of the then issued and outstanding shares of common stock outstanding at that time.

(2) Includes 250,000 shares issuable upon exercise of options exercisable within 60 days and 22,555 shares issuable upon exercise of warrants. Does not include 50,000 shares issuable upon exercise of options that are not exercisable within the next 60 days. Also does not include 10,078 shares issuable upon conversion of series A preferred stock and 12,095 shares issuable upon exercise of warrants because conversion of any of those shares of series A preferred stock or exercise of any of those warrants would result in the holder beneficially owning in excess of 4.99% of the then issued and outstanding shares of common stock outstanding at that time.

(3) Includes 95,000 shares issuable upon exercise of options exercisable within 60 days and 2,007 shares issuable upon exercise of warrants. Does not include 50,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.

(4) Includes 70,000 shares issuable upon exercise of options exercisable within 60 days and 500 shares issuable upon exercise of warrants.

(5) Includes 5,000 shares issuable upon exercise of options exercisable within 60 days and 500 shares issuable upon exercise of warrants.

(6) Includes 12,000 shares issuable upon exercise of options currently exercisable. Does not include 24,000shares issuable upon exercise of options that are not exercisable within 60 days.

(7) Includes all securities covered in footnotes (1)-(6).

(8) Includes 850,000 shares issuable upon exercise of warrants. Does not include 108,333 shares issuable upon conversion of series A preferred stock and 130,000 shares issuable upon exercise of warrants because conversion of any of those shares of series A preferred stock or exercise of those warrants would result in the holder beneficially owning in excess of 4.99% of the then issued and outstanding shares of common stock outstanding at that time.

(9) Includes 38,197 shares issuable upon exercise of warrants. Does not include 44,450 shares issuable upon conversion of series A preferred stock and 53,334 shares issuable upon the exercise of warrants because conversion of any of those shares of series A preferred stock or exercise of any of those warrants would result in the holder beneficially owning in excess of 4.99% of the then issued and outstanding shares of common stock outstanding at that time.

(10)

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

(11) Includes 42,065 shares issuable upon exercise of warrants.

(12) 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

Series A 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.

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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. The series A preferred stock also provides for adjustment of the conversion price if the Company sells common stock at a price, or issues a security convertible into common stock with a conversion price, less than the then-current conversion price for the series A preferred stock.

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 this 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 our 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, other than our series B preferred stock, 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.

Series B Preferred Stock

Dividends. Holders of series B preferred stock are entitled to a 9% per annum dividend per share. The dividend accrues and is payable semi-annually in cash or in shares of series B preferred stock, at our option, except with respect to the holder of the shares purchased by Crestview Capital Master LLC (which represents $3 million of the $5 million or 60% of the series B preferred stock) who has the right to elect the form of the dividend as it relates to its series B preferred stock. Accrued but unpaid dividends are also payable upon the conversion or redemption of the shares of series B preferred stock and upon a liquidation event.

Voting Rights. As long as any shares of series B preferred stock are outstanding, we cannot take any of the following actions without the separate class vote or written consent of all of the then outstanding shares of series B preferred stock:

- amend, alter or repeal the provisions of the series B preferred stock so as to adversely affect any right, preference, privilege or voting power of the series B preferred stock;
- authorize or create any class of stock ranking as to dividends, redemption or distribution of assets upon a liquidation event, senior to or otherwise pari passu with the series B preferred stock;
- amend our articles of incorporation or by-laws so as to adversely affect any rights of the series B preferred stock;
- increase the authorized number of shares of series B preferred stock; or
- enter into any agreement with respect to the foregoing.

Conversion. The series B preferred stock is convertible, at the option of the holders, into shares of our common stock at an initial conversion price of $.61 per share. Based on the original purchase price of $50,000 per share, each share of series B preferred stock is initially convertible into 81,968 shares of our common stock. The series B preferred stock is issuable in fractional shares. The series B preferred stock contains adjustment provisions upon the occurrence of stock splits, stock dividends, combinations, reclassifications or similar events of our capital stock. The series B preferred stock also provides for adjustment of the conversion price if Company sells common stock at a price, or issues a security convertible into common stock with a conversion price, less than the then-current conversion price for the series B preferred stock.

Redemption. In the event of:

- a consolidation, merger, or other business combination involving Chembio Diagnostics, Inc.,
- the sale of all or substantially all of our assets,
- the acquisition by another person of in excess of 50% of our voting securities, or
- certain specified triggering events (involving (A) the lapse or unavailability of a registration statement, (B) the suspension from listing of our common stock for a period of seven consecutive days, (C) our failure or inability to comply with a conversion request from a holder of series B preferred stock, (D) our breach of any of our representations or warranties contained in the series B preferred stock documentation that continues uncured for a period of 30 days, or (E) our becoming subject to certain bankruptcy events),

each holder of series B preferred stock has the right to require us to redeem all of that holder's shares of series B preferred stock at a price per share of series B preferred stock equal to the sum of (i) the greater of (a) $65,000 or (b) the product of (x) the daily volume weighted average price of our common stock as reported on the OTC Bulletin Board on the date immediately preceding such event by Bloomberg Financial L.P. and (y) the quotient of $65,000

divided by the then current conversion price for the series B preferred stock, plus (ii) any accrued but unpaid dividends, plus (iii) all liquidated damages and other amounts due in respect of the series B preferred stock.

Rank; Liquidation Preference. The holders of series B preferred stock rank pari passu to the holders of our series A preferred stock and prior to the holders of our common stock and, unless otherwise consented to by the holders of series B preferred stock, prior to all other classes of capital stock that we may establish, with respect to (i) the payment of dividends and (ii) the distribution of our assets upon a bankruptcy, liquidation or other similar event. The liquidation preference for the series B preferred stock is an amount equal to $50,000 per share plus any accrued and unpaid dividends and liquidated damages owing thereon.

General

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

HIV Rapid Tests Commercially Available	Regulatory Status	Partners Involved in the Product
HIV Rapid Tests (Sure Check™ HIV; HIV 1/2 Stat-Pak; HIV 1/2 Stat-Pak Dipstick). Rapid Tests for detection of antibodies to HIV 1 and 2 in finger-stick whole blood, venous whole blood, serum and plasma	We currently qualify under U.S. FDA export regulations to sell, subject to any required approval by the importing country, to customers outside the U.S. To date we have received approval from a number of potential importing countries, although Brazil is the only country in which we have significant sales. In December 2004 we completed clinical trials for Sure Check™ HIV and HIV 1/2 Stat-Pak in the U.S. for FDA approval for sales in the U.S. with results that we believe will exceed the performance requirements for U.S. FDA approval. We are pursuing FDA approval for these products and on February 17, 2005 we submitted our Pre-Marketing Approval application to the FDA. Our HIV 1/2 Stat-Pak and HIV 1/2 Stat-Pak Dipstick products were also evaluated by the World Health Organization in 2004. In January 2005 we received a final report that confirms that these products meet the performance criteria for inclusion in the WHO Bulk Procurement Scheme, which is a pre-requisite for these products being eligible for procurements from programs funded by the United Nations and their partners' programs. We have also received confirmation from the United	Thirteen-year supply and technology transfer agreement with FIOCRUZ-Bio-Manguinhos, an affiliate of the Ministry of Health of Brazil. FIOCRUZ-Bio-Manguinhos will supply product to Brazilian public health market and potentially other markets in the region. Other marketing partners are being actively pursued with a principal focus on those countries that are receiving funding from the United States pursuant to the Presidential Emergency Plan for AIDS Relief and from the United Nations programs and partners.

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

A majority of our revenues historically were from the contract manufacture of private label pregnancy tests for regional pharmacies, drug stores and mass merchants in the United States, Europe, Canada, and Central America. However, as a result of pricing pressures, regulatory changes and potential patent litigation in this field, we sold substantially all of the business related to our private label pregnancy test. We believe that this will result in a substantial reduction of our revenues from these products during 2005 and beyond. The extent to which we will derive a benefit from sales of these products is difficult to estimate because of uncertainties in regulatory changes, product pricing, manufacturing cost changes, and patent litigation.

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

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

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

Our Sure Check™ HIV rapid test eliminates the need for a separate sample collection system when used to collect finger-stick whole blood samples. We believe this improves ease of use and safety. Our HIV 1/2 Stat-Pak and HIV 1/2 Stat-Pak Dipstick, like other competitive rapid HIV tests, require that the finger-stick whole blood sample first be transferred to the test device. However, HIV 1/2 Stat-Pak is value priced and more flexible than Sure Check™ for samples of venous whole blood, plasma and serum. HIV 1/2 Stat-Pak Dipstick is our most economical format and also flexible as to sample types. All three of our HIV tests use a standardized test strip which we developed by using patented materials licensed non-exclusively to us from third parties as well as our own proprietary know-how and trade secrets.

