

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

AMENDMENT NO. 1  
TO  
FORM SB-2

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Chembio Diagnostics, Inc.  
(Name of small business issuer in its charter)

Nevada	6282	88-0425691
(State or Jurisdiction of Incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

3661 Horseblock Road  
Medford, New York 11763  
(631) 924-1135  
(Address and telephone number of principal executive offices)

Lawrence A. Siebert  
Medford, New York 11763  
(631) 924-1135  
(Name, address and telephone number of agent for service)

Copy of all communications to:  
Alan Talesnick, Esq.  
David McLean, Esq.  
Patton Boggs LLP  
1660 Lincoln Street, Suite 1900  
Denver, Colorado 80264  
(303) 894-6378

Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐ [ ]

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐ [ ]

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐ [ ]

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. ☒ [X]

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. ☐ [ ]

CALCULATION OF REGISTRATION FEE

Title Of Each Class of Securities To Be Registered	Amount To Be Registered	Proposed Maximum Offering Price Per Unit (1)	Proposed Maximum Aggregate Offering Price (1)	Amount Of Registration Fee (3)
common stock <sup>(2)</sup>	21,534,808	\$1.55	\$33,378,952	\$4,230

(1) Estimated solely for purposes of calculating the registration fee in accordance with Rule 457(c) under the Securities Act of 1933, as amended (the "Act"), based on the average of the bid and asked prices for the Registrant's common stock as reported on the NASDAQ OTC Bulletin Board on June 1, 2004.

(2) Includes (i) up to 6,031,868 shares issuable upon the conversion of 120.63750 shares of the Registrant's 8% series A convertible preferred stock, (ii) up to 9,438,827 shares issuable upon the exercise of outstanding warrants and (iii) up to 1,084,000 shares issuable upon the exercise of outstanding options.

(3) \$4,090 was already paid pursuant to the initial filing of this registration statement on June 4, 2004.

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(A) OF THE SECURITIES ACT OF 1933 OR UNTIL THIS REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE SECURITIES AND EXCHANGE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(A), MAY DETERMINE.

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*The information in this prospectus is not complete and may be changed. The selling security holders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and neither the selling security holders nor we are soliciting offers to buy these securities in any state where the offer or sale is not permitted.*

SUBJECT TO COMPLETION, DATED AUGUST 3, 2004

PROSPECTUS

CHEMBIO DIAGNOSTICS, INC.

21,534,808 SHARES OF COMMON STOCK

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

Our common stock is quoted on the OTC Bulletin Board under the symbol "CEMI" On July 22, 2004 the closing bid and ask prices for one share of our common stock were \$1.33 and \$1.54, 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.

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These securities are speculative and involve a high degree of risk. You should consider carefully the "Risk factors" beginning on Page 2 of this prospectus before making a decision to purchase our stock.

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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.

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The date of this prospectus is July 3, 2004

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## TABLE OF CONTENTS

<a href="#"><u>Prospectus Summary</u></a>
<a href="#"><u>Risk Factors</u></a>
<a href="#"><u>Use of Proceeds</u></a>
<a href="#"><u>Dilution</u></a>
<a href="#"><u>Selling Security Holders</u></a>
<a href="#"><u>Plan of Distribution</u></a>
<a href="#"><u>Legal Proceedings</u></a>
<a href="#"><u>Directors, Executive Officers and Control Persons</u></a>
<a href="#"><u>Security Ownership of Certain Beneficial Owners and Management</u></a>
<a href="#"><u>Description of Securities</u></a>
<a href="#"><u>Interest of Named Experts and Counsel</u></a>
<a href="#"><u>Disclosure of Commission Position of Indemnification for Securities Act Liabilities</u></a>
<a href="#"><u>Description of Business</u></a>
<a href="#"><u>Management's Discussion and Analysis and Plan of Operation</u></a>
<a href="#"><u>Description of Property</u></a>
<a href="#"><u>Certain Relationships and Related Transactions</u></a>
<a href="#"><u>Market for Common Equity and Related Stockholder Matters</u></a>
<a href="#"><u>Executive Compensation</u></a>
<a href="#"><u>Financial Statements</u></a>
<a href="#"><u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u></a>
<a href="#"><u>Additional Information</u></a>

## PROSPECTUS SUMMARY

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

### Overview

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

### Our Business

**We are a manufacturer of lateral flow rapid diagnostic tests that detect infectious diseases. Our main products and products under development are as follows:**

Existing or Proposed Product	Regulatory Status	Development Status	Partners Involved in the Development or Marketing of the Products
HIV Rapid Tests (Sure Check™ HIV; HIV 1/2 Stat Pak). Rapid Tests for detection of antibodies to HIV 1 and 2 in whole blood.	We currently qualify under U.S. FDA export regulations to sell, subject to any required approval by the importing country, to customers outside the U.S. To date we have received approval from a number of potential importing countries, although Brazil is the only country in which we have significant sales. In addition, we have commenced clinical trials for Sure Check™ and HIV Stat Pak in US for FDA approval for sales in the U.S.	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. Other marketing partners are being actively pursued.
Rapid test for detection of Bovine Spongiform Encephalopathy in cattle	Upon completion of product it will be submitted for US and European regulatory approval which we expect will occur in 2005.	Product under development. We are waiting to complete technology transfer with Prionics.	Prionics AG, Zurich, Switzerland has contracted with Chembio to provide manufacturing services. Prionics will exclusively market product directly and through its designated distributors. Prionics provides certain components to Chembio
Dental Bacteria Test	Regulatory submission will be made in 2005 if product development is satisfactorily completed and in accordance with development timetable	Currently in Phase 2 (Optimization of Test)-of three phase development project. Timetable is to complete by late 2004/early 2005	Ivoclar-Vivadent, AG, Schaan Liechtenstein will exclusively market product and is the exclusive licensee of patented antibodies being incorporated by Chembio in product development
Rapid diagnostic test for detection of antibodies to active pulmonary tuberculosis in human whole blood samples	No plans for US or EU approval. Evaluations to support use in international public health programs are pending.	Product validation completed.	Public Health Research Institute, Newark, NJ provided initial research collaboration on product development, but will not be involved in the marketing of the product.
Rapid diagnostic test for the detection of antigens for active pulmonary tuberculosis in sputum	Regulatory submission plan and timetable not possible until further progress on product development is made.	Product under development pursuant to grant from the World Health Organization.	None.
Rapid diagnostic test for the detection of antibodies to active pulmonary tuberculosis in non-human primate whole blood samples	Will be submitted for regulatory approvals in the US in 2005.	Product validation completed.	Sequella Corporation, Rockville, Maryland is funding product development and clinical testing costs. Chembio will market this product directly and/or through distributors.
Private Label Pregnancy Tests	Cleared for marketing by FDA.	Completed.	Independent and regional drug store chains and distributors thereto in select markets.

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

### The Offering

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

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

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

## Summary Financial Data

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

	Three Months Ended March 31, 2004	Year Ended December 31, 2003
Revenue	585,312	2,818,351
Operating Expenses	520,523	1,605,975
Net Loss	(510,458)	(1,300,911)
Current Assets	3,402,141	n/a
<b>Total Assets</b>	3,830,857	n/a
Current Liabilities	1,459,039	n/a
<b>Total Liabilities</b>	2,200,341	n/a
<b>Stockholders' Equity</b>	1,630,516	n/a

## RISK FACTORS

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

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

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

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

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

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

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

For example, the European Union and other jurisdictions have recently established a requirement that diagnostic medical devices used to test human biological specimens must receive regulatory approval known as a CE mark, or be registered under the ISO 13485 medical device directive. The letters "CE" are the abbreviation of the French phrase "Conforme Européenne" which means "European conformity". ISO ("International Organization for Standardization") is the world's largest developer of standards with 148 member countries. As such, export to the European and other jurisdictions without the CE or ISO 13485 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 13485 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 13485 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. If we fail to maintain and enhance our competitive position, our customers may decide to use products developed by competitors which could result in a loss of revenues.

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

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

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

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

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

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

We received \$275,730 or 9.78% of our revenues in 2003 and \$91,342 or 15.61% of our revenues for the three months ended March 31, 2004 from grant and contract development work in connection with grants from the United States National Institute of Health, as well as from universities and commercial companies related to product development efforts for our tuberculosis, mad cow, and dental bacteria rapid test development work. These revenues have funded some of our personnel and other research and developmental costs and expenses for us. As a result of new grants and development contracts awarded to collaborative partners by the National Institute of Health and to us by the World Health Organization and other entities, revenue from funding grants is anticipated to increase in 2004. However, if these awards are not funded in their entirety or if new grants and contracts are not awarded in the future, our ability to fund future research and development and implement technological improvements would be jeopardized which would negatively impact our ability to compete in our industry.

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

We believe that our current cash balances, together with cash generated from operations, will be sufficient to fund operations for the next 12 months. However, this estimate is based on certain assumptions and we may face additional unanticipated expenses. We currently anticipate that we will be required to sell additional equity or debt securities or obtain additional credit facilities within 12 months. Any additional equity financing will result in dilution to existing shareholders. If we are unable to obtain financing on satisfactory terms, we will not be able to effectively carry out our business plan.

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

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

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

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

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

We believe that factors such as the technological and creative skills of our personnel, strategic relationships, new product developments, frequent product enhancements, and name recognition are essential to our success. All management personnel are bound by non-disclosure agreements. If personnel leave our employment, in some cases we would be required to protect our

intellectual property rights pursuant to common law theories which may be less protective than provision of employment, non-competition or non-disclosure agreements.

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

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

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

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

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

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

Our success will depend to a large extent upon the contributions of our executive officers, management, and sales, marketing, operations and scientific staff. 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 believe our success depends on our ability to participate in large government programs in the United States and worldwide and we may not be able to do so.

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

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

Since the inception of Chembio Diagnostics Diagnostic Systems, Inc. in 1985 and through the period ended March 31, 2004, we have incurred net losses. As of March 31, 2004, we have an accumulated deficit of \$7.487 million. We expect to continue to make substantial expenditures for sales and marketing, regulatory submissions, product development and other purposes. Our ability to achieve profitability in the future will primarily depend on our ability to increase sales of our products, reduce production and other costs and successfully introduce new products and enhanced versions of our existing products into the marketplace. If we are unable to increase our revenues at a rate that is sufficient to achieve profitability, our operating results would be materially harmed.

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

We may be held liable if any of our products, or any product which is made with the use or incorporation of any of the technologies belonging to us, causes injury of any type or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or usage. Although we have obtained product liability insurance, this insurance may not fully cover our potential liabilities. In addition,



as we attempt to bring new products to market, we may need to increase our product liability coverage which would be a significant additional expense that we may not be able to afford. If we are unable to obtain sufficient insurance coverage at an acceptable cost to protect us, we may be forced to abandon efforts to commercialize our products or those of our strategic partners, which would reduce our revenues.

#### Risks related to our common stock

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

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

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

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

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

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

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

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

On May 5, 2004, we completed three separate private placements in which we issued 151,579,84 shares of our series A preferred stock and warrants to acquire 9,904,801 shares of our common stock at an exercise price of \$.90 per share. The shares of series A preferred stock are convertible into 7,578,985 shares of our common stock. We also issued warrants to purchase 425,000 shares of our common stock at an exercise price of \$0.72 per share and warrants to purchase 510,000 shares of common stock at an exercise price of \$1.08 per share to designees of our placement agents. We also issued warrants pursuant to an employment agreement with Mark L. Baum, our former president and a current member of our board of directors, to purchase 425,000 shares and 425,000 shares of our common stock, respectively, at exercise prices of \$0.60 and \$0.90 per share respectively. In connection with the acquisition of Chembio Diagnostics Diagnostic Systems, Inc., we assumed warrants to purchase an aggregate of 690,000 shares of our common stock, at exercise prices ranging from \$0.45 to \$4.00 per shares and we adopted the stock option plan of Chembio Diagnostics Diagnostic Systems, Inc. and assumed all outstanding options. As of May 31, 2004, there were 704,000 options issued and outstanding under the stock option plan and 796,000 options available for issuance under the stock option plan. As a result, the conversion of the outstanding preferred stock and the exercise of the outstanding warrants and options will result in substantial dilution to the holders of our common stock.

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

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

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

#### USE OF PROCEEDS

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

#### DILUTION

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

## SELLING SECURITY HOLDERS

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

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

The remainder of the entities or individuals listed below acquired the shares offered hereby in connection with our May 5, 2004 private placement of series A preferred stock. In connection with that private placement, 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 issued in the private placement and the shares of common stock issuable upon exercise of the warrants issued in the private placement.

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

- the number of shares of common stock beneficially owned as of May 31, 2004 and prior to the offering contemplated hereby,
- the number of shares of common stock eligible for resale and to be offered by each selling security holder pursuant to this prospectus,
- the number of shares owned by each selling security holder after the offering contemplated hereby assuming that all shares eligible for resale pursuant to this prospectus actually are sold; and
- the percentage of shares of common stock beneficially owned by each selling security holder after the offering contemplated hereby.

Selling Security holders	Number of Shares of Common Stock Owned Before Offering <sup>(1)</sup>	Number of Shares To Be Offered <sup>(2)</sup>	Number of Shares Owned After Offering	Percentage of Shares of Common Stock Owned After Offering
Alan Perlmutter	60,000	60,000	—	0.00%
Alchemy, LLC	40,471	40,471	—	0.00%
Alex Shapiro	112,412	112,412	—	0.00%
Ami Dabush	494,694	494,694	—	0.00%
Andrew Merz Hanson	117,530	117,530	—	0.00%
Anne Ross	63,236	63,236	—	0.00%
Ari Fuchs	49,058	49,058	—	0.00%
Avi Pelossof	570,282	570,282	—	0.00%
Bill Ledowitz	7,118	7,118	—	0.00%
Bio-Equity Partners, Inc.	175,000	175,000	—	0.00%
Bruce J. Ide	496,539	496,539	—	0.00%
Christopher & Lynn Eckert	183,333	183,333	—	0.00%
Chris Phillips	40,471	40,471	—	0.00%
Claudio Beller	143,063	143,063	—	0.00%
Colin Lawrence	7,115	7,115	—	0.00%
Colin Poole	138,579	138,579	—	0.00%
Daniel Gressel	472,501	472,501	—	0.00%
David Hunt	100,000	100,000	—	0.00%
Elior Pelossof	83,148	83,148	—	0.00%
Eduardo Haim	7,115	7,115	—	0.00%
Edwin McGusty	125,000	125,000	—	0.00%
Elaine Klaus	17,242	17,242	—	0.00%
Ellen Siebert Best	42,936	42,936	—	0.00%
Eric Schwartz	5,496	5,496	—	0.00%
Felicia Lew	31,250	31,250	—	0.00%
Frank J. Guzikowski	178,114	178,114	—	0.00%
Gilbert Raker	83,148	83,148	—	0.00%
Gunther Weiss	28,334	28,334	—	0.00%
Hanka Lew	31,250	31,250	—	0.00%
H.C. Wainwright & Co., Inc.	390,867	390,867	—	0.00%
J & S Sandler	8,287	8,287	—	0.00%
J.G. Poole	68,365	68,365	—	0.00%
J.P. Turner	41,250	41,250	—	0.00%
Javan Esfandiari	167,080	167,080	—	0.00%
Jean-Paul Calamaro	304,542	304,542	—	0.00%

Jeff Dashefsky	12,500	12,500	—	0.00%
Jeffrey Goldberg	52,875	52,875	—	0.00%
John R. Clarke	158,400	158,400	—	0.00%
John Tyson	30,000	30,000	—	0.00%
Joshua Lifshitz	133,037	133,037	—	0.00%
Kaare Kolstad Jr.	50,589	50,589	—	0.00%
Karen Keskinen	31,579	31,579	—	0.00%
KNB Communications LLC	45,000	45,000	—	0.00%
Konstantin Lyashchenko	10,500	10,500	—	0.00%
Kurzman Partners, LP	73,333	73,333	—	0.00%
Kurt Haendler	250,955	250,955	—	0.00%
Lawrence Siebert	5,305,060	500,000	4,805,060	46.58%
Alpha Capital AG	1,210,000	1,210,000	—	0.00%
Lon E. Bell	277,159	277,159	—	0.00%
Marc Glass	20,708	20,708	—	0.00%
Mark Baum	1,788,333	1,438,333	350,000	4.66%
Mark & Lori Sandler	183,333	183,333	—	0.00%
Mark Wachs	27,716	27,716	—	0.00%
Total M.I.S., Inc.	550,000	550,000	—	0.00%
Metasequoia LLC	36,666	36,666	—	0.00%
Michael McCarthy	4,145	4,145	—	0.00%
Mike Ginsberg	2,375	2,375	—	0.00%
Mike Mayer-Wolf	18,379	18,379	—	0.00%
MSAS Trust	733,333	733,333	—	0.00%
Patton Boggs LLP	37,319	37,319	—	0.00%
Paul & Ellen Knasin	149,788	149,788	—	0.00%
Phil Greenblatt	10,347	10,347	—	0.00%
R. Edward Spilka	309,805	309,805	—	0.00%
R. Lankenau	102,835	102,835	—	0.00%
R. Siderowf	85,874	85,874	—	0.00%
Renata Haendler	44,829	44,829	—	0.00%
Richard A. Jacoby	462,675	462,675	—	0.00%
Richard Bruce	75,500	75,500	—	0.00%
Richard Larkin	108,182	108,182	—	0.00%
Robin Smith	119,883	119,883	—	0.00%
Russ Colby	12,500	12,500	—	0.00%
Sam Engel	4,118	4,118	—	0.00%
Sam Jacob	10,000	10,000	—	0.00%
Sandy Speer	65,468	65,468	—	0.00%
Scott F. Koch	158,400	158,400	—	0.00%
Scott W. Phillips	50,589	50,589	—	0.00%
Victus Capital	5,500,000	5,500,000	—	0.00%
Sive Paget & Reisel	2,055	2,055	—	0.00%
Spencer Reibman	18,780	18,780	—	0.00%
Stanley Seren	8,287	8,287	—	0.00%
Starobin Partners	110,000	110,000	—	0.00%
Stephen Feldman	2,055	2,055	—	0.00%
Steve Chrust	127,656	127,656	—	0.00%
Steve Schnipper	199,554	199,554	—	0.00%
Little Gem Life Sciences Fund LLC	91,666	91,666	—	0.00%
Straightline Capital Opp. Fund, LLC	737,117	737,117	—	0.00%
Ted Breitbart	18,208	18,208	—	0.00%
Alan Talesnick	238,194	238,194	—	0.00%
Thunderbird Global Corporation	1,011,672	1,011,672	—	0.00%
Tomas Haendler	698,933	698,933	—	0.00%
Truman Bassett	42,526	42,526	—	0.00%
Wendy Joffe	36,847	36,847	—	0.00%
Westbury Diagnostics	141,905	141,905	—	0.00%
Zilma Rojas	5,500	5,500	—	0.00%
<b>TOTALS</b>	<b>26,689,868</b>	<b>21,534,808</b>	<b>5,155,060</b>	<b>—</b>

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

#### PLAN OF DISTRIBUTION

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

The selling security holders also may sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus. The selling security holders may engage in short sales against the box, puts and calls and other transactions in our securities or derivatives of our securities, and may sell or deliver shares in connection with these trades. The selling security holders

may pledge their shares to their brokers under the margin provisions of customer agreements. If a selling security holder defaults on a margin loan, the broker may, from time to time, offer and sell the pledged shares.