CHAGAS RAPID TEST: Chembio has completed development of a rapid test for the detection of antibodies to Chagas Disease. This product was developed in collaboration with a consortium of researchers in Latin America. Chagas Disease is found only in Latin America and is named after Carlos Chagas, a Brazilian doctor who first described the disease about 100 years ago. There are estimated to be 16-18 million Chagas Disease cases globally resulting in 21,000 deaths annually, with an estimated 300,000 new cases each year. It is transmitted by a parasitic bug which lives in cracks and crevices of poor-quality houses usually in rural areas, through blood transfusion or congenitally from infected mother to fetus. There is an effective therapy available to treat the early chronic phase.

Lateral Flow Technology

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

Our lateral flow technology allows the development of easy-to-perform, single-use diagnostic tests for rapid, visual detection of specific antigen-antibody complexes on a test strip. This format provides a test that is simple (requires neither electricity nor expensive equipment for test execution or reading, nor skilled personnel for test interpretation), rapid (turnaround time approximately 15 minutes), safe (minimizes handling of specimens potentially infected), non-invasive (requires 5-20 microliters of whole blood easily obtained with a finger prick, or alternatively, serum or plasma), stable (24 months at room temperature storage in the case of our HIV tests), and highly reproducible.

We can develop and produce lateral flow tests that are qualitative (reactive/non-reactive), as in the case of our HIV tests, and we can develop semi-quantitative tests, reflecting different concentrations of the target marker(s) using

different colored latex test lines for each concentration We can also develop tests for multiple conditions, using different colored lines. We have developed proprietary techniques that enable us to achieve high levels of sensitivity and specificity [see definition below] in our diagnostic tests using our proprietary latex conjugate and buffer systems. These techniques include the methods we employ in manufacturing and fusing the reagents with the colored latex, or colloidal gold, blocking procedures used to reduce false positives, and methods used in treating the materials used in our tests to obtain maximum stability and resulting longer shelf life. We also have extensive experience with a variety of lateral flow devices, including the sample collection device used in our Sure Check™ HIV rapid test which we believe is easier to use than other finger-stick whole blood rapid tests. Sure Check™ eliminates the need for transferring finger-stick whole blood samples from the 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™.***

The sensitivity of a test indicates how strong the sample must be before it can be detected by the test. The specificity of a test measures the ability of the test to analyze, isolate, and detect only the matters targeted by the test.

Target Market

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

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

Chagas Rapid Test. Chembio had developed this test several years ago but the market for the product was not meaningful as most prevention efforts were made using laboratory tests used for blood bank screening of blood. However, there has now been a greater interest in Chembio's rapid test because of an important publication that demonstrated the effectiveness of the rapid test in the screening of blood donors (as opposed to the blood in blood banks), and the need to screen in rural populations. Also, studies that have been completed at multiple sites in Central and South America showing sensitivity of between 98.5% and 99.6% and specificity between 94.8% and 99.9%, shows that the test is a good alternative to standard laboratory testing methods.

Other Products Under Development. Our products under development with partners in the areas of mad cow disease, dental bacteria, veterinary tuberculosis, and cerebral spinal fluid leak detection reflect our business strategy of leveraging our core competency, which is in the development and manufacture of lateral flow rapid diagnostic tests, and diversifying our markets beyond the HIV, human tuberculosis and Chagas Disease markets, which are primarily donor-funded markets. We do not necessarily have an expertise in assessing the markets in each of these new product undertakings, and so we often are relying on the market knowledge and position that our chosen partners have in these fields.

Distribution Channels

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

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

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

The market for the non-human primate tuberculosis test that we have developed, and for which we will begin clinical testing by the third 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 may increase as we get closer to FDA approval of our rapid HIV tests and/or as we complete the development of, and the requisite regulatory approvals related to, our other products, including those that we have under development.

To date, we believe we have been competitive in the industry in attracting and retaining qualified personnel. Because of the greater financial resources of many of our competitors, we may not be able to complete effectively for the same individuals to the extent that a competitor uses its substantial resources to attract any such individuals. With respect to the availability of patent protection, we do not have our own portfolio of patents or the financial resources to develop and/or acquire a portfolio of patents similar to those of our larger competitors. We have been able to obtain patent protection by entering into licensing arrangements.

Competitive factors specifically related to our HIV tests are product quality, price and ease of use. Product quality for an HIV rapid test primarily means accuracy (sensitivity and specificity), early detection of cases, time elapsed between testing and confirmation of results, and product shelf life. We believe that our HIV 1/2 Stat-Pak, HIV 1/2 Stat-Pak Dipstick, and Sure Check™ HIV rapid tests are very competitive with the best products in the market on the basis of these competitive factors.

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

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

Research and Development

Our research and development activities have been in four areas, all related to lateral flow rapid diagnostic product development: HIV, Bovine Spongeiform Encephalopathy, which is also known as mad cow disease, dental bacteria, and tuberculosis. We have also entered into research and development collaboration with The State University of New York at Stony Brook for the development of a marker for the detection of Cerebral Spinal Fluid Leak and also have begun other preliminary collaborations that are related to new lateral flow platforms and related instrumentation.

We have collaborated with Prionics AG, Zurich, Switzerland since late 2002 to develop and produce certain components of a rapid test for mad cow disease to be marketed by Prionics and/or their distributors under their name. In March 2004 we signed a contract to be one of two contract manufacturers of this product following Prionics' transfer of the completed product know-how to us and approval of the product in Europe. These steps are in process but have not been completed. The contract is for three years, which begins when the product approval is granted in Europe. Although we expected that the technology transfer and European regulatory approval would be completed in

2004, and that initial sales would occur in 2005, we cannot estimate the timing and extent of these events as there are many factors that are beyond our control that could delay this timetable, including delays or changes in regulatory requirements, delays in the technology transfer or changes to the product specifications. In this connection, on February 14, 2005, we entered into a license agreement by which Prionics will license certain technology owned by Chembio. The agreement provides for certain additional milestones for technology transfer which will need to be successfully concluded in order for the Supply Agreement to be maintained in full force and effect, as Prionics has indicated that it needs Chembio's technology in order to complete the know-how transfer in a way such that the product can be manufactured reproducibly.

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

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

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

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

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

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

The foregoing research and development efforts are summarized below:

Existing or Proposed Product	Regulatory Status	Development Status	Partners involved in the development or marketing of the products
Rapid test for detection of Bovine Spongeiform 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) Work has been suspended and discussing new development plan.	Ivoclar-Vivadent, AG, Schaan Liechtenstein
Tuberculosis Stat Pak II- rapid diagnostic test for detection of antibodies to active pulmonary tuberculosis in human whole blood samples	Not yet submitted for approval	Product validation completed	Public Health Research Institute and Statens Serum Institute
TBD Non-Human Primate Rapid Tuberculosis Test for the detection of antibodies to active pulmonary tuberculosis in non-human primate whole blood samples	Submitted for approval first quarter of 2005	Product validation completed	Sequella Corporation, Rockville, Maryland
Combination HIV/Tuberculosis Rapid Test for the detection of antibodies to active pulmonary tuberculosis and HIV in human whole blood samples using different color latex test lines	Not yet submitted for approval	Initial Prototype	None
New Generation HIV Test	Not yet submitted for approval	Initial Prototype	None
Cerebral Spinal Fluid Leak Test	Not yet submitted for approval	Initial R&D on Monoclonal Antibodies	State University of New York at Stony Brook

During 2004 and 2003, $1,433,403 and $313,891, respectively, was spent on research and development activities. A significant portion of these expenditures have been on our human and non-human primate tuberculosis product development efforts.

Research & Development Expenditures

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

Employees

At December 31, 2004, we employed 60 people, including 58 full-time employees. In May 2004, we entered into employment agreements with Lawrence Siebert, President and Chairman, Avi 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 county to which it is intended for export; (3) is labeled on the outside of the shipping package that it is intended for export; and (4) is not sold or offered for sale in the United States. Some medical devices face additional statutory requirements before they can be exported. If an unapproved device does not comply with an applicable performance standard or premarket approval requirement, is exempt from either such requirement because it is an investigational device, or is a banned device, the device may be deemed to be adulterated or misbranded unless the FDA has determined that exportation of the device is not contrary to the public health and safety and has the approval of the country to which it is intended for export. However, the Federal Food, Drug and Cosmetic Act does permit the export of devices to any country in the world, if the device complies with the laws of the importing country and has valid marketing authorization in one of several “listed” countries under the theory that these listed countries have sophisticated mechanisms for the review of medical devices for safety and effectiveness.

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

Chembio’s HIV rapid tests have been evaluated and approved for marketing in several foreign jurisdictions, including Mexico, India, and other nations in the developing world. Chembio has received an FDA Investigational Device Exemption to begin clinical trials for the Sure Check™ HIV and HIV 1/2 Stat Pak rapid tests and is currently beginning clinical trials as the initial step toward FDA approval of these products.

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

Environmental Laws

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

Intellectual Property

Intellectual Property Strategy

Subject to our available financial resources, our intellectual property strategy is: (1) to pursue licenses, trade secrets, and know-how within the area of lateral flow technology, and (2) to develop and acquire proprietary positions to reagents and new hardware platforms for the development and manufacture of rapid diagnostic tests.

Trade Secrets and Know-How

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

Lateral Flow Technology and Reagent Licenses

Although we own no patents covering lateral flow technology, we have obtained a non-exclusive license from Abbott Laboratories to a portfolio of its lateral flow patents. The issue of potential patent challenges is ongoing for us as well as for our competitors, and we continue to monitor the situation, consult with patent counsel, and seek licenses and/or redesigns of products that we believe to be in the best interests of Chembio Diagnostics, Inc. and our stockholders. Because of the costs and other negative consequences of time-consuming litigation regardless of whether we would ultimately prevail, if we foresee a significant possibility of patent infringement litigation, our first priority will be to attempt to obtain a license on reasonable terms. Nevertheless there is no assurance that Abbott's lateral flow patents may not be challenged or that licenses will be available on reasonable terms, if any.

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

The peptides used in our HIV rapid tests are patented by Adaltis Inc. and are licensed to us under a 10-year license agreement dated August 30, 2002. We also have licensed the antigens used in our tuberculosis and Chagas disease tests.

Legal Issues

FTC Matter

On February 27, 2001, a "Stipulated Final Order for Permanent Injunction and Other Equitable Relief" was signed and entered by the United States District Court for the Eastern District of New York. The stipulation is a settlement agreement between Chembio Diagnostics, Inc. and the United States Federal Trade Commission arising out of certain events that occurred in 1999. The events resulted in allegations by the FTC that Chembio Diagnostics, Inc. misrepresented performance claims relating to a previous generation of its HIV test kits. Chembio Diagnostics, Inc. denied these allegations. Nevertheless, due to the nature of the product and other circumstances, this matter consumed a very substantial amount of Chembio Diagnostics, Inc.'s resources from mid-1999 through the beginning of 2001. Because an even greater expense would have had to be incurred in litigating this matter against an agency with virtually unlimited resources and because Chembio Diagnostics, Inc. was able to negotiate a settlement that it deemed acceptable and in Chembio Diagnostics, Inc.'s best interest, the settlement was concluded. The stipulation requires Chembio Diagnostics, Inc., among other things, to not misrepresent product performance claims, to not make any claims without "competent and reliable scientific evidence" as substantiation for such claims and to also comply with mandated record keeping, notification, and monitoring provisions. The settlement agreement further provides that Chembio Diagnostic Systems Inc. must provide all of its principals, officers, directors, managers and all other employees of Chembio Diagnostic Systems Inc. having responsibilities related to Chembio Diagnostic Systems Inc.'s business with a copy of the settlement agreement and must have them acknowledge the receipt of the settlement agreement. The settlement specifically states that Chembio Diagnostic Systems Inc. does not admit that it made any statements or took any other action that was a violation of law. The record-keeping, notification and monitoring provisions of the stipulation have a term of five years from the date of the stipulation, or February 27, 2006.

Our Business Prior to the Merger

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

We were not successful with our online trading school and on August 18, 2001, we entered into an exchange agreement with Springland Beverages, Inc., an Ontario, Canada corporation. Pursuant to the agreement, we exchanged 15,542,500 shares of common stock for all the issued and outstanding shares of Springland Beverages, Inc., making Springland our wholly-owned subsidiary. Concurrent with the agreement, there was a change in control and we changed our business plan to focus on developing and marketing soft drinks. Springland Beverages, Inc. was not able to implement its business plan and failed to achieve profitable operations. On March 28, 2003, we sold the subsidiary back to its president, leaving us with no immediate potential revenue sources.

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

The Merger

On May 5, 2004, Chembio Diagnostic Systems Inc. completed the merger through which it became our wholly-owned subsidiary, and through which the management and business of Chembio Diagnostic Systems Inc. became our management and business. As part of this transaction, we changed our name to Chembio Diagnostics, Inc.

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 forwarding-looking words such as “may,” “will,” “expect,” “intend,” “anticipate,” “believe,” “estimate,” “continue” and other similar words. You should read statements that co 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.

MANAGEMENT’S DISCUSSION AND ANALYSIS AND PLAN OF OPERATION

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

In addition, certain statements made in this report may constitute “forward-looking statements”. These forward-looking statements involve known or unknown risks, uncertainties and other factors that may cause the actual results, performance, or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Specifically, 1) our ability to obtain necessary regulatory approvals for our products; and 2) our ability to increase revenues and operating income, is dependent upon our ability to develop and sell our products, general economic conditions, and other factors. You can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continues" or the negative of these terms or other comparable terminology. Although we believe that the expectations reflected-in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

OVERVIEW

The following management discussion and analysis relates to the business of Chembio Diagnostic Systems, Inc., our 100% wholly-owned subsidiary. Prior to our merger with Chembio Diagnostics Systems, Inc. in early May 2004, we had no assets or liabilities and no operations. As a result of the merger, we added the assets, liabilities and business and operations of Chembio Diagnostics Systems, Inc. We sold substantially all of the business related to our private label pregnancy test and we are focusing on developing products and then obtaining applicable clearances or approvals in the areas of rapid tests for HIV, tuberculosis, mad cow disease and dental disease. We either have or are pursuing collaborative agreements that may include distribution arrangements in each of these areas. We believe that our research and development, manufacturing overhead, selling, marketing and general and administrative costs will increase as we create the necessary infrastructure to focus in these new areas.

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

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

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

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

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

Components of other income and expense include the following; interest expenses decreased by $17,974 for the year ended December 31, 2004 compared with the year ended December 31, 2003. This was primarily attributable to the conversion of $1,332,292 of existing debt of Chembio Diagnostic Systems, Inc, at the time of the merger which

reduced interest expense by $78,624. This was offset by a non-cash expense related to the issuance of 140,000 warrants to existing debt holders of Chembio Diagnostic Systems, Inc. which increased interest expense by $60,650. Additional components of other income and expense include the retirement and transfer of assets in the fourth quarter of 2004 which resulted in a loss of $22,469. In addition, approximately $209,000 is attributable to settlements of old outstanding payables due that were settled during the second quarter of 2004 are reflected in other income as forgiveness of debt.

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2005 AS COMPARED WITH THE THREE MONTHS ENDED MARCH 31, 2004

Revenues are comprised of $346,125 in net sales, $250,000 in license revenue and $135,760 in grants and development income for the three months ended March 31, 2005 as compared with $493,970 in net sales, no license revenue and $91,342 in grant and development income for the three months ended March 31, 2004. The decrease in sales is attributable to decreased sales of our HIV product of $86,022, decreased sales of our pregnancy test kit of $67,696 and increased other product sales of $5,873. The increase in license revenue was $250,000 and is due to a technology transfer agreement. The Company does not expect that this revenue will continue in the future. The increase in grant and development income was $44,418 and was due to increased activity in our non-human primate project. A substantial portion of the grant-related income is expected to recur until the third quarter of 2005.

Cost of goods sold for the three months ended March 31, 2005 was $464,550, or 134.2% of net sales, as compared to $465,402, or 94.2% of net sales, for the three months ended March 31, 2004. The decrease in gross margin is primarily attributable to underutilization of manufacturing capacity as sales volume for the quarter decreased. We also had increased costs due to the creation of separate quality assurance and quality control departments and the hiring of a new manager to head up the quality assurance department. Decreased sales of our HIV products, which were at a higher margin than our other product lines, contributed to the decreased gross margin. We anticipate that we will receive significant orders from our customer in Brazil to be delivered over the next three quarters. These additional sales of our HIV product should generate increased gross margins for the balance of 2005.