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

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

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

## LEGAL PROCEEDINGS

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

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

On March 17, 2004, Saliva Diagnostic made further allegations of patent infringement against Chembio Diagnostic Systems Inc. In connection with the foregoing, Chembio Diagnostic Systems Inc. filed a complaint against Saliva Diagnostic in the United States District Court for the Eastern District of New York on March 18, 2004 (Civil Action No. 04-1149-JS-ETB). The complaint asks the court for declaratory and other relief that our Sure Check™ HIV test does not infringe the Saliva Diagnostic patent, that the Saliva Diagnostic patent is invalid, and that the Saliva Diagnostic patent is unenforceable due to inequitable procurement. On April 8, 2004, Saliva Diagnostic filed its answer and counterclaim, alleging that we were infringing on the Saliva Diagnostic Patent. We filed our Reply to Counterclaim on May 3, 2004, denying the allegation of infringement of the Saliva Diagnostic Patent. A pretrial scheduled conference has been set for August 13, 2004.

## DIRECTORS, EXECUTIVE OFFICERS AND CONTROL PERSONS

Lawrence A. Siebert (47), President and Director. Mr. Siebert was appointed President of Chembio Diagnostics, Inc. and a member of our board of directors upon consummation of the merger. Mr. Siebert has been Chairman of Chembio Diagnostic Systems Inc. for approximately 12 years and its President since May 2002. Mr. Siebert’s background is in private equity and venture capital investing. From 1982 to 1991, Mr. Siebert was associated with Stanwich Partners, Inc, which during that period invested in middle market manufacturing and distribution companies. From 1992 to 1999, Mr. Siebert was an investment consultant and business broker with Siebert Capital Corp. and Siebert Associates LLC, and was a principal investor in a privately held test and measurement company which was sold in 2002. Mr. Siebert received a J D 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 (47), 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 (41), Vice President Sales, Marketing and Business Development. Mr. Pelossof joined Chembio Diagnostic Systems Inc. in 1996 and has been responsible for developing Chembio Diagnostic System’s marketing strategy and collaborations. From 1991 to 1996, he was Managing Director and co-founder of The IMS Group, Inc., which provided strategic marketing advisory services to companies involved in Latin American markets including Chembio Diagnostics, Inc. Prior to IMS he was a Citibank Vice President in the

International Corporate Finance Group focused on Latin America. Mr. Pelossof received his MBA in finance and international business from New York University in 1986 and a BA with Distinction in economics from the University of Michigan in 1984.

Javan Esfandiari (39), Director of Research & Development in 1993. Mr. Esfandiari co-founded, and became a co-owner of Sinovus Biotech AB where he served as Director of Research and Development concerning lateral flow technology until Chembio Diagnostic Systems Inc. acquired Sinovus Biotech AB in 2000. From 1993 to 1997, Mr. Esfandiari was Director of Research and Development with On-Site Biotech/National Veterinary Institute, Uppsala, Sweden, which was working in collaboration with Sinovus Biotech AB on development of veterinary lateral flow technology. Mr. Esfandiari received his B.Sc. in Clinical Chemistry and his M. Sc. in Molecular Biology from Lund University, Sweden. He has published articles in various veterinary journals and has co-authored articles on tuberculosis serology with Dr. Lyashchenko.

Rick Bruce (50), Director of Operations. Mr. Bruce has been Director of Operations since April 2000. In this capacity, he directs our production, maintenance, inventory, shipping and receiving, and warehouse operations. Prior to joining Chembio Diagnostic Systems Inc. he held director level positions at American Home Products from 1984 to 1993. From 1998 to 2000, he held a management position at V.I. Technologies. From 1993 to 1998, he held various management positions at Biomerieux. Mr. Bruce has over 25 years of operations management experience with Fortune 500 companies in the field of in-vitro diagnostics and blood fractionation. Mr. Bruce received his BS in Management from National Louis University in 1997.

Mark L. Baum (31), Director. Mr. Baum was elected to our Board of Directors on December 11, 2003. Mr. Baum has more than 10 years experience in creating, financing and growing development stage enterprises in a variety of industries. Mr. Baum has participated in numerous public spin-offs, venture fundings, private-to-public mergers, and various asset acquisitions and divestitures. Mr. Baum is a licensed attorney in the State of California and the principal attorney for The Baum Law Firm. Mr. Baum’s law practice focuses on securities laws and related issues for small-cap and micro-cap publicly reporting companies.

## SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding the beneficial ownership of our common stock by each person or entity known by us to be the beneficial owner of more than 5% of the outstanding shares of common stock, each of our directors and each of our “named executive officers” and all of our directors and executive officers as a group as of June 1, 2004.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percent of Class
Lawrence Siebert <sup>(1)</sup> 75 Shady Knoll Drive Stamford, CT 06903	1,801,402	26.44%
Mark Baum <sup>(2)</sup> 249 Highway 101, Suite 432 Solana Beach, CA 92075	1,550,000	21.33%
Avi Pelossof <sup>(3)</sup> 51A Edgewood Road Port Washington, NY 11050	398,109	6.04%
Richard Bruce <sup>(4)</sup> 17 Amalia Lane Comack, NY 11725	40,500	0.63%
All officers and directors as a group <sup>(5)</sup>	3,790,011	48.16%
Tomas Haendler <sup>(6)</sup> 31 Cogswell Lane Stamford, CT 06902	521,154	7.97%
Thunderbird Global Corporation <sup>(7)</sup> c/o The Baum Law Firm 580 Second Street, Suite 102 Encinitas, CA 92024	457,353	7.13%
Daniel Gressel <sup>(8)</sup> 460 E. 79 <sup>th</sup> Street, Apt. 17B New York, NY 10021	467,501	7.23%
H.C. Wainwright & Co., Inc. <sup>(9)</sup> 245 Park Avenue, 44 <sup>th</sup> Floor New York, NY 10167	390,867	5.74%

Beneficial ownership is determined in accordance with the Rule 13d-3(a) of the Securities Exchange Act of 1934, as amended, and generally includes voting or investment power with respect to securities. Except as subject to community property laws, where applicable, the person named above has sole voting and investment power with respect to all shares of our common stock shown as beneficially owned by him.

The term “named executive officer” refers to our chief executive officer and each of our other executive officers who received at least \$100,000 of compensation in 2003.

This table does not include convertible securities which, due to contractual restrictions, are not exercisable within 60 days of the date of this prospectus. Specifically, a holder of series A preferred stock may not convert greater than twenty percent (20%) of its shares of series A preferred stock until the earlier of six (6) months following the effective date of this registration statement or March 4, 2005. Additionally, at no time may a holder of shares of series A preferred stock convert shares of the series A preferred stock if the number

of shares of common stock to be issued pursuant to such conversion would exceed, when aggregated with all other shares of common stock owned by such holder at such time, the number of shares of common stock which would result in such holder beneficially owning (as determined in accordance with Section 13(d) of the Securities Exchange Act in excess of either 4.999% or 9.999% of the then issued and outstanding shares of common stock outstanding at such time, unless the holder has provided us with sixty-one (61) days notice that the holder would like to waive this restriction.

- (1) Includes 120,000 shares issuable upon exercise of options exercisable within 60 days and 274,435 warrants. Does not include 100,000 shares issuable upon exercise of options that are not exercisable within the next 60 days, 1,547,117 shares issuable upon conversion of series A preferred stock and 1,856,541 shares issuable upon exercise of warrants because at no time may a holder of shares of series A preferred stock or a holder of warrants issued in connection with the series A preferred stock convert the shares of series A preferred stock or exercise the warrants if the number of shares to be issued pursuant to the conversion or exercise would exceed, when aggregated with all other shares of common stock of that holder at that time, the number of shares of common stock would result in the holder beneficially owning in excess of 4.99% of the then issued and outstanding shares of common stock outstanding at that time, unless the holder waives this restriction upon 61 days' notice to the Company.
- (2) Includes 850,000 shares issuable upon exercise of warrants. Does not include 108,333 shares issuable upon conversion of series A preferred stock and 130,000 shares issuable upon exercise of warrants because at no time may a holder of shares of series A preferred stock or a holder of warrants issued in connection with the series A preferred stock convert the shares of series A preferred stock or exercise the warrants if the number of shares to be issued pursuant to the conversion or exercise would exceed, when aggregated with all other shares of common stock of that holder at that time, the number of shares of common stock would result in the holder beneficially owning in excess of 4.99% of the then issued and outstanding shares of common stock outstanding at that time, unless the holder waives this restriction upon 61 days' notice to the Company.
- (3) Includes 150,000 shares issuable upon exercise of options exercisable within 60 days and 22,555 shares issuable upon exercise of warrants. Does not include 150,000 shares issuable upon exercise of options that are not exercisable within the next 60 days, 10,078 shares issuable upon conversion of series A preferred stock and 12,095 shares issuable upon exercise of warrants because at no time may a holder of shares of series A preferred stock or a holder of warrants issued in connection with the series A preferred stock convert the shares of series A preferred stock or exercise the warrants if the number of shares to be issued pursuant to the conversion or exercise would exceed, when aggregated with all other shares of common stock of that holder at that time, the number of shares of common stock would result in the holder beneficially owning in excess of 4.99% of the then issued and outstanding shares of common stock outstanding at that time, unless the holder waives this restriction upon 61 days' notice to the Company.
- (4) Includes 35,000 shares issuable upon exercise of options exercisable within 60 days and 500 shares issuable upon exercise of warrants. Does not include 35,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
- (5) Includes footnotes (1)-(4).
- (6) Includes 80,000 shares issuable upon exercise of options exercisable within 60 days and 38,197 shares issuable upon exercise of warrants. Does not include 80,000 shares issuable upon exercise of options that are not exercisable within the next 60 days, 44,450 shares issuable upon conversion of series A preferred stock and 53,334 shares issuable upon the exercise of warrants because at no time may a holder of shares of series A preferred stock or a holder of warrants issued in connection with the series A preferred stock convert the shares of series A preferred stock or exercise the warrants if the number of shares to be issued pursuant to the conversion or exercise would exceed, when aggregated with all other shares of common stock of that holder at that time, the number of shares of common stock would result in the holder beneficially owning in excess of 4.99% of the then issued and outstanding shares of common stock outstanding at that time, unless the holder waives this restriction upon 61 days' notice to the Company.
- (7) Does not include 251,963 shares issuable upon conversion of series A preferred stock and 302,356 shares issuable upon exercise of warrants because at no time may a holder of shares of series A preferred stock or a holder of warrants issued in connection with the series A preferred stock convert the shares of series A preferred stock or exercise the warrants if the number of shares to be issued pursuant to the conversion or exercise would exceed, when aggregated with all other shares of common stock of that holder at that time, the number of shares of common stock would result in the holder beneficially owning in excess of 4.99% of the then issued and outstanding shares of common stock outstanding at that time, unless the holder waives this restriction upon 61 days' notice to the Company. Gustavo Montilla may be deemed to have voting or investment control over the shares held by Thunderbird Global Corporation.
- (8) Includes 5,000 shares issuable upon exercise of options exercisable within 60 days and 42,065 shares issuable upon exercise of warrants. Does not include 5,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
- (9) Includes 390,867 shares issuable upon exercise of warrants. ZGNY Investments Limited Partnership may be deemed to have voting or investment control over the shares held by H.C. Wainwright & Co., Inc. Bryan Zwan may be deemed to have voting or investment control over ZGNY Investments Limited Partnership.

#### DESCRIPTION OF SECURITIES

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

#### Common stock

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

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

Action Stock Transfer acts as our transfer agent and registrar

## Preferred Stock

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

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

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

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

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

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

A holder of series A preferred stock cannot convert more than twenty percent (20%) of the shares of series A preferred stock that the holder owns into shares of common stock until the earlier to occur of six (6) months following the effective date of this registration statement or March 5, 2005.

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

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

**Redemption.** In the event of:

- a consolidation, merger, or other business combination involving Chembio Diagnostics, Inc.,
- the sale of more than 50% of our assets, or
- the closing of a purchase,

tender or exchange offer made to holders of more than 50% of our outstanding shares of common stock, each holder of series A preferred stock has the right to require us to redeem all or a portion of such holder's shares of series A preferred stock at a price per share of series A preferred stock equal to 100% of the then current liquidation preference amount for the series A preferred stock, plus any accrued and unpaid dividends; provided that we will have the sole option to pay the redemption price in cash or shares of common

stock. If we elect to pay the redemption price in shares of common stock, the price per share will be based upon the lesser of the conversion price for the series A preferred stock or the closing bid price for the common stock, in each case measured on the day preceding the date of delivery of the notice of redemption by such holder. In the event we elect to pay the redemption price in shares of common stock, demand registration rights will be granted on those additional shares.

Upon the occurrence of any of the following events:

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

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

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

#### INTEREST OF NAMED EXPERTS AND COUNSEL

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

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

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

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

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

#### DESCRIPTION OF BUSINESS

Our business prior to the merger

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

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

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



## The Merger

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

## Our business following the merger

### General

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

HIV Rapid Tests Commercially Available	Regulatory Status	Partners Involved in the Product
HIV Rapid Tests (Sure Check™ HIV; HIV 1/2 Stat Pak). Rapid Tests for detection of antibodies to HIV 1 and 2 in finger-stick whole blood, venous whole blood, serum and plasma	We currently qualify under U.S. FDA export regulations to sell, subject to any required approval by the importing country, to customers outside the U.S. To date we have received approval from a number of potential importing countries, although Brazil is the only country in which we have significant sales. In addition, we have commenced clinical trials for Sure Check™ and HIV Stat Pak in US for FDA approval for sales in the U.S.	Thirteen-year supply and technology transfer agreement with FIOCRUZ-Bio-Manguinhos, a division of the Ministry of Health of Brazil. FIOCRUZ-Bio-Manguinhos will supply product to Brazilian public health market and potentially other markets in the region. Other marketing partners are being actively pursued.

A majority of our revenues historically and in 2004 have been from the contract manufacture of private label pregnancy tests for regional pharmacies, drug stores and mass merchants in the United States, Europe, Canada, and Central America. However, as a result of pricing pressures, regulatory changes and potential patent litigation in this field, we are endeavoring to transfer this product line to a third party manufacturer and maintain a profit share derived from these products by the third party. We believe that this will result in a substantial reduction of our revenues from these products during the balance of 2004 and beyond. The timing of this transfer and the extent to which we will derive a benefit from it are difficult to estimate because of uncertainties in regulatory changes, product pricing and manufacturing cost changes, and patent litigation.

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

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

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

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

### Lateral Flow Technology

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

Our lateral flow technology allows the development of easy-to-perform, single-use diagnostic tests for rapid, visual detection of specific antigen-antibody complexes on a test strip. This format provides a test that is simple (requires neither electricity nor expensive equipment for test execution or reading, nor skilled personnel for test interpretation), rapid (turnaround time approximately 20 minutes), safe (minimizes handling of specimens potentially infected), non-invasive (requires 5-20 microliters of serum or whole blood easily obtained with a finger prick), stable (18 months at room temperature storage in the case of our HIV tests), and highly reproducible.

We can develop and produce lateral flow tests that are qualitative (reactive/non-reactive), as in the case of our HIV tests, and we can develop semi-quantitative tests, reflecting different concentrations of the target marker(s) using different colored latex test lines for each concentration, as is the objective in our dental bacteria test for bacterial levels under development. We can also develop tests for multiple conditions, using different colored lines as is the case in our prototype HIV/tuberculosis test. We have developed proprietary techniques that enable us to achieve high levels of sensitivity and specificity in our diagnostic tests using our proprietary latex conjugate and buffer systems. These techniques include the methods we employ in manufacturing and fusing the reagents with the colored latex, or colloidal gold, blocking procedures used to reduce false positives, and methods used in treating the materials used in

our tests to obtain maximum stability and resulting longer shelf life. We also have extensive experience with a variety of lateral flow devices, including the sample collection device used in our Sure Check™ HIV rapid test which we believe is easier to use than other finger-stick whole blood rapid tests. Sure Check™ eliminates the need for transferring finger-stick whole blood samples from the finger-tip onto a test device, because the collection of the sample is performed within a tubular test chamber, which contains the lateral flow test strip. The whole blood sample is absorbed directly onto the test strip through a small opening in one end of the test chamber and an absorbent pad positioned just inside this same end of the test chamber.

*Please refer to the section of this prospectus entitled “Legal Proceedings” for a discussion of the legal issues we face with regard to Sure Check™.*

## Target Market

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

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

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

## Distribution Channels

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

In February of this year we signed an agreement with FIOCRUZ-Bio-Manguinhos, an affiliated entity of the Brazilian Ministry of Health. This agreement provides for a three year period during which Chembio will transfer its know-how for the production and assembly of its HIV ½ Stat Pak and during which period Bio-Manguinhos will purchase a minimum of approximately 1 million tests from us. The know-how transfer process has begun. The tests that will be purchased will initially be fully completed and assembled at Chembio, but will increasingly during this three year period have components assembled and manufactured by Bio-Manguinhos in Brazil. Chembio will receive a royalty of 5% on net sales for ten years following completion of the technology transfer. Approximately 150,000 tests have been purchased through June 30, 2004, and we anticipate receiving orders for an additional 300,000 units in 2004.

We are seeking to leverage the experience we have in Brazil by establishing other local assembly, and technology transfer collaborations for our HIV tests where local demand and labor conditions justify such ventures. We are also seeking to have our HIV tests evaluated and used in programs for voluntary counseling and testing and prevention of mother to child transmission testing. The programs we are pursuing are overseen and/or led by the United States Centers for Disease Control Global Aids Program, the United States Agency for International Development, United Nations-affiliated programs including the World Health Organization, the health ministries and national AIDS control organizations in the host countries, and many other local and multi-national non-governmental and private organizations. Our efforts to have our tests evaluated and used in these programs were recently facilitated through our attendance and exhibition at the World Aids Conference in Bangkok, Thailand from July 11-15, 2004.

Our distribution and marketing strategy for our existing HIV rapid tests and for our human tuberculosis rapid tests under development will include seeking direct purchases by governmental and non-governmental organizations, commercial relationships with distributors, and/or partnering for local production and assembly in key markets.

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

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

## Competition

The diagnostics industry is a multi-billion dollar international industry and is intensely competitive. Many of our competitors are substantially larger and have greater financial, research, manufacturing, and marketing resources.

Industry competition in general is based on the following:

- Scientific and technological capability
- Proprietary know-how
- The ability to develop and market products and processes;
- The ability to obtain FDA or other required regulatory approvals;
- The ability to manufacture products that meet applicable FDA requirements, (i.e. FDA's Quality System Regulations) See Governmental Regulation section;
- Access to adequate capital;
- The ability to attract and retain qualified personnel; and
- The availability of patent protection.