Research and development expenses for the three months ended March 31, 2005 were $334,750compared with $138,329for the three months ended March 31, 2004. Expenses for Clinical & Regulatory Affairs, totaled $138,767 for the three months ended March 31, 2005, an increase of $125,701 over the three months ended March 31, 2004, and accounted for most of this increase. This category includes costs incurred for regulatory approvals, clinical studies, product evaluations and registrations. These costs are expected to continue in the 2nd quarter of 2005 when the HIV rapid test applications and review will be completed. We expect this category to be reduced in the third quarter of 2005. Increased salaries and wages and related costs of the R&D group and recruitment charges to hire additional staff has contributed to the increase in R&D costs and the balance is due to hiring of a vice-president of regulatory affairs.

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

Project	**Rapid Test for Mad Cow Disease**
Current status	We are waiting for technology transfer from Prionics AG in order to begin production scale-up, validation and regulatory submission. In February 2005 we entered into a license agreement with Prionics AG related to our licensing certain technology that Prionics desired in order for Prionics to complete the technology transfer to Chembio. The agreement provides for additional contingent payments based upon our attainment of certain milestones relating to product performance specified in the agreement. If the milestones are not achieved, there may be a significant reduction or complete elimination of any additional payments under this license agreement. Moreover, the manufacturing agreement we signed with Prionics AG in 2004 would be of no further force or effect.
Nature, timing and estimated costs of the efforts necessary to complete	We should know by the end of the second quarter of this year whether our technology can overcome changes to the product

	formulation that Prionics AG implemented last year. Initial results were unfavorable, though we have continued to work on this project and have an additional opportunity to meet the specifications under the agreement. Testing to determine whether these modifications can meet the agreed-upon specifications will commence in late May. Assuming a favorable outcome of these tests (Milestone 2), one additional milestone (training) would be required before the maximum payments under the agreement will be due and payable and before the Manufacturing & Supply Agreement would remain in effect. Assuming that to be the case, 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 and product specifications developed by Prionics, including certain changes they have made to their formulation since the product underwent a successful evaluation. As stated above, there is therefore a risk that the technology transfer from Chembio will not be completed and that the Manufacturing agreement will be of no further force and effect. The risks associated with the product involve regulatory and technology risks. We had anticipated that we would start to see revenues form this program in 2005. This is now in substantial doubt. The Manufacturing Contract provides for a minimum purchase of one million units during the first year following approval in the EU. We understand that the product has in fact been approved in the EU based upon the above-referenced evaluation but because of the problems described herein, Prionics has been unable to complete the production specifications for this product.
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

Project	Dental Bacteria Test
Current status	We expected to complete Phase 2 of the Project Plan (Optimization of Test) and move into Phase 3 (Scale Up of Production and validation) in 2005. However, one of the monoclonal antibodies has sensitivity and specificity problem with lateral flow test system. We are therefore discussing strategies in order to overcome this technical problem. We are also considering another detection system, which could be applied instead of the lateral flow system. Such a system could be based on antibodies labeled with fluorescence markers. However, a correspondent reader would have to be used for an analysis of the risk of caries (dental decay).
Nature, timing and estimated costs of the efforts necessary to complete	In April 2004, Chembio received 80% of the Phase 2 project funding of $65,000, or $52,000 and this reflected the estimate of the costs anticipated to be incurred to complete Phase 2 during a three to five month period. It is now assumed that Phase 2 will not be satisfactorily completed and that any additional funding from Ivoclar-Vivadent will be pursuant to a new development contract, which is under discussion. Chembio has completed the level of effort needed to earn the 80% funded.
Anticipated completion date	It is not known at this time whether or how long it will take to develop the product or obtain regulatory approvals in the US, Europe, Japan and other potential markets.
Risks and uncertainties associated with completing development on schedule, and the consequences to operations, financial position and liquidity if not completed timely	Technical challenges remain that must be overcome in order for this product to meet the performance specifications that Ivoclar-Vivadent had set forth in the Agreement. If we do not achieve the performance specifications, the product will not be completed.
Timing of commencement of expected material net cash inflows	It is not known or estimable when net cash inflows from this project will commence due to the uncertainties associated with the completion of the product, regulatory submissions, and the nature and timing of Ivoclar-Vivadent's distribution network and strategy.

Project	Rapid Test for the detection of antibodies to active pulmonary tuberculosis in non-human primate whole blood samples
Current status	Product validation completed.
Nature, timing and estimated costs of the efforts necessary to complete	We submitted the initial documentation required to commence our application to the United States Department

	of Agriculture (USDA) for the approval of the product and of our facility where it will be manufactured.
Anticipated completion date	We anticipate that we could have USDA approval by the end of 2005.
Risks and uncertainties associated with completing development on schedule, and the consequences to operations, financial position and liquidity if not completed timely	The requirements for clinical testing and the outcomes of such clinical testing can not be known at this time, and this information poses substantial risk and uncertainty as to whether or when this product will contribute to the operations, financial position and liquidity.
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 2005 from any of these products.

Selling, general and administrative expense increased $200,338 to $556,061 in the three months ended March 31, 2005 compared with the same period in 2004. This increase was attributable to $15,000 of recruiting expenses incurred in the hiring of sales and marketing personnel, $34,550 for marketing consultants (including $17,986 non-cash amortization of options issued to consultants), costs relating to investor relations of $50,000 (including $15,000 non-cash Common Stock issued to consultant), insurance coverage for Directors & Officers of $10,812 and increased legal and accounting expenses of $103,780 relating to patent applications, patent litigation, the filling of a registration statement and other required year-end filings.

LIQUIDITY AND CAPITAL RESOURCES

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

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

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

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

We had a working capital surplus of $3,488,559 at March 31, 2005 and a working capital deficiency of $452,136 at December 31, 2004. On January 28, 2005, we completed a private placement offering which raised $5,047,500 before costs in the form of 9% Convertible Series B Preferred Stock and associated warrants (“Series B Offering”). The proceeds from the Series B Offering will be used primarily for general corporate purposes including for sales and marketing, research and development, and intellectual property, and also for working capital, investor relations, and capital expenditures.

Subsequent to March 31, 2005 we currently have paid for or committed to purchasing fixed assets aggregating $26,600. This equipment will allow us to save labor cost and improve efficiencies. In addition, we are considering additional fixed asset purchases for the future, but we have no firm commitments at this time.

We anticipate that the funds from the Series B Offering will be enough to fund our needs at least through the third quarter of 2005. We anticipate this based upon our recently completed operating budget which assumes significant new expenditures this year that are intended to help us increase revenues and cash flow, and to achieve a variety of other corporate objectives that are aimed to increase shareholder value. The Company is considering alternatives to

provide for its capital requirements for late 2005 and beyond. There are no assurances that it will be successful in raising sufficient capital.

Our liquidity will ultimately depend on several factors. These factors primarily include (1) whether we can generally achieve revenue growth; (2) the extent to which, if any, that revenue growth improves operating cash flows; (3) our investments in research and development, facilities, marketing, regulatory approvals, and other investments we may determine to make, and (4) the investment in capital equipment and the extent to which it improves cash flow through operating efficiencies.

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

The following table lists the future payments required on our debt and any other contractual obligations as of March 31, 2005:

OBLIGATIONS	Total	Less than 1 Year	1-3 Years	4-5 Years	Greater than 5 Years
Long Term Debt(1)	$ 303,160	$ 120,000	$ 183,160	$ -	$ -
Capital Leases (2)	$ 111,443	$ 46,868	$ 64,575	-	-
Operating Leases	$ 198,450	$ 98,000	$ 100,450	-	-
Other Long Term Obligations(3)	$ 863,250	$ 478,167	$ 247,583	$ 25,000	$ 112,500
Total Obligations	$ 1,476,303	$ 743,035	$ 595,768	$ 25,000	$ 112,500

(1) This represents accrued interest which is currently being paid out at the rate of $10,000 per month.

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

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

CHEMBIO'S PLAN OF OPERATIONS FOR THE NEXT TWELVE MONTHS

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

- Completion of clinical trials for our HIV rapid tests in the United States and submission of this data with our Pre-Marketing Approval application to the United States Food and Drug Administration.

- Grant of "waiver" status by the United States Agency for International Development for our rapid HIV tests for procurements being made under the Presidential Emergency Plan for AIDS Relief which enables our products to be procured pending FDA approval.

- Qualification under the World Health Organization Bulk Procurement Scheme for our HIV rapid tests. This provides United Nations funded programs and their beneficiary countries with the ability to purchase our products.

- Submission of our initial application documentation for our Non-Human primate TB test to the USDA.

- Completion of the License and Technology Transfer Agreement with Prionics AG.

- Completion of the Series B Five Million Dollar Private Placement of Convertible Preferred Stock.