We believe our scientific and technological capabilities and our proprietary know-how relating to lateral flow rapid tests, particularly for HIV and tuberculosis, are very strong.

Our ability to develop and market other products is in large measure dependent on our having additional resources and/or collaborative relationships, particularly where we can have our product development efforts funded on a project or milestone basis. We believe that our proprietary know-how in lateral flow technology has been instrumental in our obtaining the collaborations we have developed in mad cow disease and dental bacteria.

We have limited experience with regard to obtaining FDA or other required regulatory approvals, and no experience with obtaining pre-marketing approval of a biologic product such as HIV. See "Governmental Regulation" for definition of pre-marketing approval. For this reason, we have hired employees and consultants that collectively have that experience with other companies. We believe this will be very helpful in our obtaining these approvals and in ensuring that we manufacture our products in accordance with FDA and other regulatory requirements.

Our access to capital is much less than that of several of our competitors, and this is a competitive disadvantage. We believe however that our access to capital will increase as we get closer to FDA approval of our rapid HIV tests and/or as we complete the development of, and the requisite regulatory approvals related to, our other products, including those that we have under development.

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

Competitive factors specifically related to our HIV tests are product quality, price and ease of use. Product quality for an HIV rapid test primarily means accuracy (sensitivity and specificity), detection of early cases, time to reading result, and product shelf life. We believe that our HIV ½ Stat Pak and SureCheck™ HIV rapid tests are very competitive with the best products in the market on the basis of these competitive factors.

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

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

## Research and Development

Our research and development activities have been in four areas, all related to lateral flow rapid diagnostic product development: Bovine Spongiform Encephalopathy, which is also known as mad cow disease, dental bacteria, tuberculosis, and HIV.

We have collaborated with Prionics AG, Zurich, Switzerland since late 2002 to develop and produce certain components of a rapid test for mad cow disease to be marketed by Prionics and/or their distributors under their name. In March we signed a contract to be one of two contract manufacturers of this product following their transfer of the completed product know-how to us and approval of the product in Europe. These steps are in process but have not been completed. The contract is for three years, which begins when the product approval is granted in Europe. Although we expect that the technology transfer and European regulatory approval can be completed this year, and that initial sales will occur in 2005, we cannot estimate the timing and extent of these events as there are many factors that are beyond our control that could delay this timetable, including delays or changes in regulatory requirements, delays in the technology transfer or changes to the product specifications. Moreover, even once the product is approved in Europe, we do not control the marketing of the product, and we will have limited information about the marketing and distribution strategy of Prionics AG, including competitive products, market size and Prionics' existing market share, although we do expect to receive supply requirements forecasts from Prionics if and when the technology transfer is complete and the product is approved.

In the dental bacteria test, we have a contract with Ivoclar-Vivadent, Schaan, Liechtenstein to develop a rapid test that can detect different levels of bacteria found in saliva samples that have been found to be associated with tooth decay. The test employs intellectual property developed at University of California Los Angeles Dental School for which Ivoclar-Vivadent is the exclusive licensee. Our

contract with Ivoclar-Vivadent provides for a three phase development program for which we are being compensated a total of \$180,000. We are now in the second phase. If the development program results in a completed product in accordance with Ivoclar-Vivadent's specifications, then we will be the exclusive manufacturer and Ivoclar-Vivadent will have exclusive marketing and distribution rights. The contract is for five years and may be renewed by Ivoclar-Vivadent for an indefinite number of two-year renewals. Although our contract with Ivoclar-Vivadent contemplated that product development will be completed this year, and that regulatory approvals and products launch will be in 2005, there are factors beyond our control that make it impossible to predict the timing, nature and extent of revenues from this product, if any.

Our tuberculosis rapid tests for humans are being designed to significantly increase the accuracy of existing tuberculosis screening methods. Our initial tuberculosis test was developed pursuant to a Phase I and II Small Business Innovative Research grant from the National Institute of Health with Public Health Research Institute, Newark, New Jersey that was in place from 1998 until 2002, and our test was completed in 2003. In 1998 we entered into a license agreement with Public Health Research Institute which provides for us to pay a royalty on sales of our antibody detection tuberculosis tests that incorporate any of the antigens covered by the agreement. A study of our serological test for active pulmonary tuberculosis in humans by Sumitomo Seiyaku Biomedical of Japan has shown that sensitivity can increase from 45% to 82% when used in combination with the spu tum smear method (the current standard in high incidence settings), and from 45% to 91% when used with the two- step confirmatory combination of sputum smear and culture testing. However, we know that serological testing for tuberculosis is very complex and challenging, and we therefore believe that much further testing in a variety of geographic settings will be needed in order to confirm the performance of this test across diverse populations. Our test is now involved in one evaluation in Uganda, and we are discussing several other evaluations, some of which we believe could take place in 2004. However, the timing and results of these evaluations cannot be predicted and therefore the timing and extent of any sales that would be derived from this product can also not be estimated at this time.

We have also begun work on a \$100,000 grant we received beginning in March, 2004 from the World Health Organization to develop a simple and rapid lateral flow test for antigen detection in tuberculosis. We also have developed a prototype of a combination lateral flow rapid test for detecting antibodies to HIV and active pulmonary tuberculosis using separate test lines of different colors on a single test strip. Given the developmental stage of this research, there is no expectation of revenues from this product in the foreseeable future. We have also expended efforts related to the detection of active pulmonary tuberculosis in animals and are currently seeking a collaboration partner. We do not anticipate any sales from this product line in 2004 and most of 2005.

Our HIV development efforts are on a next generation rapid test that can detect cases even earlier than all currently marketed rapid tests do without compromising the specificity of the test. A prototype has been developed and needs to undergo substantial revision and optimization. No reagent license agreements are in place with regard to the materials used in this prototype at this time. We do not anticipate any sales from this product line in 2004 and most of 2005.

The foregoing research and development efforts are summarized below:

Existing or Proposed Product	Regulatory Status	Development Status	Partners involved in the development or marketing of the products
Rapid test for detection of Bovine Spongiform Encephalopathy, also known as mad cow disease, in cattle Dental Bacteria Test	Not yet submitted for approval Not yet submitted for approval	Under development Phase 2 (Optimization of Test)	Prionics AG, Zurich, Switzerland Ivoclar-Vivadent, AG, Schaan Liechtenstein
Tuberculosis Stat Pak II- rapid diagnostic test for detection of antibodies to active pulmonary tuberculosis in human whole blood samples	Not yet submitted for approval	Product validation completed	Public Health Research Institute and Satens Serum Institute
TBD rapid diagnostic test for the detection of antigens for active pulmonary tuberculosis in sputum	Not yet submitted for approval	Product under development pursuant to grant from the World Health Organization	World Health Organization- Special Program for Research and Training in Tropical Diseases
TBD Non-Human Primate Rapid Tuberculosis Test for the detection of antibodies to active pulmonary tuberculosis in non-human primate whole blood samples	Not yet submitted for approval	Product validation completed	Sequella Corporation, Rockville, Maryland
Combination HIV/Tuberculosis Rapid Test for the detection of antibodies to 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

During 2003 and 2002, approximately \$313,891 and \$378,089 respectively was spent on research and development activities. A significant portion of these expenditures have been on our human and non-human primate tuberculosis product development efforts.

Research & Development Expenditures		
	2002	2003
Human Tuberculosis	\$265,118	\$59,491
Veterinary Tuberculosis	39,169	116,239
HIV, Dental, Mad Cow	20,000	100,000
Other	53,802	48,161
Totals	\$378,089	\$313,891

Employees

At May 31, 2004, we employed 51 employees, including 48 full-time employees. At the time of closing of the merger, we entered into employment agreements with Lawrence Siebert, President and Chairman, Avi Pelossof, VP Sales, Marketing and Business Development, and Javan Esfandiari, Director of research and development. We also entered into an employment agreement with Mark L. Baum, a member of our board of directors, to provide advice and guidance with respect to management, marketing, strategic planning, corporate structure, business operations, expansion of services, acquisitions and business opportunities, matters related to our public reporting obligations, and our overall needs.

## Governmental Regulation

All of Chembio's existing and proposed diagnostic products are regulated by the FDA, U.S. Department of Agriculture, certain state and local agencies, and/or comparable regulatory bodies in other countries. This regulation governs almost all aspects of development, production, and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing, and record keeping. All of Chembio's FDA and U.S. Department of Agriculture regulated products require some form of action by that agency before they can be marketed in the United States, and, after approval or clearance, Chembio must continue to comply with other FDA requirements applicable to marketed products. Both before and after approval or clearance, failure to comply with the FDA's requirements can lead to significant penalties.

Most of Chembio's diagnostic products are regulated as medical devices, and some are regulated as biologics. There are two review procedures by which medical devices can receive FDA clearance or approval. Some products may qualify for clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, in which the manufacturer provides a pre-market notification that it intends to begin marketing the product, and shows that the product is substantially equivalent to another legally marketed product (i.e., that it has the same intended use and is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness). In some cases, the submission must include data from human clinical studies. Marketing may commence when the FDA issues a clearance letter finding such substantial equivalence. An applicant must submit a 510(k) application at least 90 days before marketing of the affected product commences. Although FDA clearance may be granted within that 90-day period, in some cases as much as a year or more may be required before clearance is obtained, if at all.

If the medical device does not qualify for the 510(k) procedure (either because it is not substantially equivalent to a legally marketed device or because it is required by statute and the FDA's implementing regulations to have an approved application), the FDA must approve a pre-market approval application before marketing can begin. Pre-market approvals must demonstrate, among other matters, that the medical device provides a reasonable assurance of safety and effectiveness. A pre-market approval is typically a complex submission, including the results of preclinical and clinical studies. Preparing a pre-market approval is a detailed and time-consuming process. Once a pre-market approval has been submitted, the FDA is required to review the submission within a statutory period of time. However, the FDA's review may, and often is, much longer, often requiring one year or more, and may include requests for additional data.

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

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

Every company that manufactures biologic products or medical devices distributed in the United States must comply with the FDA's Quality System Regulations. These regulations govern the manufacturing process, including design, manufacture, testing, release, packaging, distribution, documentation, and purchasing. Compliance with the Quality System Regulations is required before the FDA will approve an application, and these requirements also apply to marketed products. Companies are also subject to other post-market and general requirements, including compliance with restrictions imposed on marketed products, compliance with promotional standards, record keeping, and reporting of certain adverse reactions or events. The FDA regularly inspects companies to determine compliance with the Quality System Regulations and other post-approval requirements. Failure to comply with statutory requirements and the FDA's regulations can lead to substantial penalties, including monetary penalties, injunctions, product recalls, seizure of products, and criminal prosecution.

The Clinical Laboratory Improvement Act of 1988 prohibits laboratories from performing in vitro tests for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of, the health of human beings unless there is in effect for such laboratories a certificate issued by the U.S. Department of Health and Human Services applicable to the category of examination or procedure performed. Although a certificate is not required for Chembio, Chembio considers the applicability of the requirements of the Clinical Laboratory Improvement Act in the design and development of its products. A Clinical Laboratory Improvement Act waiver will remove certain quality control and other requirements that must be met for certain customers to use Chembio's products, and this is in fact critical to the marketability of a product into the point of care diagnostics market.

In addition, the FDA regulates the export of medical devices that have not been approved for marketing in the United States. The Federal Food, Drug and Cosmetic Act contains general requirements for any medical device that may not be sold in the United States and is intended for export. Specifically, a medical device intended for export is not deemed to be adulterated or misbranded if the product: (1) accords to the specifications of the foreign purchaser; (2) is not in conflict with the laws of the country to which it is intended for export; (3) is labeled on the outside of the shipping package that it is intended for export; and (4) is not sold or offered for sale in the United States. Some medical devices face additional statutory requirements before they can be exported. If an unapproved device does not comply with an applicable performance standard or premarket approval requirement, is exempt from either such requirement because it is an investigational device, or is a banned device, the device may be deemed to be adulterated or misbranded unless the FDA has determined that exportation of the device is not contrary to the public health and safety and has the approval of the country to which it is intended for export. However, the Federal Food, Drug and Cosmetic Act does permit the export of devices to any country in the world, if the device complies with the laws of the importing country and has valid marketing authorization in one of several "listed" countries under the theory that these listed countries have sophisticated mechanisms for the review of medical devices for safety and effectiveness.

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

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

## Environmental Laws

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

## Intellectual Property

### *Intellectual Property Strategy*

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

### *Trade Secrets and Know-How*

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

### *Lateral Flow Technology and Reagent Licenses*

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

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

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

## Legal Issues

### *FTC Matter*

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

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

### OVERVIEW

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

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

### RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2004 AS COMPARED WITH THE THREE MONTHS ENDED MARCH 31, 2003

Revenues were \$585,312 for the three months ended March 31, 2004 as compared with \$720,077 for the three months ended March 31, 2003, representing a decrease of \$134,765, or 19%. The decrease in sales is primarily attributable to reduced pregnancy test kit sales and reduced sales of one of our veterinary rapid tests offset by approximately \$90,000 in grant-related income. A substantial portion of the grant-related income will recur for the balance of 2004 and in 2005.

Cost of goods sold for the three months ended March 31, 2004 was \$445,924, or 76.2% of revenues, as compared to \$616,766, or 85.7% of revenues, for the three months ended March 31, 2003. The increase in gross margin is primarily attributable to approximately \$90,000 of contract and grant income received during the three months ended March 2004 as compared with no such income during the three-month period ended March 31, 2003, together with income associated with the technology transfer and supply agreement with Bio-Manguinhos that commenced during this period. Gross margin in the three-month period ended March 31, 2003 was negatively impacted by a combination of a lower margin product sales mix and production losses.

Selling, general and administrative expense increased \$97,074 to \$401,436 in the first three months of 2004 compared with the same period in 2003. Driving this increase in expense was primarily compensation expense related to stock awards granted to key employees as well as increased commissions resulting from the commencement of the Bio-Manguinhos program.

Research and development expenses for the three months ended March 31, 2004 were \$112,095, or 19.2% of revenues, compared with \$85,262, or 11.8% of revenues, for the three months ended March 31, 2003. 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 R&D group since the March 31, 2003 period as new grants and development contracts were awarded and also due to the addition of an R&D Technician hired in late 2003 for the purpose of fulfilling obligations under grants from the National Institute of Health and World Health Organization as well as other product development contracts.

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

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
Nature, timing and estimated costs of the efforts necessary to complete	The timing of production scale-up and validation is anticipated to be approximately three to six months from the date of the completion of the technology transfer. Thereafter, we will incur costs to establish the production capacity required for this product, which we presently anticipate to be approximately \$100,000.
Anticipated completion date	Not Known
Risks and uncertainties associated with completing development on schedule, and the consequences to operations, financial position and liquidity if not completed timely	We are relying on technology developed by Prionics and so there is a risk that the product validation will encounter difficulties that at present are not known or foreseeable. The risks associated with the product involve regulatory and technology risks.
Timing of commencement of expected material net cash inflows	It is not known or estimable when net cash inflows from this project will commence due to the uncertainties associated with the completion of the product, regulatory submissions, and the nature and timing of Prionics' distribution network

Project	Dental Bacteria Test
Current status	During the balance of 2004, we expect to complete Phase 2 of the Project Plan (Optimization of Test) and move into Phase 3 (Scale Up of Production and validation).
Nature, timing and estimated costs of the efforts necessary to complete	In April 2004, Chembio received 80% of the Phase 2 project cost of \$65,000, or \$52,000 and this reflects the estimate of the costs anticipated to be incurred to complete Phase 2 during a three to five month period. We expect to complete Phase 2 in September. Upon completion of Phase 2 we will provide a report to Ivoclar-Vivadent. If the report is acceptable, we will receive the \$13,000 balance from Phase 2 and 80% of the Phase III project cost, also \$65,000. Phase 3 is also estimated to take three to five months to complete
Anticipated completion date	Assuming the project plan is achieved, the anticipated completion date of the product is first quarter 2005. It is not known at this time how long it will take to obtain regulatory approvals in the US, Europe, Japan and other potential markets
Risks and uncertainties associated with completing development on schedule, and	Technical challenges remain that must be overcome in order for this product to meet the performance specifications that Ivoclar Vivadent has set forth in the Agreement. If we do not achieve the performance specifications, the product will not be completed.



the consequences to operations, financial position and liquidity if not completed timely	
Timing of commencement of expected material net cash inflows	It is not known or estimable when net cash inflows from this project will commence due to the uncertainties associated with the completion of the product, regulatory submissions, and 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	Not known
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	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 2004 and 2005 from any of these products.

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

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

Cost of goods sold for the twelve months ended December 31, 2003 was \$2.153 million, or 76.4% of revenues, as compared with \$2.458 million, or 78.4% of revenues, for the twelve months ended December 31, 2002. Although costs of raw materials, labor and overhead associated with manufacturing remained level during the twelve months ended December 31, 2003, improved material usage due to the implementation of an inventory purchasing and production control (known as Material Requirements Planning or "MRP") system in January 2003, as well as other production and quality controls implemented during 2003, began to show an effect in 2003.

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

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

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

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

#### LIQUIDITY AND CAPITAL RESOURCES

We began to improve our liquidity and capital resources position during the first quarter of 2004 as a result of the completion of the \$1,000,000 convertible note offering in March. As a result of the completion of the series A financing, \$328,000 of the \$1,000,000 of convertible 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 the series A preferred stock. Simultaneous to that conversion, 73.33330 shares of series A preferred stock were issued for \$2,200,000 in cash, and an additional \$1,332,292 of debt to our note holders was converted into 44.40972 additional shares of the series A preferred stock. Together, before accounting for costs and expenses associated with these transactions, these events resulted in new equity capital of approximately \$4,532,292 since December 31, 2003. However, the March 31, 2004 unaudited balance sheet reflects only the convertible note offering which had been completed during the month of March 2004.

During the three months ended March 31, 2004, we used \$452,854 cash in operations, \$13,900 to acquire fixed assets, \$18,512 to fund capital lease payments, and \$67,434 to fund the bank overdraft existing as of December 31, 2003. The cash was funded primarily from the \$1,000,000 of convertible notes issued during March, the accrual of interest on all debt due for both term debt and convertible debt, and the funding of \$64,229 of compensation expense by the issuance of common stock to some of our key employees. All the convertible notes and the existing debt, which has since been converted into capital as noted above, is reflected on the March 31, 2004 balance sheet



as long term debt, because the conditions to closing of the merger and the series A financing had not been met as of the March 31, 2004 balance sheet date.

Accordingly, we had a working capital deficiency of \$(730,738) at December 31, 2003 and a working capital deficiency of \$(183,999) at March 31, 2004. This decrease in the deficiency is due to the completion of the convertible note offering. Our current assets increased 65.3% to \$1.277 million at March 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.

Compared with corresponding balances at December 31, 2003, current liabilities as of March 31, 2004 decreased 2.8% to \$1.461 million, long term liabilities increased 50.6% to \$3.074 million, and total liabilities increased 28% to \$4.535 million. The increase in long term liabilities is attributable to the completion of the \$1,000,000 convertible note offering as well as to the accrual of approximately \$50,711 of accrued interest during the period.