- Appointment of three independent members to our Board of Directors who will stand for election to our board at our annual meeting.

Our efforts are focused on one or more of our three rapid HIV tests becoming part of the testing protocols used by various governmental and non-governmental organizations in the implementation of voluntary counseling and testing (VCT), pre-natal testing for mother to child transmission, and other programs that are taking root globally. A significant portion of the capital currently available to us will be used to provide the marketing and business development resources needed to achieve wider distribution of our products for these programs.

We also are working on our non-human primate Tuberculosis test which we expect will begin to produce revenues in 2006, and we are investing additional resources to improve our human Tuberculosis test.

Our license to Prionics AG of certain of our technology has not resulted in their being able to complete for us the specifications for the manufacture of their rapid test for Mad Cow Disease, and this development will likely result in their being unable to complete this product which we were to manufacture for them.

As stated above, we believe that our current cash balances, and cash generated from future operations, will be sufficient to fund operations at least through the end of the third quarter of 2005. Therefore, we do expect that we will be required to sell additional equity or obtain additional credit facilities during the fourth quarter of 2005. Our financing requirements will depend on our progress in growing our product revenues and on our expense levels, and are expectations for those same factors in 2006 as well.

We believe that our plan of operation will build long-term value if we are able to demonstrate clear progress toward our objectives, particularly penetrating international markets with our HIV rapid tests. We also expect to obtain FDA approval of our Sure check™ and HIV Stat Pak products by the end of 2005 and we believe that this will represent significant value. We believe that our international sales efforts for our HIV tests will succeed based upon the market need, the performance of our products, their competitive pricing, the distribution and marketing channels we are pursuing, and the quality of our professional staff.

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

Critical Accounting Policies and Estimates

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

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

Revenue Recognition -

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

Research & Development Costs -

Research and development activities consist primarily of new product development, continuing engineering for existing products, regulatory and clinical trial costs. Costs related to research and development efforts on existing or potential products are expensed as incurred. Research and development costs for 2004 increased 357% over 2003. This increased costs by over $1,000,000, a majority of this increase was due to clinical trails which are not expected to recur at the levels incurred in 2004.

Valuation of Inventories -

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

Allowance for doubtful accounts -

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

Income Taxes -

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

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

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

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

DESCRIPTION OF PROPERTY

Our administrative offices and research facilities are located in Medford, New York. We lease approximately 14,000 square feet of industrial space for $7,224 per month. The space is utilized for R&D (approximately 1,500 square feet), offices (approximately 2,700 square feet) and production (approximately 9,800 square feet). The lease term expires on April 30, 2005. We are completing a new lease for two years with an option for two more years. The rent in this new lease is expected to be $8,167 per month. We believe the space is adequate for our immediate needs. Additional space may be required as we expand our research and development activities. We do not foresee any significant difficulties in obtaining any required additional facilities.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

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

Lawrence A. Siebert, the president and chairman of the board of directors of Chembio Diagnostics, Inc. beginning at the time of and after the merger, and the president and chairman of Chembio Diagnostic Systems Inc. since May 2002, held two promissory notes issued by Chembio Diagnostic Systems Inc. One note was issued on August 1, 1999 in the original principal amount of $338,125, bearing interest at a rate of 11% per annum. The other was issued on April 25, 2001 in the original principal amount of $795,937, bearing interest at a rate of 12% per annum. Mr. Siebert converted the entire outstanding principal amount of the 11% note and $561,875 principal amount of the 12% note into 30 shares of Chembio Diagnostics, Inc.'s series A preferred stock, together with warrants to acquire 1,800,000 shares of common stock at $.90 per share, pursuant to Chembio Diagnostics, Inc.'s private placement of its series A preferred stock on May 5, 2004. The shares of series A preferred stock held by Mr. Siebert are convertible into 1,547,100 shares of Chembio Diagnostics, Inc.'s common stock. The remaining debt of $234,062 held by Mr. Siebert was exchanged on December 29, 2004 into 7.80208 shares of Chembio Diagnostics, Inc.'s series A preferred stock, together with warrants to acquire 468,125 shares of common stock at $.90 per share, pursuant to the terms of Chembio Diagnostics, Inc.'s private placement of its series A preferred stock on May 5, 2004. Approximately $236,852 of accrued interest on the debt is also due to Mr. Siebert, but is not accruing interest. The accrued interest will be paid out according to the terms of Chembio Diagnostics, Inc.'s private placement of its series B preferred stock on January 28, 2005. Mr. Siebert also invested $50,000 in our series B preferred stock private placement pursuant to which he received 1 share of series B preferred stock convertible into 81,967 shares of common stock and a warrant to purchase 77,868 shares of common stock.

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

Mr. Siebert prior to March 22, 2004 had either advanced funds to Chembio Diagnostic Systems, Inc. or paid vendors directly on Chembio Diagnostic Systems, Inc.'s behalf. The total amount so paid or advanced and not repaid totaled $183,720 as of December 31, 2004.

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

Avi Pelossof, the vice president of sales and marketing of Chembio Diagnostics, Inc., invested $4,000 in Chembio Diagnostics, Inc. pursuant to the March 22, 2004 private placement of convertible notes. Mr. Pelossof converted the entire principal amount of the note that he received, together with accrued interest thereon, into .202 shares of Chembio Diagnostics, Inc.'s series A preferred stock, together with warrants to acquire 22,555 shares of common stock at $.90 per share, pursuant to Chembio Diagnostics, Inc.'s private placement of its series A preferred stock on May 5, 2004. In November of 2004 as payment of dividends on the series A preferred he received 403 shares of common stock.

MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Market Information

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

Fiscal Year 2005	High Bid	Low Bid
First Quarter	$0.90	$0.50

Fiscal Year 2004	High Bid	Low Bid
First Quarter	$3.00	$0.34
Second Quarter	$2.00	$1.00
Third Quarter	$1.54	$1.01
Fourth Quarter	$1.29	$0.55

Fiscal Year 2003	High Bid	Low Bid
First Quarter	$0.34	$0.17
Second Quarter	$0.51	$0.17
Third Quarter	$0.34	$0.17
Fourth Quarter	$1.36	$0.17

Trades of our common stock are subject to Rule 15g-9 of the Securities and Exchange Commission, known as the Penny Stock Rule. This rule imposes requirements on broker/dealers who sell securities subject to the rule to persons other than established customers and accredited investors. For transactions covered by the rule, brokers/dealers must make a special suitability determination for purchasers of the securities and receive the purchaser's written agreement to the transaction prior to sale. The Securities and Exchange Commission also has rules that regulate broker/dealer practices in connection with transactions in "penny stocks." Penny stocks generally are equity securities with a price of less than $5.00 (other than securities registered on certain national securities exchanges or quoted on the NASDAQ system, provided that current price and volume information with respect to transactions in that security is provided by the exchange or system). 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 2, 2005, there were approximately 108 record owners of our common stock.

Dividends

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

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

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

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

EXECUTIVE COMPENSATION

The following table summarizes the annual compensation paid to Chembio Diagnostics, Inc.'s named executive officers for the three years ended December 31, 2004, 2003 and 2002:

		Annual Comp	Long-Term Compensation Awards—Securities Underlying
Name and Position	**Year**	**Salary**	**Stock Options**
Lawrence A. Siebert, President, CEO, Chairman of Board of Chembio Diagnostic Systems Inc. (1)	2004	$ 182,789	160,000
	2003	103,846	—
	2002	63,000	—
Avi Pelossof, Vice President of Chembio Diagnostic Systems, Inc. (2)	2004	154,635	250,000
	2003	83,077	—
	2002	80,500	—
Javan Esfandiari, Vice President of Chembio Diagnostic Systems, Inc. (3)	2004	129,323	110,000
	2003	88,269	—
	2002	83,224	—
Rick Bruce, Vice President of Chembio Diagnostic Systems Inc. (4)	2004	114,286	35,000
	2003	110,326	—
	2002	106,240	—
Konstantin Lyashchenko, Research Director of Chembio Diagnostic Systems, Inc.(5)	2004	106,365	2,500
	2003	77,885	—
	2002	75,500	—
Mark L. Baum, President, Secretary and Director of Chembio Diagnostics, Inc. (6)	2004	40,000	—
	2003	—	—
	2002	—	—

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

May 2004, Mr. Siebert received 50,000 options with an exercise price of $1.20 per share, becoming exercisable in May 2005 and 50,000 options with an exercise price of $1.50 per share becoming exercisable in May of 2006.