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

OBLIGATIONS	Total	Less than 1 Year	1-3 Years	4-5 Years	Greater than 5 Years
Long Term Debt(1)	\$2,693,851	-	-	-	\$2,693,851
Capital Leases (2)	\$151,162	\$61,162	\$63,252	\$26,748	-
Operating Leases	\$97,688	\$86,688	\$11,000	-	-
Other Long Term Obligations(3)	\$48,000	\$12,000	\$36,000	-	-
Total Obligations	\$2,924,701	\$147,850	\$74,252	\$26,748	\$2,693,851

- (1) This represents convertible as well as non-convertible debt. Subsequent to March 31, 2004, \$2,332,292 of this debt was converted into either series A preferred stock or common stock. The balance, if not paid by the end of 2004, will be converted into series A preferred stock.
- (2) This represents capital leases used to purchase capital equipment.
- (3) This represents contractual obligations for licenses.

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

Clinical trials for our HIV rapid tests have begun, and we believe that they will be completed during the fourth quarter. The trials will be used to support a pre-marketing approval application to the FDA. Simultaneous with this regulatory approval process, we are actively involved in increasing distribution of our HIV rapid tests through a variety of distribution channels and partners. We have engaged Bio-Equity Partners, a company that specializes in helping small biotech firms in the HIV field, to assist in these efforts. Several other marketing and business development efforts are ongoing that are aimed toward participating in the various initiatives publicly announced for the implementation of voluntary counseling and testing (VCT), pre-natal testing for mother to child transmission, and other programs that are taking root globally. A significant portion of the capital currently available to us is being used to obtain US regulatory approval of our HIV rapid tests and to provide the marketing and business development resources to achieve wider distribution of our products in the global market.

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

Our cash requirements depend on numerous factors, including product development activities, penetration of the direct sales market, market acceptance of new products, and effective management of inventory levels in response to sales forecasts. We expect to devote capital resources to continue our product development, expand manufacturing capacity and continue research and development activities. We will examine other growth opportunities, including strategic alliances, and we expect any such activities will be funded from existing cash and cash equivalents, as well as issuance of additional equity or additional borrowings, subject to market and other conditions. We believe that our current cash balances, and cash generated from future operations, will be sufficient to fund operations for the next twelve months. If cash generated from operations is not sufficient to satisfy our working capital and capital expenditure requirements, we may be required to sell additional equity or obtain additional credit facilities. We cannot be certain that this financing will be available or that we will be able to complete financing on satisfactory terms, if at all.

Notwithstanding the numerous factors that our cash requirements depend on, and the uncertainties associated with each of the major revenue opportunities that we have, we believe that our plan of operation can build long term value if we are able to demonstrate clear progress toward our objectives, particularly FDA approval of our HIV rapid tests. We expect to complete the clinical testing portion related to our HIV rapid test FDA submission in the fourth quarter of this year, and we believe that if the results of these tests are at the level required for FDA approval, these results will provide strong evidence of our progress. We also have other important international evaluations pending of our HIV rapid tests which, if favorable, would result in additional independent proof of the quality of our products and the accretion of long term value to our shareholders. We believe that our international sales efforts for our HIV tests will succeed based upon the market need, the performance of our products, their competitive pricing, the distribution and marketing channels we are pursuing, and the quality of our professional staff. Based upon our agreement with Bio-Manguinhos alone, we expect to receive orders for our HIV rapid tests that will more than offset the net cash flow that we will no longer have from the private label manufacturing of pregnancy tests.

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

Progress in our other major product groups, particularly those for the mad cow disease and dental bacteria test, as well as the non-human primate tuberculosis test, are also likely to lend credibility to our plan to become profitable. In this regard, we have hired a director of regulatory affairs who will be directing the regulatory activities related to the veterinary products (e.g., mad cow and non-human primate tuberculosis) as well as the dental bacteria test, provided that each of the projects progresses to the point where a regulatory submission is appropriate. This individual will eventually absorb some of the responsibilities that have been performed by

our outside regulatory consultant. We have also added one person to our solutions manufacturing group and have hired an assembly supervisor. These three positions will add at least \$250,000 in annual costs. We have not decided at this juncture whether to add to our research and development team, though it is under consideration. If such a position is added, the annual cost would be at least \$100,000.

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

#### Critical Accounting Policies and Estimates

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

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

#### *Revenue Recognition –*

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

#### *Research & Development Costs –*

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

#### *Valuation of Inventories –*

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

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

We assess the realizable value of long-lived assets for potential impairment at least annually or when events and circumstances warrant such a review. The carrying value of long-lived asset is considered impaired when the anticipated fair value is less than its carrying value. In assessing the recoverability of our long-lived assets, we must make assumptions regarding estimated future cash flows and other factors to determine the fair value of the respective assets. In addition, we must make assumptions regarding the useful lives of these assets. As of December 31, 2003, we evaluated our long-lived assets for potential impairment. Based on our evaluation, no impairment charge was recognized.

#### *Income Taxes –*

We account for income taxes under SFAS No. 109, "Accounting for Income Taxes". SFAS No. 109 requires the asset and liability method of accounting for deferred income taxes. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities. Deferred tax assets or liabilities at the end of each period are determined using the tax rate expected to be in effect when taxes are actually paid or recovered.

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

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

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

#### DESCRIPTION OF PROPERTY

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

Mark L. Baum, our former president prior to the merger and a current director of Chembio Diagnostics, Inc., entered into a nine-month employment agreement with Chembio Diagnostics, Inc., effective upon the closing of the merger, pursuant to which Mr. Baum received 400,000 shares of our common stock as well as a warrant to acquire 425,000 shares of common stock at \$.60 per share and a warrant to acquire an additional 425,000 shares of common stock at \$.90 per share. The warrants expire five years after the date of grant. Pursuant to the employment agreement, Mr. Baum will advise Chembio Diagnostics, Inc. concerning management, marketing, strategic planning, corporate structure, business operations, expansion of services, acquisitions and business opportunities, matters related to our public reporting obligations, and our overall needs. Mr. Baum also invested \$65,000 in the private placement of series A preferred stock, pursuant to which he received 2,167 shares of series A preferred stock convertible into 108,350 shares of common stock, and a warrant to purchase 130,020 shares of common stock. Mr. Baum also owns 300,000 shares of our common stock in addition to the stock and warrants described above. Prior to the merger, Mr. Baum was the sole director and officer of Chembio Diagnostics, Inc.

Lawrence A. Siebert, the president and chairman of the board of directors of Chembio Diagnostics, Inc. beginning at the time of and after the merger, and the president and chairman of Chembio Diagnostic Systems Inc. since May 2002, holds two promissory notes issued by Chembio Diagnostic Systems Inc. One note was issued on August 1, 1999 in the original principal amount of \$338,125, bearing interest at a rate of 11% per annum. The other was issued on April 25, 2001 in the original principal amount of \$795,937, bearing interest at a rate of 12% per annum. Mr. Siebert converted the entire outstanding principal amount of the 11% note and \$561,875 principal amount of the 12% note into 30 shares of Chembio Diagnostics, Inc.'s series A preferred stock, together with warrants to acquire 1,800,000 shares of common stock at \$.90 per share, pursuant to Chembio Diagnostics, Inc.'s private placement of its series A preferred stock on May 5, 2004. The shares of series A preferred stock held by Mr. Siebert are convertible into 1,547,100 shares of Chembio Diagnostics, Inc.'s common stock. Approximately \$234,062 of the debt held by Mr. Siebert was not so exchanged and continues to accrue interest. Approximately \$214,241 of accrued interest on the converted and unconverted portions of the debt is also due to Mr. Siebert, but is not accruing interest. The debt and accrued interest are required to be repaid by Chembio Diagnostics, Inc. on or before December 31, 2004 or, at the option of Chembio Diagnostics, Inc., converted into shares of its series A preferred stock as of December 31, 2004.

Mr. Siebert also invested \$18,700 in Chembio Diagnostic Systems Inc. pursuant to a private placement of convertible notes on March 22, 2004. Mr. Siebert converted the entire principal amount of the note that he received, together with accrued interest thereon, into .942 shares of Chembio Diagnostics, Inc.'s series A preferred stock, together with warrants to acquire 56,520 shares of common stock at \$.90 per share, pursuant to Chembio Diagnostics, Inc.'s private placement of its series A preferred stock on May 5, 2004.

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

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

## MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

### Market Information

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

Fiscal Year 2004		High Bid	Low Bid
Second Quarter		\$2.00	\$1.00
First Quarter		\$3.00	\$0.34
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
Fiscal Year 2002		High Bid	Low Bid
First Quarter		\$5.10	\$0.16
Second Quarter		\$2.72	\$0.02
Third Quarter		\$2.04	\$0.17
Fourth Quarter		\$0.17	\$0.17

Trades of our common stock are subject to Rule 15c-9 of the Securities and Exchange Commission, known as the Penny Stock Rule. This rule imposes requirements on broker/dealers who sell securities subject to the rule to persons other than established customers and accredited investors. For transactions covered by the rule, brokers/dealers must make a special suitability determination for purchasers of the securities and receive the purchaser’s written agreement to the transaction prior to sale. The Securities and Exchange Commission also has rules that regulate broker/dealer practices in connection with transactions in “penny stocks”. Penny stocks generally are equity securities with a price of less than \$5.00 (other than securities registered on certain national securities exchanges or quoted on the NASDAQ system, provided that current price and volume information with respect to transactions in that security is provided by the exchange or system). The Penny Stock Rules requires a broker/ dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document prepared by the Commission that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker/dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker/dealer and its salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer’s account. The bid and offer quotations, and the broker/dealer and salesperson compensation information, must be given to the customer orally or in writing prior to effecting the transaction and must be given to the customer in writing before or with the customer’s confirmation. These disclosure requirements have the effect of reducing the level of trading activity in the secondary market for our common stock. As a result of these rules, investors may find it difficult to sell their shares.

### Holders

As of May 31, 2004, there were approximately 97 record owners of Chembio Diagnostics, Inc.’s common stock.

### Dividends

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

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

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

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

## EXECUTIVE COMPENSATION

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

Name and Position	Year	Annual Comp	Long-Term Compensation Awards— Securities Underlying
		Salary	Stock Options

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

- (1) Mr. Siebert currently is a director, the President and Chief Executive Officer of Chembio Diagnostics, Inc., and the President of Chembio Diagnostic Systems Inc. The compensation information represents compensation earned while employed by Chembio Diagnostic Systems Inc.
- (2) Mr. Bruce currently is a vice president of Chembio Diagnostics, Inc. and Chembio Diagnostic Systems Inc. The compensation information represents compensation earned while employed by Chembio Diagnostic Systems Inc.
- (3) Mr. Baum currently is a director and the Secretary of Chembio Diagnostics, Inc. The compensation information represents compensation earned while employed by Chembio Diagnostics, Inc.

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

## FINANCIAL STATEMENTS

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

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

On June 1, 2004, our Board of Directors voted to replace Madsen & Associates, 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 DIAGNOSTIC SYSTEMS INC. AND SUBSIDIARY**

**Index to Consolidated Financial Statements.**

**—INDEX—**

	<b>Page(s)</b>
Report of Independent Accountants	F-2
Financial Statements:	
Consolidated Balance Sheets	
March 31, 2004 (unaudited) and December 31, 2003	F-3
Consolidated Statements of Operations	
Three months ended March 31, 2004 (unaudited) and 2003 (unaudited)	F-4
The years ended December 31, 2003 and 2002	F-5
Consolidated Statements of Changes in Stockholders' Equity	F-6
Consolidated Statements of Cash Flows	
Three months ended March 31, 2004 (unaudited) and 2003 (unaudited)	F-7
The years ended December 31, 2003 and 2002	F-8
Notes to Financial Statements	F-9 – F-19
Unaudited Pro forma Financial Statements:	
Introduction	F-20
Condensed Consolidated pro forma Balance Sheet	
As of March 31, 2004	F-21
Condensed Consolidated Pro Forma Statements Of Operations	
Three months ended March 31, 2004	F-22
The year ended December 31, 2003	F-23
Notes to Unaudited Pro Forma Condensed Consolidated Financial Statements	F-24 – F-25
Page F-	

**INDEPENDENT ACCOUNTANTS' REPORT**

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

**We have audited the consolidated balance sheet of Chembio Diagnostic Systems Inc. and Subsidiary (the "Company") as of December 31, 2003 and the consolidated statements of operations, stockholders' equity and cash flows for the two years in the period ended December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.**

**We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.**

**In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Chembio Diagnostic Systems Inc. and Subsidiary as of December 31, 2003, and the consolidated results of its operations and its cash flows for the two years in the period ended December 31, 2003 in conformity with accounting principles generally accepted in the United States of America.**

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

**New York, New York  
February 27, 2004, except  
for Note 12, the date of  
which is March 19, 2004**

Page F-



**CHEMBIO DIAGNOSTIC SYSTEMS INC. AND SUBSIDIARY**  
**CONSOLIDATED BALANCE SHEETS**  
**AS OF:**

**—ASSETS (Note 5)—**

	Mar. 31, 2004	Dec. 31, 2003
	<u>                    </u>	<u>                    </u>
<b>CURRENT ASSETS:</b>	<b>(unaudited)</b>	
Cash	\$ 447,300	\$ —
Accounts receivable, net of allowance for doubtful accounts of \$17,034 and \$15,231 for March 31, 2004 and December 31, 2003, respectively (Note 11)	278,205	282,734
Inventories (Note 3)	499,820	466,498
Prepaid expenses and other current assets	52,125	23,448
	<u>                    </u>	<u>                    </u>
<b>TOTAL CURRENT ASSETS</b>	<b>1,277,450</b>	<b>772,680</b>
	<u>                    </u>	<u>                    </u>
<b>FIXED ASSETS—(Notes 4 and 6)</b>	<b>244,997</b>	<b>249,247</b>
	<u>                    </u>	<u>                    </u>
<b>OTHER ASSETS:</b>		
Deposits	55,290	55,723
Other assets	134,206	9,095
	<u>                    </u>	<u>                    </u>
	<u>                    </u>	<u>                    </u>
	<b>\$ 1,711,943</b>	<b>\$ 1,086,745</b>
	<u>                    </u>	<u>                    </u>

**—LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)—**

<b>CURRENT LIABILITIES:</b>		
Bank overdraft	\$ —	\$ 67,434
Accounts payable and accrued liabilities (Note 2(p) and Note 11)	1,387,639	1,361,547
Current portion of obligations under capital leases (Note 6)	61,162	61,789
Other current liabilities	12,648	12,648
	<u>                    </u>	<u>                    </u>
<b>TOTAL CURRENT LIABILITIES</b>	<b>1,461,449</b>	<b>1,503,418</b>
	<u>                    </u>	<u>                    </u>
<b>OTHER LIABILITIES:</b>		
Notes payable—net of current portion (Note 5 and 12)	2,693,851	1,693,851
Obligations under capital leases—net of current portion (Note 6)	90,000	107,885
Accrued interest (Note 5)	289,743	239,032
	<u>                    </u>	<u>                    </u>
<b>TOTAL LIABILITIES</b>	<b>4,535,043</b>	<b>3,544,186</b>
	<u>                    </u>	<u>                    </u>

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

**STOCKHOLDERS' EQUITY (DEFICIENCY) (NOTES 9 AND 10):**

Common stock—\$.001 par value; 55,000 shares authorized: 40,000 and 38,395 shares issued and outstanding as of March 31, 2004 and December 31, 2003, respectively	40	39
Additional paid-in capital	4,664,190	4,599,962
Accumulated deficit	(7,487,330)	(7,057,442)
	<u>                    </u>	<u>                    </u>
	<u>                    </u>	<u>                    </u>
	<b>(2,823,100)</b>	<b>(2,457,441)</b>
	<u>                    </u>	<u>                    </u>
	<u>                    </u>	<u>                    </u>
	<b>\$ 1,711,943</b>	<b>\$ 1,086,745</b>
	<u>                    </u>	<u>                    </u>

**CHEMBIO DIAGNOSTIC SYSTEMS INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**FOR THE THREE MONTHS ENDED MARCH 31, 2004 AND 2003**  
**(UNAUDITED)**

	2004	2003
<b>REVENUES:</b>		
Net sales (Notes 2(n) and 11)	\$ 493,970	\$ 720,077
Research grants and development income (Note 7)	91,342	—
	585,312	720,077
Cost of sales (Note 11)	445,923	616,766
<b>GROSS PROFIT</b>	<b>139,389</b>	<b>103,311</b>
<b>OVERHEAD COSTS:</b>		
Research and development expenses	112,095	85,262
Selling, general and administrative expenses	401,436	304,362
<b>LOSS FROM OPERATIONS</b>	<b>(374,142)</b>	<b>(286,313)</b>
<b>OTHER INCOME (EXPENSES):</b>		
Interest income (expense)—net of interest income of \$97 and \$0 for the three months ended 3/31/04 and 3/31/03 respectively	(55,746)	(47,223)
<b>LOSS BEFORE INCOME TAXES</b>	<b>(429,888)</b>	<b>(333,536)</b>
Income taxes (Note 8)	—	—
<b>NET LOSS</b>	<b>\$ (429,888)</b>	<b>\$ (333,536)</b>
<b>Pro forma basic and diluted loss per share</b> (Note 13)	<b>(11.04)</b>	<b>(8.69)</b>
<b>Weighted number of shares outstanding</b> (Note 13)	<b>38,930</b>	<b>38,395</b>

**CHEMBIO DIAGNOSTIC SYSTEMS INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**FOR THE YEARS ENDED DECEMBER 31, 2003 AND 2002**

	2003	2002
<b>REVENUES:</b>		
Net sales (Notes 2(n) and 11)	\$ 2,542,621	\$ 2,810,852
Research grants and development income(Note 7)	275,730	324,287
	<b>2,818,351</b>	<b>3,135,139</b>
Cost of sales (Note 11)	2,153,454	2,458,596
<b>GROSS PROFIT</b>	<b>664,897</b>	<b>676,543</b>
<b>OVERHEAD COSTS:</b>		
Research and development expenses	313,891	378,089
Selling, general and administrative expenses	1,202,185	1,154,799
<b>LOSS FROM OPERATIONS</b>	<b>(851,179)</b>	<b>(856,345)</b>
<b>OTHER INCOME (EXPENSES):</b>		
Interest income (expense) – net of interest income of \$7 and \$175 for years ended 12/31/03 and 12/31/02 respectively	(208,525)	(132,626)
<b>LOSS BEFORE INCOME TAXES</b>	<b>(1,059,704)</b>	<b>(988,971)</b>
Income taxes (Note 8)	-	-
<b>NET LOSS</b>	<b>\$ (1,059,704)</b>	<b>\$ (988,971)</b>
<b>Pro forma basic and diluted loss per share</b> (Note 13)	<b>(27.60)</b>	<b>(29.45)</b>
<b>Weighted number of shares outstanding</b> (Note 13)	<b>38,395</b>	<b>33,581</b>

**CHEMBIO DIAGNOSTIC SYSTEMS INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)**  
**FOR THE THREE MONTHS ENDED MARCH 31, 2004 (Unaudited).**  
**AND THE YEARS ENDED DECEMBER 31, 2003 AND 2002**

	Common stock		Additional paid-in capital Shares	Treasury stock		Accumulated Deficit	Total
	Shares	Amount			Amount		
Balance at January 1, 2001	28,766	\$29	\$4,296,971	(2,221)	\$(232,000)	\$(5,008,767)	\$(943,767)
Common stock issued	178	-	100,000	-	-	-	100,000
Common stock issued as a result of a private placement	11,672	12	434,989	-	-	-	435,001
Retirement of treasury stock	(2,221)	(2)	(231,998)	2,221	232,000	-	-
Net loss	-	-	-	-	-	(988,971)	(988,971)
Balance at December 31, 2002	38,395	39	4,599,962	-	-	(5,997,738)	(1,397,737)
Net loss	-	-	-	-	-	(1,059,704)	(1,059,704)
Balance at December 31, 2003	38,395	39	4,599,962	-	-	(7,057,442)	(2,457,441)
Common stock issued	1,605	1	64,228	-	-	-	64,229
Net loss	-	-	-	-	-	(429,888)	(429,888)
Balance at March 31, 2004 (Unaudited)	40,000	\$40	\$4,664,190	-	\$ -	\$(7,487,330)	\$(2,823,100)

**CHEMBIO DIAGNOSTIC SYSTEMS INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**FOR THE THREE MONTHS ENDED MARCH 31, 2004 AND 2003**  
**(UNAUDITED)**

	2004	2003
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (429,888)	\$ (333,536)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	18,150	19,087
Provision for doubtful accounts	1,803	4,053
Stock issued as compensation	64,229	-
Changes in:		
Accounts receivable	2,726	(112,234)
Inventories	(33,322)	42,502
Prepaid expenses and other current assets	(28,677)	(1,784)
Other assets and deposits	(124,678)	(5,373)
Accounts payable and accrued expenses	76,803	192,508
Grant and other current liabilities	-	648
<b>Net cash used in operating activities</b>	<b>(452,854)</b>	<b>(194,129)</b>
<b>CASH FLOWS USED IN INVESTING ACTIVITIES:</b>		
Acquisition of fixed assets	(13,900)	-
<b>Net cash used in investing activities</b>	<b>(13,900)</b>	<b>-</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Bank overdraft	(67,434)	43,728
Repayment of capital lease obligation	(18,512)	(2,770)
Proceeds from loans	1,000,000	125,000
<b>Net cash provided by financing activities</b>	<b>914,054</b>	<b>165,958</b>
<b>NET INCREASE (DECREASE) IN CASH</b>	<b>447,300</b>	<b>(28,171)</b>
Cash—beginning of the period	-	28,171
<b>CASH—end of the period</b>	<b>\$ 447,300</b>	<b>\$ -</b>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid during the period for interest	\$ -	\$ -
<b>Supplemental disclosures for non-cash investing and financing activities:</b>		
Fixed assets acquired under capital leases	\$ -	\$ 28,897

**CHEMBIO DIAGNOSTIC SYSTEMS INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**FOR THE YEARS ENDED DECEMBER 31, 2003 AND 2002**

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

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

CHEMBIO DIAGNOSTIC SYSTEMS INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED STATEMENTS (INFORMATION AS OF AND FOR THE THREE MONTHS ENDED MARCH 31, 2004 AND 2003 IS UNAUDITED)

NOTE 1 — DESCRIPTION OF BUSINESS/OPERATIONS:

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

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern. The Company has sustained significant operating losses in past years and at December 31, 2003 has a negative shareholders' equity of \$2,457,441. The Company has completed a reverse merger with a public shell and has entered into other bridge financing transactions (see Note 12).

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES:

*(a) Principles of Consolidation:*

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

*(b) Inventories:*

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

*(c) Fixed Assets:*

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

*(d) Use of Estimates:*

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

*(e) Income Taxes:*

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

*(f) Research and Development:*

Research and development costs are charged to expense as incurred.

*(g) Stock Based Compensation:*

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

*(h) Statement of Cash Flows:*

For purposes of the statements of cash flows the Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents.

*(i) Revenue Recognition:*

The Company recognizes revenue in accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 101, "Revenue Recognition" ("SAB 101"). Under SAB 101, revenue is recognized when there is persuasive evidence of an arrangement, delivery has occurred or Services have been rendered, the sales price is determinable, and collectibility is reasonably assured. Revenue typically is recognized at time of shipment. Sales are recorded net of discounts, rebates and returns.

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

*(j) Comprehensive Income:*

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

*(k) Concentrations of Credit Risk:*

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

*(l) Fair Value:*

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

*(m) Recent Accounting Pronouncements:*

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

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

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

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

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

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

*(n) Geographic Information:*

In June 1997, FASB issued SFAS No. 131, “Disclosures about Segments of an Enterprise and Related Information”. SFAS 131 establishes standards for the way that business enterprises report information about operating segments in annual financial statements and requires that those enterprises report selected information. It also establishes standards for related disclosures about product and services, geographic areas, and major customers. SFAS 131 was effective for financial statements for fiscal years beginning after December 15, 1997.

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



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

	Three Months Ended March 31,		Year Ended December 31,	
	2004	2003	2003	2002
USA	\$ 152,472	\$ 199,761	\$ 655,964	\$ 832,341
Brazil	120,000	-	3,930	16,846
Costa Rica	39,220	36,950	126,063	95,653
Canada	32,677	81,680	445,412	383,109
Saudi Arabia	23,076	5,950	50,577	56,978
Japan	15,000	26,649	116,111	277,637
Venezuela	12,000	-	55,424	147,552
France	10,865	6,612	50,166	38,420
Australia	10,375	8,130	25,195	21,773
Austria	1,163	9,453	72,684	82,634
India	10,252	56,711	79,052	84,692
Italy	-	37,586	294,676	138,981
Mexico	-	115,000	186,130	1,887
Korea	4,212	30,469	104,434	111,453
Others	62,658	105,126	276,803	520,896
	<u>\$ 493,970</u>	<u>\$ 720,077</u>	<u>\$ 2,542,621</u>	<u>\$ 2,810,852</u>

*(o) Interim Financial data:*

The interim financial data is unaudited. However, in the opinion of management, the interim data includes all adjustments (consisting of normal recurring accruals or adjustments only) necessary to present fairly the results of the interim periods. The results for the interim periods are not necessarily indicative of the results to be obtained for the entire year.

*(p) Accounts payable and accrued liabilities*

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

	as of	
	March 31, 2004	December 31, 2003
Accounts Payable – Suppliers	1,054,892	1,027,252
Accrued Payroll	131,852	119,236
Accrued Commissions and Royalties	96,779	80,927
Accrued Payroll and other taxes	47,040	41,737
Accrued Legal and Accounting	45,997	81,315
Accrued Expenses – other	11,079	11,079
<b>TOTAL</b>	<b>1,387,639</b>	<b>1,361,547</b>

**NOTE 3 — INVENTORY:**

Inventory consists of the following at:

	Mar. 31, 2004	Dec. 31, 2003
Raw materials	\$408,669	\$379,079
Work-in-progress	67,543	73,319
Finished goods	23,608	14,100
	<u>\$499,820</u>	<u>\$466,498</u>

**NOTE 4 — FIXED ASSETS:**

Fixed assets consist of the following at:

	Mar. 31, 2004	Dec. 31, 2003
Machinery and equipment	\$651,869	\$637,969
Furniture and fixtures	53,329	53,329
Computer and telephone equipment	81,678	81,678
Leasehold improvements	34,566	34,566

Tooling	41,900	41,900
	863,342	849,442
Less accumulated depreciation and amortization	(618,345)	(600,195)
	\$244,997	\$249,247

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

**NOTE 5 — LONG-TERM DEBT:**

Long-term debt is comprised of the following:

\$707,914 of Senior Notes bearing interest at 11% were issued in 1999 in connection with a debt restructuring. The Senior Notes are collateralized by a first lien on all of the assets of the Company. Holders of these Notes were also granted warrants to purchase an aggregate of 1,410 shares of common stock at \$180 per share. The aggregate fair value of the warrants was \$10,000, of which \$7,000 was related to the debt refinancing and is being amortized over the term of the loan. \$3,000 of the fair value of the warrants are related to the conversion of debt to equity. As of December 31, 2003 and 2002, the outstanding principal balance of the Senior Notes was \$707,914 with accrued unpaid interest of \$92,379 and \$14,508, respectively.

Per a waiver agreement dated July 10, 2002, the senior note holders agreed to extend the Company's required first principal payment until July 31, 2003 provided that the Company pay the balance of accrued and unpaid interest on or before August 31, 2002 and remain current on interest payments due during the period from September 1, 2002 through July 31, 2003. Current interest payments were not maintained nor was the first principal payment made when it became due on July 31, 2003. However, no acceleration or event of default has been claimed on these Notes and, as described in Note 12, this debt will be converted to equity unless the Board of Directors chooses to refinance or otherwise retire this debt. Accordingly the entire amount of this debt has been classified as Long Term.

Per a line of credit agreement dated April 2001, a major shareholder agreed to advance the Company up to a maximum principal amount of \$350,000. This amount was later increased to \$1,200,000. The line of credit is collateralized by a subordinated security interest in all of the assets of the Company. In consideration for the above, the Company agreed to repay such borrowed funds on a quarterly basis with accrued interest at 12% per annum, starting September 30, 2003, with a final payment due March 31, 2005, at a maximum quarterly payment of \$43,750. As of December 31, 2003 and 2002, the principal amount of the advance was \$985,937 and \$620,663, respectively with additional accrued interest of \$146,653 and \$44,434, respectively. Current payments were not being made however, no acceleration or event of default has been claimed on these Notes and as described above and in Note 12, the entire amount of this debt has been classified as long term.

**NOTE 6 — OBLIGATIONS UNDER CAPITAL LEASES:**

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

Future minimum lease payments under these capitalized lease obligations, including interest as of December 31, 2003 were as follows:

Year ending December 31,

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

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

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

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

- In 2002, \$215,118 was received from the US National Institute of Health and \$50,000 was received from a diversified Japanese health care company, both in connection with efforts to develop a rapid test for the detection of antibodies to tuberculosis in human whole blood, serum and plasma. Also in 2002, \$20,000 was received from a major university dental school to conduct a feasibility study on certain reagents related to dental bacteria in order to evaluate a possible future test. Additional amounts received in 2002 for various grant projects totaled \$39,170.
- In 2003 the Company received the following new research and development grants and contracts that are still ongoing for additional amounts in 2004.
  - \$40,000 from a leading multinational dental products company in connection with additional product development efforts begun through the above-mentioned university partner in 2002.
  - \$60,000 from a leading multinational company in the field of bovine spongiform encephalitis (BSE or mad cow disease) for development of a rapid test for BSE.
  - \$50,000 for additional development work from the above-mentioned diversified Japanese health care company for further development work on the tuberculosis product for the Japanese market.
  - \$89,000 from a research foundation focused on tuberculosis vaccines and diagnostics in connection with the commencement of a Phase II National Institute of Health grant sub-contract awarded in September 2003 for development of a whole blood rapid test for detection of tuberculosis in monkeys primarily for use in pharmaceutical research facilities.
  - Approximately \$36,000 in various other funded development for the rapid detection of tuberculosis in humans and animals.
- Additionally, in November 2003, the Company received notice of a \$100,000 grant award from the World Health Organization to develop a tuberculosis antigen detection test. However no funds were received for this award in 2003.

**NOTE 8 — INCOME TAXES:**

At March 31, 2004 and December 31, 2003, the Company has net operating loss carryforwards of approximately \$7,000,000 and \$6,800,000 available to offset future federal taxable income, which expires at various dates through 2024 and a research and development credit carryforward of approximately \$214,000, which have created net deferred tax assets. A full valuation allowance, which increased by \$79,800 during the first quarter of 2004 and \$490,600 during 2003, has been provided due to management's uncertainty as to the reliability of these deferred tax assets.

Deferred tax assets consist of the following at:

	Mar. 31, 2004	Dec. 31, 2003
Net operating loss carryforwards	\$2,870,000	\$2,791,000
Research and development credit	214,000	214,000
Bad debt reserve	7,000	6,200
Gross deferred tax assets	3,091,000	3,011,200
Valuation allowance	(3,091,000)	(3,011,200)
Net deferred tax assets	\$—	\$—

**NOTE 9 — STOCKHOLDERS' EQUITY:**

As of March 1, 2004 the Company issued approximately 1,605 shares of common stock of the Company to employees as compensation prior to the completion of the merger ( see note 12) at a price of \$40 per share.

On March 13, 2004 the Company issued 240 options as part of a consulting agreement. The exercise price for these options is \$60 per share.

At March 31, 2004 and December 31, 2003 and 2002, the Company had 1,400 warrants outstanding at an exercise price of \$180 per share, which were issued in connection with the restructuring of debt (see Note 5).

During 2002, the Company sold 11,850 shares of common stock at an average price of \$45.14 per share and raised approximately \$535,000. \$435,000 of this amount was in a rights offering to shareholders of record as of June 30, 2002 in which shares were sold at a price of \$37.27 per share.

During 2002, the Company retired 2,221 shares of common stock that had been previously repurchased for \$232,000.

**NOTE 10 — EMPLOYEE STOCK OPTION PLAN:**

In November 1999, the Company's Board of Directors and stockholders adopted the 1999 Stock Option Plan (the "Plan"). Under the terms of this plan, the 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 2,500 shares of common stock, exercisable at no amount less than fair market value on the date of grant. The options become exercisable at such times and under such conditions as determined by the Option Committee. On April 18, 2002, the Plan was amended to increase to a maximum of 5,000 options to be granted under the Plan.

The Company has elected to account for its stock-based compensation plans using APB 25.

The fair value of option grants to date was estimated on the date of grant using a Black-Scholes option-pricing model with weighted average assumptions for the years ended December 31, 2003: risk free interest rate of 3.23% volatility of 0.01%; and expected life of 3½ years, respectively. No options were issued during the year ended December 31, 2002.

Proforma information for the years ended December 31, 2003 and 2002 is not presented since compensation expenses calculated using the Black-Scholes option pricing model are immaterial.

Stock incentive plan activity is summarized as follows:

	Number of shares	Weighted Average Exercise Price
Options outstanding at December 31, 2002	3,150	\$312
Granted	500	45
Canceled	—	—
Exercised	—	—
Options outstanding at December 31, 2003	3,650	275
<b>Granted</b>	<b>240</b>	<b>60</b>
<b>Canceled</b>	<b>—</b>	<b>—</b>
<b>Exercised</b>	<b>—</b>	<b>—</b>
<b>Options outstanding at March 31, 2004</b>	<b>3,890</b>	<b>\$262</b>
Options exercisable at December 31, 2003	1,975	—
Options exercisable at March 31, 2004	2,250	

Range of Exercise Prices	Options Outstanding at 12/31/03	Weighted Average Remaining Life	Weighted Average Exercise Price	Options Exercisable at 12/31/03	Weighted Average Exercise Price
\$217—300	1,925	2.8	\$281	1,925	\$275
\$300—400	1,225	3.6	\$349	50	\$400
\$45	500	6.9	\$45	—	—

Of the 3,890 options outstanding at March 31, 2004 pursuant to the 1999 stock option plan, 3,450 are exercisable three years from the grant date and all have a seven-year life.

#### NOTE 11 — COMMITMENTS AND CONTINGENCIES:

##### *Obligations Under Operating Leases:*

The Company leases office space at three locations in buildings located at 3661 Horseback Road, Medford, New York. The following is a schedule of future minimum rental commitments as of December 31, 2003:

Year ending December 31,

2004	\$	89,792
2005		28,896
	\$	118,688

Rent expense associated with these leases for the following periods:

	Three Months Ended March 31,		Year Ended December 31,	
	2004	2003	2003	2002
Rent	\$21,000	\$22,732	\$90,693	\$85,949

##### *Economic Dependency:*

The Company had sales to one customer in excess of 10% of total sales in the three months ended March 31, 2004. Sales to this customer aggregated approximately \$120,000. Accounts receivable from this customer at March 31, 2004 was \$0.

The Company had sales to one customer in excess of 10% of total sales in the three months ended March 31, 2003. Sales to this customer aggregated approximately \$115,000. Accounts receivable from this customer at March 31, 2003 was \$0.

The Company had sales to two customers in excess of 10% of total sales in the year ended December 31, 2003. Sales to these customers aggregated approximately \$397,000 and \$292,000, respectively. Accounts receivable from these customers were \$38,334 and \$13,101, respectively at December 31, 2003.

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

The Company had purchases from four vendors in excess of 10% of total purchases for the three months ended March 31, 2004. Purchases from these vendors aggregated approximately \$21,753, \$20,730, \$20,140 and \$18,801. The corresponding accounts payable at March 31, 2004 to these vendors was \$2,123, \$0, \$8,491 and \$20.

The Company had no purchases from any vendor in excess of 10% of total purchases for the three months ended March 31, 2003.

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

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

NOTE 12 — OTHER EVENTS:

*Merger:*

On March 3, 2004, the Company entered into a merger agreement with Trading Solutions.com ("TSCO") a fully reporting non operating entity under SEC regulations. TSLU is traded on the OTC Bulletin Board. As conditions to the closing, the Company must complete a Convertible Notes financing of \$1.0 million, complete a Convertible Preferred Stock financing for at least \$1.5 million, complete its audited financial statements for the two years ended December 31, 2003, and have converted at least \$1.3 million of its secured debt into the same securities as are being issued in the aforementioned Convertible Preferred Stock financing that is being finalized. As a result of the contemplated transaction, the Company shareholders will own a minimum of 50.6% of the public company (including the conversion of at least \$1.3 million of existing secured debt into the Convertible Preferred Stock on an as-converted basis). This percentage would increase to the extent existing Company shareholders participate in either of the two financings mentioned above and as a result of the conversion of at least \$1.3 million of debt.

*Convertible Notes Financing:*

A \$1.0 million Convertible Notes financing was completed as of March 19, 2004. The investors paid \$800 per debenture for a convertible note which matures in twelve months and accrues interest at the rate of 10% per annum. Upon the closing of the reverse merger summarized above, the notes will automatically convert into either: (1) such number of shares of common stock equal to the outstanding principal amount of the Convertible Notes (plus, at the holders option, all accrued and unpaid interest) divided by the conversion price which was set at \$0.40; or (2) 150% of the amount of securities that the outstanding principal amount of the Convertible Notes (plus, at the holders option, all accrued and unpaid interest) would purchase in the \$1.5 million Convertible Preferred Stock financing that is being finalized and that is the principal remaining condition to the closing of the merger. The Convertible Notes are unsecured. Holders of the Convertible Notes have a right of first refusal to participate in any equity or equity linked private financing consummated within 12 months of the closing of the Convertible note Financing.