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

(3) Mr. Esfandiari currently is a Vice President of Chembio Diagnostics, Inc. and Chembio Diagnostic Systems, Inc. The compensation information represents compensation earned while employed by Chembio Diagnostic Systems Inc. In 2004, Mr. Esfandiari received, prior to the merger, 30,000 options exercisable at $0.75 and 5,000 options exercisable at $1.00. In addition as part of his contract signed in May 2004, Mr. Esfandiari received 25,000 options exercisable at $0.90 per share, becoming exercisable in May 2005, 25,000 options with an exercise price of $1.20 per share, becoming exercisable in May 2006 and 25,000 options with an exercise price of $1.50 per share becoming exercisable in May of 2007.

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

(5) Mr. Bruce currently is a vice president of Chembio Diagnostic Systems Inc. The compensation information represents compensation earned while employed by Chembio Diagnostic Systems Inc. Mr. Bruce received, prior to the merger, 20,000 options exercisable at $0.588, 10,000 options exercisable at $0.75 and 5,000 options exercisable at $1.00.

(6) The compensation information represents compensation earned while employed by Chembio Diagnostics, Inc.

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

	Individual Grants			
Name	**Number of Securities Underlying Options/SARsGranted(#)**	**Percentage of Total Options/SARs Granted to Employees in Fiscal Year**	**Exercise or Base Price($/Sh)**	**Expiration Date**
Lawrence A. Siebert	50,000	6.75%	1.20	5/27/11
Lawrence A. Siebert	50,000	6.75%	1.50	5/27/11
Lawrence A. Siebert	50,000	6.75%	0.75	5/04/11
Lawrence A. Siebert	10,000	1.35%	1.00	5/04/11
Avi Pelossof	100,000	13.51%	0.60	5/27/11
Avi Pelossof	50,000	6.75%	0.90	5/27/11
Avi Pelossof	50,000	6.75%	1.35	5/27/11
Avi Pelossof	40,000	5.40%	0.75	5/04/11
Avi Pelossof	10,000	1.35%	1.00	5/04/11
Javan Esfandiari	25,000	3.38%	0.90	5/27/11
Javan Esfandiari	25,000	3.38%	1.20	5/27/11
Javan Esfandiari	25,000	3.38%	1.50	5/27/11
Javan Esfandiari	30,000	4.05%	0.75	5/04/11
Javan Esfandiari	5,000	0.68%	1.00	5/04/11
Richard Bruce	20,000	2.70%	0.588	5/04/11
Richard Bruce	10,000	1.35%	0.75	5/04/11
Richard Bruce	5,000	0.68%	1.00	5/04/11
Konstantin Lyashchenko	2,500	0.34%	1.00	5/04/11

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

Employment Agreements

Mr. Siebert. On May 5, 2004, Mr. Siebert and the Company entered into an employment agreement, effective May 10, 2004, which terminates on May 10, 2006. Pursuant to the employment agreement Mr. Siebert serves as the President and Chief Executive Officer of the Company and is entitled to receive a base compensation of $150,000 per year, subject to periodic review by the Board of Directors of the Company. Mr. Siebert is eligible to participate in any profit sharing, stock option, retirement plan, medical and/or hospitalization plan, and/or other benefit plans except for disability and life insurance that the Company may from time to time place in effect for the Company's executives during the term of Mr. Siebert's employment agreement. If Mr. Siebert's employment agreement is terminated by the Company without cause, or if Mr. Siebert terminates his employment agreement for a reasonable basis, including within 12 months of a change in control, the Company is required to pay as severance Mr. Siebert's salary for six months. Mr. Siebert has agreed for a period of two years after the termination of his employment with the Company not to induce customers, agents, or other sources of distribution of the Company's business under contract or doing business with the Company to terminate, reduce, alter, or divert business with or from the Company.

Mr. Pelossof. On May 5, 2004, Mr. Pelossof and the Company entered into an employment agreement, effective May 10, 2004, which terminates on May 10, 2007. Pursuant to the employment agreement Mr. Pelossof serves as the Vice President of Sales, Marketing, and Business Development of the Company and is entitled to receive a base compensation of $120,000 per year, with annual salary increases of not less than five percent, and subject to periodic review by the Board of Directors of the Company. Mr. Pelossof is eligible to participate in any profit sharing, stock option, retirement plan, medical and/or hospitalization plan, and/or other benefit plans except for disability and life insurance that the Company may from time to time place in effect for the Company's executives during the term of Mr. Pelossof's employment agreement. If Mr. Pelossof's employment agreement is terminated by the Company without cause, or if Mr. Pelossof terminates his employment agreement for a reasonable basis, including within 12 months of a change in control, the Company is required to pay as severance Mr. Pelossof's salary for six months. Mr. Pelossof has agreed for a period of two years after the termination of his employment with the Company not to induce customers, agents, or other sources of distribution of the Company's business under contract or doing business with the Company to terminate, reduce, alter, or divert business with or from the Company.

Mr. Esfandiari. On May 5, 2004, Mr. Esfandiari and the Company entered into an employment agreement, effective May 10, 2004, which terminates on May 10, 2007. Pursuant to the employment agreement Mr. Esfandiari serves as the Director of Research & Development for the Company and is entitled to receive a base compensation of $115,000 per year, subject to periodic review by the Board of Directors of the Company. Mr. Esfandiari is eligible to participate in any profit sharing, stock option, retirement plan, medical and/or hospitalization plan, and/or other benefit plans except for disability and life insurance that the Company may from time to time place in effect for the Company's executives during the term of Mr. Esfandiari's employment agreement. If Mr. Esfandiari's employment agreement is terminated by the Company without cause, or if Mr. Esfandiari terminates his employment agreement for a reasonable basis, including within 12 months of a change in control, the Company is required to pay as severance Mr. Esfandiari's salary for six months. Mr. Esfandiari has agreed for a period of two years after the termination of his employment with the Company not to induce customers, agents, or other sources of distribution of the Company's business under contract or doing business with the Company to terminate, reduce, alter, or divert business with or from the Company.

Director Compensation

Please see "Certain Relationships and Related Transactions" for a discussion of Mr. Baum's employment agreement and warrants. All independent directors are paid an annual retainer of $18,000, paid semi-annually, and 36,000 stock options, with an exercise price equal to the market price on the date of the grant. One-third of each independent director's stock options are exercisable on the date of grant, one-third become exercisable on the first anniversary of the date of grant, and one-third become exercisable on the second anniversary of the date of grant. In addition, the

independent directors are paid $1,000 in cash for each meeting of the Board of Directors attended, and paid $500 in cash for each telephonic Board of Directors meeting. Additionally, the independent directors who are members of a committee of the Board of Directors are paid $500 in cash for each committee meeting attended, or $750 in cash for each committee meeting attended if that independent director is the committee chairman. Upon formation of the Audit Committee of the Board of Directors, it is the Company's intention to pay the chairman of the Audit Committee an annual retainer of $2,500, paid semi-annually.

FINANCIAL STATEMENTS

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

EXPERTS

Lazar, Levine & Felix LLP, a registered independent public accounting firm, have audited our consolidated balance sheet of Chembio Diagnostics, Inc. and subsidiary as of December 31, 2004 and the consolidated statements of operations, stockholders' equity, and cash flows for the two years in the period ended December 31, 2004 as set forth in this 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.

LEGAL MATTERS

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 72,681 shares of common stock, 1.44731 shares of series A preferred stock (which are convertible into 72,365 shares of common stock) and a warrant to purchase 96,042 shares of our common stock. Patton Boggs LLP owns 37,319 shares of common stock.

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.

CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

On June 1, 2004, our Board of Directors voted to replace Madsen & Associates, CPA's, 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
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REPORT OF REGISTERED INDEPENDENT PUBLIC ACCOUNTANTING FIRM

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

We have audited the consolidated balance sheet of Chembio Diagnostics Inc. and Subsidiary (the "Company") as of December 31, 2004 and the consolidated statements of operations, stockholders' equity and cash flows for the two years in the period ended December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Chembio Diagnostic Systems Inc. and Subsidiary as of December 31, 2004, and the consolidated results of its operations and its cash flows for the two years in the period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States of America.

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

New York, New York
February 24, 2005

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

—ASSETS—

CURRENT ASSETS:		
Cash	**$**	**34,837**
Restricted cash		**250,000**
Accounts receivable, net of allowance for doubtful accounts of $16,367		**165,056**
Inventories		**538,647**
Prepaid expenses		**222,520**
TOTAL CURRENT ASSETS		**1,211,060**
FIXED ASSETS, net of accumulated depreciation of $460,720		**188,399**
OTHER ASSETS:		
Deposits		**26,990**
	$	**1,426,449**

- LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT) -

CURRENT LIABILITIES:		
Working capital loan	**$**	**45,000**
Accounts payable and accrued liabilities		**1,102,428**
Current portion of obligations under capital leases		**51,029**
Accrued contingency		**60,264**
Current accrued interest payable		**120,000**
Payable to related parties		**284,475**
TOTAL CURRENT LIABILITIES		**1,663,196**
OTHER LIABILITIES:		
Obligations under capital leases - net of current portion		**74,267**
Accrued interest, net of current portion		**212,950**
TOTAL LIABILITIES		**1,950,413**
COMMITMENTS AND CONTINGENCIES		
PREFERRED STOCK -Series A 8% Convertible - $.01 par value; 10,000,000 shares authorized: 162.37241 shares issued and outstanding. (Liquidation preference-please see note 11)		**2,427,030**
STOCKHOLDERS' EQUITY (DEFICIT):		
Common stock - $.01 par value; 50,000,000 shares authorized: 6,907,143 shares issued and outstanding.		**69,071**
Additional paid-in capital		**9,079,341**
Accumulated deficit		**(12,099,406)**

	(2,950,994)
$	**1,426,449**

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

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

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

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

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

	Preferred stock		Common stock		Additional paid in capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
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-December 31, 2003	—	—	—	—	—	(1,059,704)	(1,059,704)
Balance at December 31, 2003	**—**	**—**	**4,902,608**	**49,026**	**4,550,975**	**(7,057,442)**	**(2,457,441)**
Preferred stock issued							
For cash	**73.33330**	**352,000**	—	—	**1,758,460**	—	**1,758,460**
Conversion of long-term debt	**90.29853**	**665,080**	—	—	**1,707,878**	—	**1,707,878**
Accretion of preferred dividend	—	**58,114**	—	—	—	—	—
Accretion of beneficial conversion	—	**1,373,750**	—	—	—	—	—
Common stock issued							
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 services	—	—	**118,569**	**1,185**	**59,831**	—	**61,016**
Common converted from preferred	**(1.25942)**	**(21,914)**	**62,971**	**630**	**21,284**	—	**21,914**

Payment of preferred dividend			**303,145**	**3,031**	**178,856**	—	**181,887**
Warrants and options issued to							
Employees	—	—	—	—	**969**	—	**969**
Marketing consultants	—	—	—	—	**90,620**	—	**90,620**
Existing Debt Holders (pre-merger)	—	—	—	—	**60,650**	—	**60,650**
Warrants exercised	—	—	**66,869**	**669**	**29,422**	—	**30,091**
Net loss attributable to common stockholders	—	—	—	—	—	**(5,041,964)**	**(5,041,964)**
Balance at December 31, 2004	**162.37241**	**$ 2,427,030**	**6,907,143**	**$ 69,071**	**$ 9,079,341**	**$ (12,099,406)**	**$ (2,950,994)**

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

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

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

Cash paid during the period for interest	**$**	**1,985**	$	—
Cash paid during the period for corporate taxes		**1,693**		1,040
Supplemental disclosures for non-cash investing and financing activities:				
Fixed assets acquired under capital leases	**$**	**11,032**	$	107,020
Stock issued as payment for financing fees		**39,400**		—
Options issued as payment for consulting services		**42,237**		—
Warrants issued as payment for financing fees		**337,973**		—
Warrants issued for Chembio Diagnostics Systems, Inc. shareholder consent		**144,643**		—
Bridge debt and converted interest into Common Stock		**330,698**		—
Bridge debt and converted interest into Series A Preferred Stock		**679,107**		—
Long Term debt converted to Preferred Series A Preferred Stock		**1,693,851**		—
Preferred dividend paid in common stock		**181,887**		—
Accredited dividend to preferred stock		**1,373,750**		—

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

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

NOTE 1 — DESCRIPTION OF BUSINESS/OPERATIONS:

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

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

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

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

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

MERGER AND OTHER RELATED TRANSACTIONS:

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

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:

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED STATEMENTS
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a) The Cash Offering. A total of 73.33330 shares of series A preferred stock and warrants to acquire 4,400,000 shares of common stock at $.90 per share were issued pursuant to the Cash Offering in May 2005 for total consideration of $2,200,000.

b) The Bridge Conversion Offering. On March 22, 2004, Chembio Diagnostic Systems completed a private placement (the "Bridge Financing") of $1,000,000 in face amount of Convertible Notes (the "Bridge Notes"). The Bridge Financing provided for the Bridge Note holders to elect upon merger whether to convert the Bridge Notes into shares of the Company's series A preferred stock (together with warrants to acquire shares of the Company's common stock) or into shares of the Company's common stock at the effective time of the Merger. As a result, $672,000 in principal amount of the Bridge Notes, together with accrued and unpaid interest, was converted into 33.83682 shares of the Company's series A preferred stock (together with warrants to acquire an additional 2,030,217 shares of the Company's common stock at $.90 per share). The balance of the Bridge Financing, or $328,000, was converted into 826,741 shares of the Company's common stock.

c) The Existing Debt Exchange Offering. Per the merger agreement a minimum of $1,300,000 of existing debt of Chembio Diagnostic Systems, Inc. was required to be converted to series A preferred stock. Any balances not converted were to be, if not paid by December 31, 2004, automatically converted to series A preferred stock as of December 31, 2004. Pursuant to this offering, which was consummated at the effective time of the Merger, the Company issued 44.40972 shares of series A preferred stock and warrants to acquire 2,664,584 shares of common stock at $.90 per share in exchange for the conversion of $1,332,292 of Chembio Diagnostic Systems' debt existing on its balance sheet as of the date of merger.

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

RECENT DEVELOPMENTS:

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

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

Our cash requirements depend on numerous factors, including product development activities, penetration of the direct sales market, market acceptance of new products, and effective management of inventory levels in response to sales forecasts. We expect to devote capital resources to improve our sales and marketing efforts, continue our product

development, expand manufacturing capacity and continue research and development activities. We will examine other growth opportunities, including strategic alliances, and we expect any such activities will be funded from existing cash and cash equivalents, as well as utilization of the funds provided from the Series B offering. We believe that our current cash balances, and cash generated from future operations, will be sufficient to fund operations through the end of 2006.

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

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES:

(a) Principles of Consolidation:

The consolidated financial statements include the accounts of the Company, Chembio Diagnostics, Inc. and its wholly owned subsidiary, Chembio Diagnostic Systems, Inc. All material intercompany transactions and balances have been eliminated in consolidation.

(b) Inventories:

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

(c) Fixed Assets:

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

(d) Use of Estimates:

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

(e) Income Taxes:

The Company accounts for income taxes under the provisions of Statement of Financial Accounting Standards No. 109, “Accounting for Income Taxes” (SFAS 109). Under SFAS 109, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and the tax bases of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse.

(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.

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(i) Revenue Recognition:

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

The Company recognizes income from research grants when earned. Grants are invoiced after expenses are incurred. Some grants are funded up front; these funds are then deferred until earned.

(j) Comprehensive Income:

In 1998, the Company adopted Financial Accounting Standards Boards No. 130 "Reporting Comprehensive Income", which prescribes standards for reporting other comprehensive income and its components. The Company currently does not have any items of other comprehensive income and accordingly no separate statements are required.

(k) Concentrations of Credit Risk:

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of temporary cash investments and trade receivables. The Company places its temporary cash instruments with quality financial institutions and, at times, may maintain balances in excess of the $100,000 FDIC Insurance limit. The Company monitors the credit ratings of its financial institutions to mitigate this risk. Concentrations of credit risk with respect to trade receivables are principally mitigated by the Company's large customer base and their customers' national and international locations.

(l) Fair Value:

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

(m) Recent Accounting Pronouncements:

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

In December 2004, the FASB issued a revision of SFAS No. 123 "Share-Based Payment" 123(R). The statement establishes standards for the accounting for transactions in which an entity exchanges its equity investments for goods and services. It also addresses transactions in which an entity incurs liabilities in exchange for goods or services that are based on the fair value of the entity's equity instruments or that may be settled by the issuance of those equity

instruments. The statement does not change the accounting guidance for share-based payments with parties other than employees.

The statement requires a public entity to measure the cost of employee service received in exchange for an award of equity instruments based on the grant-date fair value of the award (with limited exception). That cost will be recognized over the period during which an employee is required to provide service in exchange for the award (usually the vesting period). A public entity will initially measure the cost of employee services received in exchange for an award of a liability instrument based on its current fair value; the fair value of that award will be re-measured subsequently at each reporting date through the settlement date. Changes in fair value during the requisite service period will be recognized as compensation over that period.