As a result of the completion of the Convertible Notes financing and the completion of the audited financial statements for 2002 and 2003, the only remaining conditions to the closing of the merger are the (1) completion of at least an additional \$1.5 million of financing; and, (2) existing note holders representing at least \$1.3 million of the approximately \$2.0 million of outstanding secured obligations (at December 31, 2003) must have agreed to convert their debt into the Convertible Preferred Stock being issued in connection with the \$1.5 million financing. Since the Company has now completed the Convertible Note Financing and the Company and an investor has executed a term sheet for the \$1.5 million Convertible Preferred stock financing, this \$1.3 million of debt was classified as long-term on the accompanying balance sheet. Since the remaining \$700,000 of secured debt is to be converted on the same basis if it is not retired by December 31, 2004, it has also been reflected as long-term (see Note 5).

*Placement Agent Agreement:*

On February 9, 2004 and then amended on February 27, 2004, the Company engaged a placement agent for the period through April 30, 2004 in connection with the \$1.5 million financing to be completed as a condition to the merger agreement detailed above. If the placement agent is successful in the \$1.5 million financing the Company agrees to enter into an exclusive six month agreement whereby the placement agent will participate in an additional private placement for up to \$4.0 million in securities. The placement agent will receive as fees for the initial private placement: (a) 8% of the amount of cash received by the Investors introduced to the Company by the placement agent. (b) a non accountable 2% cash allowance of the amount of cash received by the Company from Investors introduced by the placement agent. (c) Warrants to purchase such a number of shares of common stock of the Company equal to 12.5% of the aggregate number of fully diluted and/or converted shares as are purchased by the Investors in the \$1.5 million dollar offering. The warrants will have a five year life and be exercisable at 120% of the

effective share price paid by the Investors in the offering. The placement fees for the \$4.0 million dollar offering would be the same as described above.

*Amendment of Articles of Incorporation:*

On February 19, 2004, the Board of Directors of the Company voted to amend its articles of incorporation to increase the authorized shares to 55,000. In addition, the Board also authorized an increase in the amount of shares authorized for issuance under the 1999 stock option plan to 15,000. Shareholder approval was obtained for each of the above effective February 19, 2004.

*Litigation:*

The Company filed a complaint in the United States District Court for the Eastern District of New York against Saliva Diagnostic Systems, Inc. Saliva Diagnostic is the assignee of patent #5,935,864 (“the ‘864 patent”) that describes a method for collecting samples. The complaint asks the court for declaratory and other relief that the Company’s Sure Check™ HIV test does not infringe the ‘864 patent, that the ‘864 patent is invalid, and that the ‘864 patent is unenforceable due to inequitable procurement. In 2001 and 2002, pursuant to various agreements it had entered into with Saliva Diagnostic, the Company developed, manufactured and sold an HIV rapid test that Saliva Diagnostic had represented incorporates the sample collection method described in the ‘864 patent. Saliva Diagnostic also represented that the ‘86 4 patent is valid. During 2001-2003, the Company paid royalties to Saliva Diagnostic and took several other actions based upon Saliva Diagnostic’s representations. In 2003, Saliva Diagnostic sought to abrogate the agreements between the companies and alleged that the Company was infringing the ‘864 patent. The Company has received opinions from its patent counsel that the product manufactured by the Company is in fact not covered by this patent, that the patent is invalid, and that the patent was obtained through inequitable procurement. On March 17, 2004, allegations of patent infringement were made against the company with which the Company has signed a merger agreement, Trading Solutions.com. The Company filed the complaint on March 18, 2004.

**NOTE 13 – LOSS PER SHARE**

*Computation of pro forma per share loss*

Basic loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted loss per share reflects the potential dilution from the exercise or conversion of other securities into common stock, but only if dilutive. Diluted loss per share for 2003 and 2002 is the same as basic loss per share, since the effects of the calculation were anti-dilutive. The following securities, presented on a common share equivalent basis, have been excluded from the per share computations:

	Three Months Ended March 31,		Year Ended December 31,	
	2004	2003	2003	2002
Stock Options	3,890	3,150	3,650	3,150
Warrants	1,400	1,400	1,400	1,400
Convertible Debt	25,000,000	-	-	-

**CHEMBIO DIAGNOSTICS, INC.**  
**(f/k/a Trading Solutions.com)**  
**INTRODUCTION TO CONDENSED CONSOLIDATED PROFORMA FINANCIAL STATEMENTS**  
**(Unaudited)**

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

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

**CHEMBIO DIAGNOSTICS, INC.**  
**(formerly Trading Solutions.com)**  
**CONDENSED CONSOLIDATED PRO FORMA BALANCE SHEET**  
**AS OF MARCH 31, 2004**  
**(Unaudited)**

	HISTORICAL		PROFORMA ADJUSTMENTS		
	Trading Solutions.Com, Inc.	Chembio Diagnostic Systems, Inc.	Debit	Credit	Consolidated Proforma
<b>CURRENT ASSETS:</b>					
Cash	\$—	\$447,300	\$2,200,000 (b)	300,000 (c) 1,976 (d)	\$2,345,324
Accounts receivable	—	278,205			278,205
Inventories	—	499,820			499,820
Prepaid expenses and other current assets	—	52,125	226,667 (h)		278,792
<b>TOTAL CURRENT ASSETS</b>	<b>—</b>	<b>1,277,450</b>			<b>3,402,141</b>
<b>FIXED ASSETS</b>	<b>—</b>	<b>244,997</b>			<b>244,997</b>
<b>OTHER ASSETS</b>	<b>—</b>	<b>189,496</b>	113,333 (h)	119,110 (d)	183,719
	\$—	\$1,711,943			\$3,830,857
<b>CURRENT LIABILITIES:</b>					
Accounts payable and accrued liabilities	—	1,387,639			\$1,387,639
Current portion of obligations under capital leases	—	61,162			61,162
Other current liabilities	—	12,648	11,781 (d)	9,371 (d)	10,238
<b>TOTAL CURRENT LIABILITIES</b>	<b>—</b>	<b>1,461,449</b>			<b>1,459,039</b>
<b>OTHER LIABILITIES:</b>					
Notes payable	—	2,693,851	1,332,292 (e) 1,000,000 (d)		361,559
Accrued interest		289,743			289,743
Obligations under capital leases— net of current portion	—	90,000			90,000
<b>TOTAL LIABILITIES</b>	<b>—</b>	<b>4,535,043</b>			<b>2,200,341</b>
<b>STOCKHOLDERS' EQUITY (DEFICIENCY):</b>					
Series A Preferred Stock				2,200,000 (b) 679,107 (d) 1,332,292 (e)	4,211,399
Common stock	10,632	40	40 (a)	40,000 (a) 657 (d) 8,267 (e) 4,000 (g)	63,556
Additional paid-in capital	378,980	4,664,190	39,960 (a) 300,657 (c) 119,110 (d) 389,612 (f)	322,431 (d) 156,000 (g) 340,000 (h)	5,012,262
Accumulated deficit	(389,612)	(7,487,330)	160,000 (g)	389,612 (f)	(7,656,701)
			9,371 (d)		



Total Equity (Deficit)	—	(2,823,100)		1,630,516
	\$—	\$1,711,943	5,902,823	5,902,823\$3,830,857

CHEMBIO DIAGNOSTICS, INC.  
(formerly Trading Solutions.com)  
CONDENSED CONSOLIDATED PRO FORMA STATEMENTS OF OPERATIONS  
FOR THE THREE MONTHS ENDED MARCH 31, 2004  
(Unaudited)

	HISTORICAL		PROFORMA ADJUSTMENTS		
	Trading Solutions.Com, Inc.	Chembio Diagnostic Systems, Inc.	Debit	Credit	Consolidated Pro forma
<b>REVENUES:</b>					
Net sales	\$—	\$493,970			\$493,970
Grant income		—91,342			91,342
		—585,312			585,312
Cost of sales		—445,924			445,924
<b>GROSS PROFIT</b>		— 139,388			139,388
<b>OVERHEAD COSTS:</b>					
Research and development expenses		—112,095			112,095
Clinical Trials					
Selling, general and administrative expenses			56,667 (h)		
		19,920401,436	42,500 (k)		520,523
<b>LOSS FROM OPERATIONS</b>		(19,920)(374,143)			(493,230)
<b>OTHER INCOME (EXPENSES):</b>					
Gain from debt settlement		—			
Interest(expense)		—(55,743)		38,518 (i)	(17,228)
<b>LOSS BEFORE INCOME TAXES</b>		(19,920)(429,889)			(510,458)
Income taxes		— —			—
<b>NET LOSS</b>	<b>\$(19,920)</b>	<b>\$(429,889)</b>			<b>\$(510,458)</b>
<b>PRO FORMA DIVIDEND PAYABLE</b>			(90,948)(j)		\$(90,948)
<b>NET LOSS AVAILABLE TO COMMON SHAREHOLDERS</b>					<b>\$(601,406)</b>
<b>Basic and Diluted Loss per share</b> (Shares used for calculation 6,417,908)					<b>\$(.09)</b>



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

	HISTORICAL		PROFORMA ADJUSTMENTS		
	Trading Solutions.Com, Inc.	Chembio Diagnostic Systems, Inc.	Debit	Credit	Consolidated Pro forma
<b>REVENUES:</b>					
Net sales	\$—	\$2,542,621			\$2,542,621
Grant income	—	275,730			275,730
					2,818,351
Cost of sales	—	2,153,454			2,153,454
					664,897
<b>GROSS PROFIT</b>	—	<b>664,897</b>			<b>664,897</b>
<b>OVERHEAD COSTS:</b>					
Research and development expenses	—	313,891			313,891
Clinical Trials					
Selling, general and administrative expenses			226,667 (h)		
	7,123	1,202,185	170,000 (k)		1,605,975
<b>LOSS FROM OPERATIONS</b>	<b>(7,123)</b>	<b>(851,179)</b>			<b>(1,254,969)</b>
<b>OTHER INCOME (EXPENSES):</b>					
Gain from debt settlement	8,513				8,513
Interest(expense)	—	(208,525)		154,070 (i)	(54,455)
<b>LOSS BEFORE INCOME TAXES</b>	<b>1,390</b>	<b>(1,059,704)</b>			<b>(1,300,911)</b>
Income taxes	—	—			—
<b>NET LOSS</b>	<b>\$1,390</b>	<b>\$(1,059,704)</b>			<b>\$(1,300,911)</b>
<b>PRO FORMA DIVIDEND PAYABLE</b>			(363,792) (j)		<b>\$(363,792)</b>
<b>NET LOSS AVAILABLE TO COMMON SHAREHOLDERS</b>					<b>\$(1,664,703)</b>
<b>Basic and Diluted Loss per share</b> (Shares used for calculation 6,417,908)					<b>\$(.26)</b>

CHEMBIO DIAGNOSTICS, INC.  
(formerly Trading Solutions.com)  
NOTES TO UNAUDITED PRO FORMA CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2004 AND DECEMBER 31, 2003  
(Unaudited)

On May 5, 2004, TSLU and Systems closed on a merger agreement, which will result in Systems being a wholly owned subsidiary of TSLU, with Systems as the operating Company. The pro forma Balance Sheet assumes the transaction occurred on the balance sheet and the pro forma Statement of Operations assumes the transaction occurred as of the first day of the earliest period presented. The pro forma adjustments reflecting this transaction are described below:

- a. Share exchange of 100 shares of TSLU common stock for each share of issued and outstanding stock of Systems. (4,000,000 shares issued in TSLU in exchange for 40,000 shares of Systems). Existing shareholders of Systems also received an
- b. Receipt of \$2,200,000 as a result of the sale of Series A Convertible Preferred Stock with warrants. This Preferred Stock has a \$30,000 per share stated value and an 8% dividend per annum, payable semi-annually in cash, common stock or in kind at the option of the Company. The Preferred Stock shall be convertible at \$0.60 per share and has a mandatory conversion if beginning 180 days after closing, the closing bid price of the Company's common stock exceeds \$1.50 for a period of 10 consecutive trading days. The associated warrants (60,000 for each share of Preferred Stock) have a five-year term and an exercise price of \$0.90. The agreement includes several other provisions regarding lock-up periods, registration etc.
- c. Investment banking and legal fees associated with the Preferred Stock A offering are anticipated at \$300,000. Also, 65,667 shares of Common Stock were issued as fees associated with the Preferred Stock A offering. In addition warrants were issued to the investment bankers totaling 12.5% of the fully diluted and/or converted shares as purchased in the preferred stock transaction.
- d. Reflects the conversion of \$672,000 of the convertible debt along with \$7,107 of accrued unpaid interest into Series A Convertible Preferred stock. The debt would be convertible into 33,836,82 shares of Preferred Stock. The remaining \$328,000 of the convertible debt along with \$2,698 of accrued unpaid interest was converted into Common stock. This remaining debt was converted into 826,741 shares of Common Stock. The total accrued and unpaid interest on the convertible debt was \$11,781, of which \$9,371 was not accrued as of March 31, 2004. The balance of the interest (\$1,976) that was not converted to Common or Preferred Stock was paid in cash.
- e. Reflects the conversion of \$1,332,292 of pre-merger debt into Series A Convertible Preferred Stock. The conversion results in an additional 44,409,72 shares of Series A Preferred Stock being issued and outstanding.
- f. Elimination of TSLU accumulated deficit.
- g. Issuance of 400,000 shares of common stock, with restrictions as payment of salary to a former Officer of TSLU. This is reflected on the balance sheet as it has a continuing impact on the equity section; however it is not reflected in the statements of operation as it has no continuing impact on future operations.
- h. Issuances of warrants to purchase 850,000 shares of Common Stock were issued to the individual in (m) above, with restrictions as payment for future services. The total value of the warrants is \$340,000. The contract is for eighteen months therefore 3 months or \$56,667 and 12 months or \$226,667 was reflected in the March 31, 2004 and December 31, 2003 pro forma Statement of Operations respectively. In both the pro forma Balance Sheets the \$226,667 is reflected as other current assets and the balance (\$113,333) is reflected in Other Assets.
- i. Elimination of historical interest expense on converted debt reflected in note (k) above \$38,518 for the three months ended March 31, 2004 and \$154,070 for the twelve months ended December 31, 2003.
- j. The preferred stock pays an 8% dividend. The total number of outstanding shares of preferred stock is 151,580 shares at \$30,000 per share. Dividends therefore would be \$90,948 for the three months ended March 31, 2004 and \$363,792 for the twelve months ended December 31, 2003.
- k. In connection with the closing of the merger employment agreements were entered into. The expected additional salary expense is \$42,500 for the three months ended March 31, 2004 and \$170,000 for the twelve months ended December 31, 2003.

## PART II

### Information Not Required in Prospectus

#### Item 24. Indemnification of Directors and Officers

The articles of incorporation of Chembio Diagnostics, Inc. (the “Registrant”) provide for the indemnification of the directors, officers, employees and agents of the Registrant to the fullest extent permitted by the laws of the State of Nevada. Section 78.7502 of the Nevada General Corporation Law permits a corporation to indemnify any of its directors, officers, employees or agents against expenses actually and reasonably incurred by such person in connection with any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (except for an action by or in right of the corporation) by reason of the fact that such person is or was a director, officer, employee or agent of the corporation, provided that it is determined that such person acted in good faith and in a manner which he reasonably believed to be in, or not opposed to, the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful.

Section 78.751 of the Nevada General Corporation Law requires that the determination that indemnification is proper in a specific case must be made by (a) the stockholders, (b) the board of directors by majority vote of a quorum consisting of directors who were not parties to the action, suit or proceeding or (c) independent legal counsel in a written opinion (i) if a majority vote of a quorum consisting of disinterested directors is not possible or (ii) if such an opinion is requested by a quorum consisting of disinterested directors.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 (the “Act”) may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable.

#### Item 25. Other Expenses of Issuance and Distribution

We will pay all expenses in connection with the registration and sale of our common stock. The estimated expenses of issuance and distribution are set forth below.

Type of Expense	Amount
Registration Fees	\$4,230
Transfer Agent Fees	\$5,000
Costs of Printing and Engraving	\$2,000
Legal Fees	\$25,000
Accounting Fees	\$10,000
Total	\$46,230

#### Item 26. Recent Sales of Unregistered Securities

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

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

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

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

- i. *The Cash Offering.* A total of 73.33330 shares of series A preferred stock and warrants to acquire 4,400,000 shares of common stock at \$.90 per share were issued pursuant to the Cash Offering in May 2005 for total consideration of \$2,200,000. The Company relied on Regulation D promulgated under Section 4(2) of the Act and on Section 4(2) of the Act as the basis for its exemption from registration of this offering. Nine accredited and zero non-accredited investors received securities of the Company in the offering. All of the investors, including the non-accredited investors, were provided with an information statement meeting the informational requirements of Rule 502 (b)(2) of the Securities Act.

- ii. *The Bridge Conversion Offering.* On March 22, 2004, Chembio Diagnostic Systems completed a private placement (the “Bridge Financing”) of \$1,000,000 in face amount of Convertible Notes (the “Bridge Notes”). The Bridge Financing provided for the Bridge Note holders to elect whether to convert the Bridge Notes into shares of the Company’s series A preferred stock (together with warrants to acquire shares of the Company’s common stock) or into shares of the Company’s common stock at the effective time of the Merger. As a result, \$672,000 in principal amount of the Bridge Notes, together with accrued and unpaid interest, was converted into 33.83632 shares of the Company’s series A preferred stock (together with warrants to acquire an additional 2,030,217 shares of the Company’s common stock at \$.90 per share). The balance of the Bridge Financing, or \$328,000, was converted into 826,741 shares of the Company’s common stock. The Company relied on Regulation D promulgated under Section 4(2) of the Act and on Section 4(2) of the Act as the basis for its exemption from registration of this offering. 33 accredited and zero non-accredited investors received securities of the Company in the offering. All of the investors, including the non-accredited investors, were provided with an information statement meeting the informational requirements of Rule 502 (b)(2) of the Securities Act.
- iii. *The Existing Debt Exchange Offering.* Pursuant to the Existing Debt Exchange Offering, which was consummated at the effective time of the Merger, the Company issued 44,40972 shares of series A preferred stock and warrants to acquire 2,664,584 shares of common stock at \$.90 per share in exchange for the conversion of \$1,332,292 of Chembio Diagnostic Systems’ debt existing on its balance sheet as of December 31, 2003. 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. 11 accredited and zero non-accredited investors received securities of the Company in the offering. All of the investors, including the non-accredited investors, were provided with an information statement meeting the informational requirements of Rule 502 (b)(2) of the Securities Act.

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

Also in May, 2004, the Company issued 25,000 shares of common stock and options to acquire 75,000 shares of common stock with an exercise price of \$0.60 per share to a consultant for services performed. One-quarter of these options vested on July 1, 2004, and an additional one-quarter vests every six months until January 1, 2006. The Company also issued options to acquire 30,000 shares to a second consultant for services performed, of which 2,500 options vest each month beginning June 15, 2004 with an exercise price of \$1.00 per share.