The grant-date for fair value of employee share options and similar instruments will be estimated using option-pricing models adjusted for the unique characteristics of these instruments. The Company will be required to comply with this pronouncement with periods beginning after December 15, 2005.

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

In November 2004, the Financial Accounting Standards Board ratified the Emerging Issues Task Force’s Statement No. 04-08, “The Effect of Contingently Convertible Debt on Diluted Earnings per Share” (“EITF 04-08”). EITF 04-08 addresses the issue of when the dilutive effects of contingently convertible debt instruments should be included in diluted earnings per share. This statement concludes that contingently convertible debt instruments should be included in diluted earnings per share regardless of whether any of the conversion criteria has been met. In addition, prior period earnings per share amounts presented for comparative purposes should be restated. EITF 04-08 is effective for reporting periods ending after December 15, 2004. Accordingly, the Company has included the dilutive effect from the assumed conversion of 8% series A preferred stock in the computation of diluted earnings per share for the year ended December 31, 2004 and has recalculated the diluted earnings per share for the year ending December 31, 2003, however the effect of such calculations were anti-dilutive and as such were not included in the diluted earnings per share. The common stock equivalents for these preferred shares were shown as part of Note 2 (q).

(n) Shipping and Handling Charges:

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

(o) Geographic Information:

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

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

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

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

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

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

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

(q) ***Earnings Per Share***

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

	For the years ended	
	December 31, 2004	**December 31, 2003**
Basic	5,966,769	4,919,191
Diluted	5,966,769	4,919,191

Computation of per share loss

Basic loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted loss per share reflects the potential dilution from the exercise or conversion of other securities into common stock, but only if dilutive. Diluted loss per share for the years ended December 31, 2004 and 2003 are the same as basic loss per share, since the effects of the calculation using common stock equivalents were anti-dilutive due to the fact that the Company incurred losses for all periods presented. The following securities, presented on a common share equivalent basis, have been excluded from the per share computations:

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
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	Year Ended December 31,	
	2004	2003
Stock Options	1,300,250	365,000
Warrants	12,226,054	140,000
Preferred stock	8,118,611	-

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

NOTE 3 — EMPLOYEE STOCK OPTION PLAN:

As part of the merger, the Company adopted the 1999 Stock Option Plan (the "Plan") of Chembio Diagnostic Systems, Inc. Under the terms of this plan, the Company's option committee is authorized to grant incentive options to key employees and to grant non-qualified options to key employees and key individuals. The option committee has been authorized to grant options to purchase up to 1,500,000 shares of common stock. The options become exercisable at such times and under such conditions as determined by the option committee. The Company has assumed 704,000 options outstanding from Chembio Diagnostic Systems, Inc.

The Company applies Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" and related Interpretations to account for the options issued to employees and or directors using the intrinsic value method. Had compensation cost for the options been determined using the fair value based method, as defined in Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"), the Company's net earnings and earnings per share would have been adjusted to the pro forma amounts indicated below. The Company also adopted Statement of Financial Accounting Standards No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure - an amendment of FASB Statement No. 123" as of January 1, 2003, which amended SFAS 123. The effect of the fair value method allowed under SFAS 123 is shown below.

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

The fair value of each option grant for 2004 was estimated on the date of the grant using the Black-Scholes option-pricing model with the following weighted-average assumptions for the year ended December 31, 2004: expected volatility of 82.6%; risk-free interest rate of 3.31%; and expected lives of 4 to 7 years for all periods presented.

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

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

Stock incentive plan activity is summarized as follows:

	Number of shares	Weighted Average Exercise Price
Options outstanding at December 31, 2002	315,000	3.12
Granted	50,000	.45
Canceled	-	-
Exercised	-	-
Options outstanding at December 31, 2003	365,000	2.75
Granted	740,000	0.95
Canceled	-	-
Exercised	-	-
Options outstanding at December 31, 2004	1,105,000	$ 1.55
Options exercisable at:		
December 31, 2003	197,500	
December 31, 2004	805,000	

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

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

NOTE 4 — RELATED PARTIES:

Lawrence A. Siebert, the president and chairman of the board of directors of Chembio Diagnostics, Inc. beginning at the time of and after the merger, and the president and chairman of Chembio Diagnostic Systems Inc. since May 2002, held two promissory notes issued by Chembio Diagnostic Systems Inc. One note was issued on August 1, 1999 in the

original principal amount of $338,125, bearing interest at a rate of 11% per annum. The other was issued on April 25, 2001 in the original principal amount of $795,937, bearing interest at a rate of 12% per annum. Mr. Siebert converted the entire outstanding principal amount of the 11% note and $561,875 principal amount of the 12% note into 30 shares of Chembio Diagnostics, Inc.'s series A preferred stock, together with warrants to acquire 1,800,000 shares of common stock at $.90 per share, pursuant to Chembio Diagnostics, Inc.'s private placement of its series A preferred stock on May 5, 2004. The shares of series A preferred stock held by Mr. Siebert are convertible into 1,547,100 shares of Chembio Diagnostics, Inc.'s common stock. The remaining debt of $234,062 held by Mr. Siebert was exchanged on December 29, 2004 into 7.80208 shares of Chembio Diagnostics, Inc.'s series A preferred stock, together with warrants to acquire 468,125 shares of common stock at $.90 per share, pursuant to the terms of Chembio Diagnostics, Inc.'s private placement of its series A preferred stock on May 5, 2004. Approximately $236,852 of accrued interest on the debt is also due to Mr. Siebert, but is not accruing additional interest. The accrued interest is being paid out according to the terms of Chembio Diagnostics, Inc.'s private placement of its series B preferred stock on January 28, 2005, which permits the payment of $10,000 per month to the holders thereof. Mr. Siebert also invested $50,000 in our series B preferred stock private placement pursuant to which he received 1 share of series B preferred stock convertible into 81,967 shares of common stock and a warrant to purchase 77,868 shares of common stock at a price of $0.61 per share.

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

Mr. Siebert prior to March 22, 2004 had either advanced funds to Chembio Diagnostic Systems, Inc. or paid vendors directly on Chembio Diagnostic Systems, Inc.'s behalf. The total amount so paid or advanced and not repaid totaled $183,720 as of December 31, 2004.

Patton Boggs LLP, an outside attorney for the Company's SEC filings is also a holder of 37,319 shares of the Company's common stock and in addition a partner of Patton Boggs LLP is also an investor in the Company. The partner owns 69,787 shares of common stock, 1.44731 shares of Series A preferred stock with warrants to purchase 86,839 shares of common stock and other warrants to purchase 9,203 shares of common stock. Legal expenses of $199,384 were attributable to Patton Boggs LLP and $100,755 remained unpaid as of December 31, 2004.

NOTE 5 — INVENTORIES:

Inventory consists of the following at December 31, 2004:

Raw Materials	$ 399,204
Work in Process	156,063
Finished Goods	93,380
Inventory Reserve for Obsolescence	(110,000)
	$ 538,647

NOTE 6 — FIXED ASSETS:

Fixed assets consist of the following at December 31, 2004:

Machinery and equipment	$ 490,322
Furniture and fixtures	12,636
Computer and telephone equipment	56,540
Leasehold improvements	47,721
Tooling	41,900
	649,119
Less accumulated depreciation and amortization	(460,720)
	$ 188,399

Included in the above fixed assets is $224,816 of assets under capital leases as of December 31, 2004.

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During 2004, the Company retired fixed assets that were no longer in use. The net book value of these assets aggregated $22,469 ($271,907 in cost less $249,438 in accumulated depreciation), and is being shown as a loss on disposal.

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

a) ***Long-term debt:***

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

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

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

b) W*orking Capital Loan and Restricted Cash*:

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

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

NOTE 8 — OBLIGATIONS UNDER CAPITAL LEASES:

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

Future minimum lease payments under these capitalized lease obligations, including interest as of December 31, 2004 were as follows:

Year ending December 31,

2005	$ 62,510

2006	42,688
2007	35,928
2008	4,470
	145,596
Less: imputed interest	20,300
Present value of future minimum lease payments	125,296
Less: current maturities	51,029
	$ 74,267

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

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NOTE 9 — RESEARCH GRANTS AND DEVELOPMENT CONTRACTS:

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

NOTE 10 — INCOME TAXES:

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

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

Deferred tax assets consist of the following at:

	31-Dec-04	31-Dec-03
Net operating loss carryforwards	**$ 4,424,000**	$ 3,116,000
Research and development credit		