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

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

## EXHIBITS

- 2.1(2) Agreement and Plan of Merger dated as March 3, 2004 (the “Merger Agreement”), by and among the Registrant, New Trading Solutions, Inc. (“Merger Sub”) and Chembio Diagnostic Systems Inc.
- 2.2(1) Amendment No. 1 to the Merger Agreement dated as May 1, 2004, by and among the Registrant, Merger Sub and Chembio Diagnostic Systems Inc.
- 3.1(2) Articles of Incorporation.
- 3.2(2) Certificate of Amendment to Articles of Incorporation.
- 3.3(2) Bylaws.
- 3.4(1) Amendment No. 1 to Bylaws dated May 3, 2004.
- 4.2(1) Certificate of Designation of the Relative Rights and Preferences of the series A convertible preferred stock of the Registrant.
- 4.3(1) Registration Rights Agreement, dated as of May 5, 2004, by and among the Registrant and the Purchasers listed therein.
- 4.4(1) Lock-Up Agreement, dated as of May 5, 2004, by and among the Registrant and the shareholders of the Registrant listed therein.
- 4.5(1) Form of Common Stock Warrant issued pursuant to the Stock and Warrant Purchase Agreement.
- 4.6(1) Form of \$.90 Warrant issued to Mark L. Baum pursuant to the Consulting Agreement dated as of May 5, 2004 between the Registrant and Mark L. Baum.
- 4.7(1) Form of \$.60 Warrant issued to Mark L. Baum pursuant to the Consulting Agreement dated as of May 5, 2004 between the Registrant and Mark L. Baum.
- 4.8 Form of Warrant issued to Placement Agents pursuant to the Series A Convertible Stock Private Placement
- 5.1(3) Opinion and Consent of Patton Boggs LLP.
- 10.1(1) Employment Agreement between the Registrant and Mark L. Baum dated as of May 5, 2004.
- 10.2(3) Employment Agreement between the Registrant and Lawrence A. Siebert dated as of May 5, 2004.
- 10.3(3) Employment Agreement between the Registrant and with Avi Pelossof dated as of May 5, 2004.
- 10.4(3) Employment Agreement between the Registrant and with Javan Esfandiari dated as of May 5, 2004.
- 10.5(1) Series A Convertible Preferred Stock and Warrant Purchase Agreement (the “Stock and Warrant Purchase Agreement”), dated as of May 5, 2004, by and among the Registrant and the Purchasers listed therein.
- 10.6(3) License and Supply Agreement dated as of August 30, 2002 by and between Chembio Diagnostic Systems Inc. and Adaltis Inc.
- 10.8 Contract for Transfer of Technology and Materials with Bio-Manguinhos.

**10.9(4)**      **Agreement with Abbott Laboratories.**  
**21(1)**        **List of Subsidiaries.**  
**23.1**        **Consent of Lazar, Levine & Felix LLP, Independent Accountants.**  
**23.25**       **Consent of Patton Boggs LLP (Included in Exhibit 5.1).**

- (1)           Incorporated by reference to the Registrant’s Current Report on Form 8-K filed with the Commission on May 14, 2004.**
- (2)           Incorporated by reference to the Registrant’s registration statement on Form SB-2 filed with the Commission on August 23, 1999.**
- (3)           Previously filed with the Registrant’s registration statement on Form SB-2 filed with the Commission on June 7, 2004.**
- (4)           To be filed by amendment.**

II-



## UNDERTAKINGS

The undersigned registrant hereby undertakes:

1. To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement to:
  - a. Include any prospectus required by section 10(a)(3) of the Securities Act of 1933;
  - b. Reflect in the prospectus any facts or events which, individually or together, represent a fundamental change in the information in the registration statement;
  - c. Include any additional or changed material information on the plan of distribution.
2. For determining liability under the Securities Act of 1933, treat each post-effective amendment as a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
3. File a post-effective amendment to remove from registration any of the securities that remain unsold at the end of offering.
4. Insofar as indemnification for liabilities arising under the Securities Act of 1933 (the "Act") may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy .as expressed in the Act and is, therefore, unenforceable.
5. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant 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, the registrant will, unless in the opinion of its 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.

II-

SIGNATURES

In accordance with the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form SB-2 and authorized this Amendment No. 1 to Registration Statement to be signed on its behalf by the undersigned, in the City of Medford, State of New York, on August 3, 2004.

Chembio Diagnostics, Inc.,  
Nevada corporation

By:

/s/ Lawrence A. Siebert

Lawrence A. Siebert

Its:

President, Chief Executive Officer  
and Chairman of the Board

In accordance with the requirements of the Securities Act of 1933, this Amendment No. 1 to Registration Statement on Form SB-2 has been signed by the following persons in the capacities and on the dates indicated.

By: August 3, 2004

/s/ Lawrence A. Siebert

Lawrence A. Siebert

President, Chief Executive Officer  
and Chairman of the Board  
(Principal Executive Officer)

By: August 3, 2004

\*

Richard J. Larkin

Secretary, Chief Financial Officer

(Principal Financial and Accounting  
Officer)

By: August 3, 2004

\*

Mark L. Baum

Director

\*By: August 3, 2004

/s/ Lawrence A. Siebert

Lawrence A. Siebert

*Attorney-in-Fact*

**THIS WARRANT AND THE SHARES OF COMMON STOCK ISSUABLE UPON EXERCISE HEREOF HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), OR ANY STATE SECURITIES LAW AND MAY NOT BE SOLD, TRANSFERRED OR OTHERWISE DISPOSED OF UNLESS REGISTERED UNDER THE SECURITIES ACT AND UNDER APPLICABLE STATE SECURITIES LAWS OR THE ISSUER SHALL HAVE RECEIVED AN OPINION OF COUNSEL TO THE HOLDER OF THE SECURITIES (UNLESS THE ISSUER IN ITS SOLE DISCRETION DETERMINES TO USE ITS OWN COUNSEL), WITH ANY SUCH COUNSEL TO THE HOLDER AND ANY SUCH OPINION OF SUCH COUNSEL TO BE REASONABLY ACCEPTABLE TO THE ISSUER, THAT REGISTRATION OF SUCH NOTE UNDER THE SECURITIES ACT AND UNDER THE PROVISIONS OF APPLICABLE STATE SECURITIES LAWS IS NOT REQUIRED.**

WARRANT TO PURCHASE  
SHARES OF COMMON STOCK  
OF  
**CHEMBIO DIAGNOSTICS, INC.**

Expires May 5, 2009

No.: W-04-\_\_Number of Shares: \_\_\_\_\_  
Date of Issuance: May 5, 2004

FOR VALUE RECEIVED, subject to the provisions hereinafter set forth, the undersigned, Chembio Diagnostics, Inc., a Nevada corporation (together with its successors and assigns, the "Issuer"), hereby certifies that \_\_\_\_\_ or its registered assigns is entitled to subscribe for and purchase, during the Term (as hereinafter defined), up to \_\_\_\_\_ (\_\_\_\_\_) shares (subject to adjustment as hereinafter provided) of the duly authorized, validly issued, fully paid and non-assessable Common Stock of the Issuer, at an exercise price per share equal to the Warrant Price then in effect, subject, however, to the provisions and upon the terms and conditions hereinafter set forth. Capitalized terms used in this Warrant and not otherwise defined herein shall have the respective meanings specified in Section 9 hereof.

1. Term. The term of this Warrant shall commence on May 5, 2004 and shall expire at 5:00 p.m., eastern time, on May 5, 2009 (such period being the "Term").

2. Method of Exercise Payment; Issuance of New Warrant; Transfer and Exchange.

(a) Time of Exercise. The purchase rights represented by this Warrant may be exercised in whole or in part during the Term commencing on the effective date of a registration statement under the Securities Act providing for the resale of the Warrant Stock and the shares of Common Stock issuable upon conversion of the Issuer's Series A Convertible Preferred Stock issued pursuant to the Purchase Agreement and expiring on May 5, 2009.

(b) Method of Exercise. The Holder hereof may exercise this Warrant, in whole or in part, by the surrender of this Warrant (with the exercise form attached hereto duly executed) at the principal office of the Issuer, and by the payment to the Issuer of an amount of consideration therefor equal to the Warrant Price in effect on the date of such exercise multiplied by the number of shares of Warrant Stock with respect to which this Warrant is then being exercised, payable by certified or official bank check or by wire transfer to an account designated by the Issuer.

(c) Issuance of Stock Certificates. In the event of any exercise of the rights represented by this Warrant in accordance with and subject to the terms and conditions hereof, (i) certificates for the shares of Warrant Stock so purchased shall be dated the date of such exercise and delivered to the Holder hereof within a reasonable time, not exceeding three (3) Trading Days after such exercise or, at the request of the Holder (provided that a registration statement under the Securities Act providing for the resale of the Warrant Stock is then in effect), issued and delivered to the Depository Trust Company ("DTTC") account on the Holder's behalf via the Deposit Withdrawal Agent Commission System ("DWAC") within a reasonable time, not exceeding three (3) Trading Days after such exercise, and the Holder hereof shall be deemed for all purposes to be the holder of the shares of Warrant Stock so purchased as of the date of such exercise and (ii) unless this Warrant has expired, a new Warrant representing the number of shares of Warrant Stock, if any, with respect to which this Warrant shall not then have been exercised (less any amount thereof which shall

have been canceled in payment or partial payment of the Warrant Price as hereinabove provided) shall also be issued to the Holder hereof at the Issuer's expense within such time.

(d) Transferability of Warrant. Subject to Section 2(f) and Section 2(g), this Warrant may be transferred by a Holder without the consent of the Issuer. If transferred pursuant to this paragraph and subject to the provisions of subsection (f) of this Section 2, this Warrant may be transferred on the books of the Issuer by the Holder hereof in person or by duly authorized attorney, upon surrender of this Warrant at the principal office of the Issuer, properly endorsed (by the Holder executing an assignment in the form attached hereto) and upon payment of any necessary transfer tax or other governmental charge imposed upon such transfer. This Warrant is exchangeable at the principal office of the Issuer for Warrants for the purchase of the same aggregate number of shares of Warrant Stock, each new Warrant to represent the right to purchase such number of shares of Warrant Stock as the Holder hereof shall designate at the time of such exchange. All Warrants issued on transfers or exchanges shall be dated the Original Issue Date and shall be identical with this Warrant except as to the number of shares of Warrant Stock issuable pursuant thereto.

(e) Continuing Rights of Holder. The Issuer will, at the time of or at any time after each exercise of this Warrant, upon the request of the Holder hereof, acknowledge in writing the extent, if any, of its continuing obligation to afford to such Holder all rights to which such Holder shall continue to be entitled after such exercise in accordance with the terms of this Warrant, provided that if any such Holder shall fail to make any such request, the failure shall not affect the continuing obligation of the Issuer to afford such rights to such Holder.

(f) Compliance with Securities Laws.

(i) The Holder of this Warrant, by acceptance hereof, acknowledges that this Warrant or the shares of Warrant Stock to be issued upon exercise hereof are being acquired solely for the Holder's own account and not as a nominee for any other party, and for investment, and that the Holder will not offer, sell or otherwise dispose of this Warrant or any shares of Warrant Stock to be issued upon exercise hereof except pursuant to an effective registration statement, or an exemption from registration, under the Securities Act and any applicable state securities laws.

(ii) Except as provided in paragraph (iii) below, this Warrant and all certificates representing shares of Warrant Stock issued upon exercise hereof shall be stamped or imprinted with a legend in substantially the following form:

THIS WARRANT AND THE SHARES OF COMMON STOCK ISSUABLE UPON EXERCISE HEREOF HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), OR ANY STATE SECURITIES LAW AND MAY NOT BE SOLD, TRANSFERRED OR OTHERWISE DISPOSED OF UNLESS REGISTERED UNDER THE SECURITIES ACT AND UNDER APPLICABLE STATE SECURITIES LAWS OR THE ISSUER SHALL HAVE RECEIVED AN OPINION OF COUNSEL TO THE HOLDER OF THE SECURITIES (UNLESS THE ISSUER IN ITS SOLE DISCRETION DETERMINES TO USE ITS OWN COUNSEL), WITH ANY SUCH COUNSEL TO THE HOLDER AND ANY SUCH OPINION OF SUCH COUNSEL TO BE REASONABLY ACCEPTABLE TO THE ISSUER, THAT REGISTRATION OF SUCH NOTE UNDER THE SECURITIES ACT AND UNDER THE PROVISIONS OF APPLICABLE STATE SECURITIES LAWS IS NOT REQUIRED.

(iii) The Issuer agrees to reissue certificates representing any of the Warrant Stock, without the legend set forth above if at such time, prior to making any transfer of any such securities, the Holder shall give written notice to the Issuer describing the manner and terms of such transfer and removal as the Issuer may reasonably request. Such proposed transfer and removal will not be effected until: (a) either (i) the Issuer has received an opinion of counsel reasonably satisfactory to the Issuer, to the effect that the registration of such securities under the Securities Act is not required in connection with such proposed transfer, (ii) a registration statement under the Securities Act covering such proposed disposition has been filed by the Issuer with the Securities and Exchange Commission and has become effective under the Securities Act, (iii) the Issuer has received other evidence reasonably satisfactory to the Issuer that such registration and qualification under the Securities Act and state securities laws are not required, or (iv) the Holder provides the Issuer with reasonable assurances that such security can be sold pursuant to Rule 144 under the Securities Act; and (b) either (i) the Issuer has received an opinion of counsel reasonably satisfactory to the Issuer, to the effect that registration or qualification under the securities or "blue sky" laws of any state is not required in connection with such proposed disposition, or (ii) compliance with applicable state securities or "blue sky" laws has been effected or a valid exemption exists with respect thereto. The Issuer will respond to any such notice from a holder within five (5) business days. In the case of any proposed transfer under this Section 2(f), the Issuer will use reasonable efforts to comply with any such applicable state securities or "blue sky" laws, but shall in no event be required, (x) to qualify to do business in any state where it is not then qualified, (y) to take any action that would subject it to tax or to the general service of process in any state where it is not then subject, or (z) to comply with state securities or "blue sky" laws of any state for

which registration by coordination is unavailable to the Issuer. The restrictions on transfer contained in this Section 2(f) shall be in addition to, and not by way of limitation of, any other restrictions on transfer contained in any other section of this Warrant. Whenever a certificate representing the Warrant Stock is required to be issued to a the Holder without a legend, in lieu of delivering physical certificates representing the Warrant Stock, provided the Issuer's transfer agent is participating in the DTC Fast Automated Securities Transfer program, the Issuer shall use its reasonable best efforts to cause its transfer agent to electronically transmit the Warrant Stock to the Holder by crediting the account of the Holder's Prime Broker with DTC through its DWAC system (to the extent not inconsistent with any provisions of this Warrant or the Purchase Agreement).

(g) In no event may the Holder exercise this Warrant in whole or in part unless the Holder is an "accredited investor" as defined in Regulation D under the Securities Act.

3. Stock Fully Paid; Reservation and Listing of Shares; Covenants.

(a) Stock Fully Paid. The Issuer represents, warrants, covenants and agrees that all shares of Warrant Stock which may be issued upon the exercise of this Warrant or otherwise hereunder will, when issued in accordance with the terms of this Warrant, be duly authorized, validly issued, fully paid and non-assessable and free from all taxes, liens and charges created by or through the Issuer. The Issuer further covenants and agrees that during the period within which this Warrant may be exercised, the Issuer will at all times have authorized and reserved for the purpose of the issue upon exercise of this Warrant a sufficient number of shares of Common Stock to provide for the exercise of this Warrant.

(b) Reservation. If any shares of Common Stock required to be reserved for issuance upon exercise of this Warrant or as otherwise provided hereunder require registration or qualification with any governmental authority under any federal or state law before such shares may be so issued, the Issuer will in good faith use its reasonable best efforts as expeditiously as possible at its expense to cause such shares to be duly registered or qualified. If the Issuer shall list any shares of Common Stock on any securities exchange or market it will, at its expense, list thereon, maintain and increase when necessary such listing, of, all shares of Warrant Stock from time to time issued upon exercise of this Warrant or as otherwise provided hereunder (provided that such Warrant Stock has been registered pursuant to a registration statement under the Securities Act then in effect), and, to the extent permissible under the applicable securities exchange rules, all unissued shares of Warrant Stock which are at any time issuable hereunder, so long as any shares of Common Stock shall be so listed. The Issuer will also so list on each securities exchange or market, and will maintain such listing of, any other securities which the Holder of this Warrant shall be entitled to receive upon the exercise of this Warrant if at the time any securities of the same class shall be listed on such securities exchange or market by the Issuer.

(c) Covenants. The Issuer shall not by any action including, without limitation, amending the Articles of Incorporation or the by-laws of the Issuer, or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of the Holder hereof against dilution (to the extent specifically provided herein) or impairment. Without limiting the generality of the foregoing, the Issuer will (i) not permit the par value, if any, of its Common Stock to exceed the then effective Warrant Price, (ii) not amend or modify any provision of the Articles of Incorporation or by-laws of the Issuer in any manner that would adversely affect the rights of the Holders of the Warrants in their capacity as Holders of the Warrants, (iii) take all such action as may be reasonably necessary in order that the Issuer may validly and legally issue fully paid and nonassessable shares of Common Stock, free and clear of any liens, claims, encumbrances and restrictions (other than as provided herein) upon the exercise of this Warrant, and (iv) use its reasonable best efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof as may be reasonably necessary to enable the Issuer to perform its obligations under this Warrant.

(d) Loss, Theft, Destruction of Warrants. Upon receipt of evidence satisfactory to the Issuer of the ownership of and the loss, theft, destruction or mutilation of any Warrant and, in the case of any such loss, theft or destruction, upon receipt of indemnity or security satisfactory to the Issuer or, in the case of any such mutilation, upon surrender and cancellation of such Warrant, the Issuer will make and deliver, in lieu of such lost, stolen, destroyed or mutilated Warrant, a new Warrant of like tenor and representing the right to purchase the same number of shares of Common Stock.

4. Adjustment of Warrant Price. The price at which such shares may be purchased upon exercise of this Warrant shall be subject to adjustment from time to time as set forth in this Section 4. The Issuer shall give the Holder notice of any event described below which requires an adjustment pursuant to this Section 4 in accordance with Section 5.

(a) Recapitalization, Reorganization, Reclassification, Consolidation, Merger or Sale.

(i) In case the Issuer after the Original Issue Date shall do any of the following (each, a "Triggering Event"): (a) consolidate or merge with or into another corporation where the holders of outstanding Voting Stock prior to such merger or consolidation do not own over 50% of the outstanding Voting Stock of the merged or consolidated entity immediately after

such merger or consolidation, or (b) sell all or substantially all of its properties or assets to any other Person, or (c) change the Common Stock to the same or different number of shares of any class or classes of stock, whether by reclassification, exchange, substitution or otherwise (other than by way of a stock split or combination of shares or stock dividends or distributions provided for in Section 4(b) or Section 4(c)), or (d) effect a capital reorganization (other than by way of a stock split or combination of shares or stock dividends or distributions provided for in Section 4(b) or Section 4(c)), then, and in the case of each such Triggering Event, proper provision shall be made so that, upon the basis and the terms and in the manner provided in this Warrant, the Holder of this Warrant shall be entitled upon the exercise hereof at any time after the consummation of such Triggering Event, to the extent this Warrant is not exercised prior to such Triggering Event, to receive at the Warrant Price in effect at the time immediately prior to the consummation of such Triggering Event in lieu of the Common Stock issuable upon such exercise of this Warrant prior to such Triggering Event, the securities, cash and property to which such Holder would have been entitled upon the consummation of such Triggering Event if such Holder had exercised the rights represented by this Warrant immediately prior thereto, subject to adjustments (subsequent to such corporate action) as nearly equivalent as possible to the adjustments provided for elsewhere in this Section 4.

(ii) Notwithstanding anything contained in this Warrant to the contrary, a Triggering Event shall not be deemed to have occurred if, prior to the consummation thereof, each Person (other than the Issuer) which may be required to deliver any securities, cash or property upon the exercise of this Warrant as provided herein shall assume, by written instrument delivered to, and reasonably satisfactory to, the Holder of this Warrant, (A) the obligations of the Issuer under this Warrant (and if the Issuer shall survive the consummation of such Triggering Event, such assumption shall be in addition to, and shall not release the Issuer from, any continuing obligations of the Issuer under this Warrant) and (B) the obligation to deliver to such Holder such shares of securities, cash or property as, in accordance with the foregoing provisions of this subsection (a), such Holder shall be entitled to receive, and such Person shall have similarly delivered to such Holder a written acknowledgement executed by the President or Chief Financial Officer of the Company, stating that this Warrant shall thereafter continue in full force and effect and the terms hereof (including, without limitation, all of the provisions of this subsection (a)) shall be applicable to the securities, cash or property which such Person may be required to deliver upon any exercise of this Warrant or the exercise of any rights pursuant hereto.

(b) Stock Dividends, Subdivisions and Combinations. If at any time the Issuer shall:

(i) make or issue or set a record date for the holders of its Common Stock for the purpose of entitling them to receive a dividend payable in, or other distribution of, shares of Common Stock,

(ii) subdivide its outstanding shares of Common Stock into a larger number of shares of Common Stock, or

(iii) combine its outstanding shares of Common Stock into a smaller number of shares of Common Stock,

then (1) the number of shares of Common Stock for which this Warrant is exercisable immediately after the occurrence of any such event shall be adjusted to equal the number of shares of Common Stock which a record holder of the same number of shares of Common Stock for which this Warrant is exercisable immediately prior to the occurrence of such event would own or be entitled to receive after the happening of such event, and (2) the Warrant Price then in effect shall be adjusted to equal (A) the Warrant Price then in effect multiplied by the number of shares of Common Stock for which this Warrant is exercisable immediately prior to the adjustment divided by (B) the number of shares of Common Stock for which this Warrant is exercisable immediately after such adjustment.

Notwithstanding the foregoing, if such record date shall have been fixed and such dividend is not fully paid or if such distribution is not fully made on the date fixed therefor, the Warrant Price shall be adjusted pursuant to this paragraph as of the time of actual payment of such dividends or distributions.

(c) Certain Other Distributions. If at any time the Issuer shall make or issue or set a record date for the determination of the holders of its Common Stock for the purpose of entitling them to receive any dividend or other distribution of:

(i) cash (other than a cash dividend payable out of earnings or earned surplus legally available for the payment of dividends under the laws of the jurisdiction of incorporation of the Issuer),

(ii) any evidences of its indebtedness, any shares of stock of any class or any other securities or property of any nature whatsoever (other than cash, Convertible Securities or Additional Shares of Common Stock), or

(iii) any warrants or other rights to subscribe for or purchase any evidences of its indebtedness, any shares of stock of any class or any other securities or property of any nature whatsoever (other than cash, Convertible

then (1) the number of shares of Common Stock for which this Warrant is exercisable shall be adjusted to equal the product of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such adjustment multiplied by a fraction (A) the numerator of which shall be the Per Share Market Value of Common Stock at the date of taking such record and (B) the denominator of which shall be such Per Share Market Value minus the amount allocable to one share of Common Stock of any such cash so distributable and of the fair value (as determined in good faith by the Board of Directors of the Issuer and supported by an opinion from an investment banking firm of recognized national standing acceptable to (but not affiliated with) the Holder) of any and all such evidences of indebtedness, shares of stock, other securities or property or warrants or other subscription or purchase rights so distributable, and (2) the Warrant Price then in effect shall be adjusted to equal (A) the Warrant Price then in effect multiplied by the number of shares of Common Stock for which this Warrant is exercisable immediately prior to the adjustment divided by (B) the number of shares of Common Stock for which this Warrant is exercisable immediately after such adjustment. A reclassification of the Common Stock (other than a change in par value, or from par value to no par value or from no par value to par value) into shares of Common Stock and shares of any other class of stock shall be deemed a distribution by the Issuer to the holders of its Common Stock of such shares of such other class of stock within the meaning of this Section 4(c) and, if the outstanding shares of Common Stock shall be changed into a larger or smaller number of shares of Common Stock as a part of such reclassification, such change shall be deemed a subdivision or combination, as the case may be, of the outstanding shares of Common Stock within the meaning of Section 4(b).

Notwithstanding the foregoing, if such record date shall have been fixed and such dividend is not fully paid or if such distribution is not fully made on the date fixed therefor, the Warrant Price shall be adjusted pursuant to this Section 4(c) as of the time of actual payment of such dividends or distributions.

(d) Issuance of Additional Shares of Common Stock. In the event the Issuer shall at any time following the Original Issue Date issue any Additional Shares of Common Stock (otherwise than as provided in the foregoing subsections (a) through (c) of this Section 4), at a price per share less than \$.60 or without consideration, then the Warrant Price upon each such issuance shall be adjusted to the price equal to the consideration per share paid for such Additional Shares of Common Stock.

(e) Issuance of Common Stock Equivalents. If at any time the Issuer shall issue or sell any Common Stock Equivalents, whether or not the rights to exchange or convert thereunder are immediately exercisable, and the aggregate price per share for which Common Stock is issuable upon such conversion or exchange plus the consideration received by the Issuer for issuance of such Common Stock Equivalent divided by the number of shares of Common Stock issuable pursuant to such Common Stock Equivalent shall be less than \$.60 or without consideration, then the Warrant Price then in effect shall be adjusted as provided in Section 4(d). No further adjustment of the Warrant Price then in effect shall be made under this Section 4(e) upon the issuance of any Common Stock Equivalents which are issued pursuant to the exercise of any warrants or other subscription or purchase rights therefor, if any such adjustment shall previously have been made upon the issuance of such warrants or other rights pursuant to this Section 4(e). No further adjustments of the Warrant Price then in effect shall be made upon the actual issue of such Common Stock upon conversion or exchange of such Common Stock Equivalents.

(f) Other Provisions applicable to Adjustments under this Section. The following provisions shall be applicable to the making of adjustments of the number of shares of Common Stock for which this Warrant is exercisable and the Warrant Price then in effect provided for in this Section 4:

(i) Computation of Consideration. To the extent that any Additional Shares of Common Stock shall be issued for cash consideration, the consideration received by the Issuer therefor shall be the amount of the cash received by the Issuer therefor, or, if such Additional Shares of Common Stock are offered by the Issuer for subscription, the subscription price, or, if such Additional Shares of Common Stock are sold to underwriters or dealers for public offering without a subscription offering, the initial public offering price (in any such case subtracting any amounts paid or receivable for accrued interest or accrued dividends and without taking into account any compensation, discounts or expenses paid or incurred by the Issuer for and in the underwriting of, or otherwise in connection with, the issuance thereof). In connection with any merger or consolidation in which the Issuer is the surviving corporation (other than any consolidation or merger in which the previously outstanding shares of Common Stock of the Issuer shall be changed to or exchanged for the stock or other securities of another corporation), the amount of consideration therefore shall be, deemed to be the fair value, as determined reasonably and in good faith by the Board, of such portion of the assets and business of the nonsurviving corporation as the Board may determine to be attributable to such Additional Shares of Common Stock. The consideration for any Additional Shares of Common Stock issuable pursuant to any Convertible Securities or warrants or other rights to subscribe for or purchase the same shall be the consideration received by the Issuer for issuing such Convertible Securities or warrants or other rights plus the additional consideration payable to the Issuer upon exercise of such warrants or other rights. In the event of any consolidation or merger of the Issuer in which the Issuer is not the surviving corporation or in which the previously outstanding shares of Common Stock of the Issuer shall be changed into or exchanged for the stock or other securities of another corporation, or in the event of any sale of all or substantially all of the assets of the Issuer for stock or other securities of any corporation, the Issuer shall be deemed to have issued a number of shares of its Common Stock for

stock or securities or other property of the other corporation computed on the basis of the actual exchange ratio on which the transaction was predicated, and for a consideration equal to the fair market value on the date of such transaction of all such stock or securities or other property of the other corporation. In the event any consideration received by the Issuer for any securities consists of property other than cash, the fair market value thereof at the time of issuance or as otherwise applicable shall be as determined in good faith by the Board. In the event Common Stock is issued with other shares or securities or other assets of the Issuer for consideration which covers both, the consideration computed as provided in this Section 4(f)(i) shall be allocated among such securities and assets as determined in good faith by the Board.

(ii) When Adjustments to Be Made. The adjustments required by this Section 4 shall be made whenever and as often as any specified event requiring an adjustment shall occur, except that any adjustment of the number of shares of Common Stock for which this Warrant is exercisable that would otherwise be required may be postponed (except in the case of a subdivision or combination of shares of the Common Stock, as provided for in Section 4(b)) up to, but not beyond the date of exercise if such adjustment either by itself or with other adjustments not previously made adds or subtracts less than one percent (1%) of the shares of Common Stock for which this Warrant is exercisable immediately prior to the making of such adjustment. Any adjustment representing a change of less than such minimum amount (except as aforesaid) which is postponed shall be carried forward and made as soon as such adjustment, together with other adjustments required by this Section 4 and not previously made, would result in a minimum adjustment or on the date of exercise. For the purpose of any adjustment, any specified event shall be deemed to have occurred at the close of business on the date of its occurrence.

(iii) Fractional Interests. In computing adjustments under this Section 4, fractional interests in Common Stock shall be taken into account to the nearest one one-hundredth ( $1/100^{\text{th}}$ ) of a share.

(iv) When Adjustment Not Required. If the Issuer shall take a record of the holders of its Common Stock for the purpose of entitling them to receive a dividend or distribution or subscription or purchase rights and shall, thereafter and before the distribution to stockholders thereof, legally abandon its plan to pay or deliver such dividend, distribution, subscription or purchase rights, then thereafter no adjustment shall be required by reason of the taking of such record and any such adjustment previously made in respect thereof shall be rescinded and annulled.

(g) Form of Warrant after Adjustments. The form of this Warrant need not be changed because of any adjustments in the Warrant Price or the number and kind of Securities purchasable upon the exercise of this Warrant.

(h) Escrow of Warrant Stock. If after any property becomes distributable pursuant to this Section 4 by reason of the taking of any record of the holders of Common Stock, but prior to the occurrence of the event for which such record is taken, and the Holder exercises this Warrant, any shares of Common Stock issuable upon exercise by reason of such adjustment shall be deemed the last shares of Common Stock for which this Warrant is exercised (notwithstanding any other provision to the contrary herein) and such shares or other property shall be held in escrow for the Holder by the Issuer to be issued to the Holder upon and to the extent that the event actually takes place, upon payment of the current Warrant Price. Notwithstanding any other provision to the contrary herein, if the event for which such record was taken fails to occur or is rescinded, then such escrowed shares shall be cancelled by the Issuer and escrowed property returned.

5. Notice of Adjustments. Whenever the Warrant Price or Warrant Share Number shall be adjusted pursuant to Section 4 hereof (for purposes of this Section 5, each an "adjustment"), the Issuer shall cause its Chief Financial Officer to prepare and execute a certificate setting forth, in reasonable detail, the event requiring the adjustment, the amount of the adjustment, the method by which such adjustment was calculated (including a description of the basis on which the Board made any determination hereunder), and the Warrant Price and Warrant Share Number after giving effect to such adjustment, and shall cause copies of such certificate to be delivered to the Holder of this Warrant promptly after each adjustment. Any dispute between the Issuer and the Holder of this Warrant with respect to the matters set forth in such certificate may at the option of the Holder of this Warrant be submitted to one of the national accounting firms currently known as the "big four" selected by the Holder, provided that the Issuer shall have ten (10) days after receipt of notice from such Holder of its selection of such firm to object thereto, in which case such Holder shall select another such firm and the Issuer shall have no such right of objection unless the Issuer identifies a valid conflict of interest for such firm with any of the parties. The firm selected by the Holder of this Warrant as provided in the preceding sentence shall be instructed to deliver a written opinion as to such matters to the Issuer and such Holder within thirty (30) days after submission to it of such dispute. Such opinion shall be final and binding on the parties hereto. The costs and expenses of such accounting firm shall be paid equally by the Company and the Holder.

6. Fractional Shares. No fractional shares of Warrant Stock will be issued in connection with any exercise hereof, but in lieu of such fractional shares, the Issuer shall make a cash payment therefor equal in amount to the product of the applicable fraction multiplied by the Per Share Market Value then in effect.

7. Ownership Cap and Certain Exercise Restrictions. (a) Notwithstanding anything to the contrary set forth in this Warrant, at no time may a Holder of this Warrant exercise this Warrant if the number of shares of Common Stock to be issued pursuant to such exercise would exceed, when aggregated with all other shares of Common Stock owned by such Holder at such



time, the number of shares of Common Stock which would result in such Holder beneficially owning (as determined in accordance with Section 13(d) of the Exchange Act and the rules thereunder) in excess of 4.999% of the then issued and outstanding shares of Common Stock; provided, however, that upon a holder of this Warrant providing the Issuer with sixty-one (61) days notice (pursuant to Section 13 hereof) (the "Waiver Notice") that such Holder would like to waive this Section 7(a) with regard to any or all shares of Common Stock issuable upon exercise of this Warrant, this Section 7(a) will be of no force or effect with regard to all or a portion of the Warrant referenced in the Waiver Notice; provided, further, that this provision shall be of no further force or effect (i) during the sixty-one (61) days immediately preceding the expiration of the term of this Warrant or (ii) upon the Holder's receipt of a Call Notice (as defined in Section 8 hereof).

(b) The Holder may not exercise the Warrant hereunder to the extent such exercise would result in the Holder beneficially owning (as determined in accordance with Section 13(d) of the Exchange Act and the rules thereunder) in excess of 9.999% of the then issued and outstanding shares of Common Stock, including shares issuable upon exercise of the Warrant held by the Holder after application of this Section; provided, however, that upon a holder of this Warrant providing the Company with a Waiver Notice that such holder would like to waive this Section 7(b) with regard to any or all shares of Common Stock issuable upon exercise of this Warrant, this Section 7(b) shall be of no force or effect with regard to those shares of Warrant Stock referenced in the Waiver Notice; provided, further, that this provision shall be of no further force or effect (i) during the sixty-one (61) days immediately preceding the expiration of the term of this Warrant or (ii) upon the Holder's receipt of a Call Notice.

8.Call. Notwithstanding anything herein to the contrary, commencing twelve (12) months following the effective date of a registration statement under the Securities Act providing for the resale of the Warrant Stock and the shares of Common Stock issuable upon conversion of the Issuer's Series A Preferred Stock issued pursuant to the Purchase Agreement (the "Registration Statement"), the Issuer, at its option, may call up to one hundred percent (100%) of this Warrant if the Per Share Market Value of the Common Stock has been greater than \$3.00 (as may be adjusted for any stock splits or combinations of the Common Stock) for a period of twenty (20) consecutive Trading Days immediately prior to the date of delivery of the Call Notice (a "Call Notice Period") by providing the Holder of this Warrant written notice pursuant to Section 13 (the "Call Notice"); provided, that (a) the Registration Statement is then in effect and has been effective, without lapse or suspension of any kind, for a period of 60 consecutive calendar days, (b) trading in the Common Stock shall not have been suspended by the Securities and Exchange Commission or the OTC Bulletin Board and (c) the Issuer is in material compliance with the terms and conditions of this Warrant and the other Transaction Documents (as defined in the Purchase Agreement); provided, < /FONT>further, that the Registration Statement is in effect from the date of delivery of the Call Notice until the date which is the later of (i) the date the Holder exercises the Warrant pursuant to the Call Notice and (ii) the 20<sup>th</sup> day after the Holder receives the Call Notice (the "Early Termination Date"). The rights and privileges granted pursuant to this Warrant with respect to the shares of Warrant Stock subject to the Call Notice (the "Called Warrant Shares") shall expire on the Early Termination Date if this Warrant is not exercised with respect to such Called Warrant Shares prior to such Early Termination Date. In the event this Warrant is not exercised with respect to the Called Warrant Shares, the Issuer shall remit to the Holder of this Warrant (A) \$.01 per Called Warrant Share and (B) a new Warrant representing the number of shares of Warrant Stock, if any, which shall not have been subject to the Call Notice upon the Holder tendering to the Issuer the applicable Warrant certificate.

9.Definitions. For the purposes of this Warrant, the following terms have the following meanings:

"Additional Shares of Common Stock" means all shares of Common Stock issued by the Issuer after the Original Issue Date, and all shares of Other Common, if any, issued by the Issuer after the Original Issue Date, except: (i) securities issued (other than for cash) in connection with a merger, acquisition, or consolidation, (ii) securities issued pursuant to a bona fide firm underwritten public offering of the Issuer's securities, (iii) securities issued pursuant to the conversion or exercise of convertible or exercisable securities issued or outstanding on or prior to the date hereof or issued pursuant to the Purchase Agreement, (iv) the Warrant Stock, (v) securities issued in connection with strategic alliances or other partnering arrangements so long as such issuances are not for the purpose of raising capital, (vi) Common Stock issued or options to purchase Common Stock granted or issued pursuant to the Issuer's stock option plans and employee stock purchase plans as they now exist, (vii) any warrants issued to the placement agent for the transactions contemplated by the Purchase Agreement, and (viii) the payment of any dividend on the Series A Convertible Preferred Stock of the Issuer.

"Articles of Incorporation" means the Articles of Incorporation of the Issuer as in effect on the Original Issue Date, and as hereafter from time to time amended, modified, supplemented or restated in accordance with the terms hereof and thereof and pursuant to applicable law.

"Board" shall mean the Board of Directors of the Issuer.

"Capital Stock" means and includes (i) any and all shares, interests, participations or other equivalents of or interests in (however designated) corporate stock, including, without limitation, shares of preferred or preference stock, (ii) all partnership interests (whether general or limited) in any Person which is a partnership, (iii) all membership interests or limited liability company interests in any limited liability company, and (iv) all equity or ownership interests in any Person of any other type.

"Common Stock" means the Common Stock, par value \$.01 per share, of the Issuer and any other Capital Stock into which such stock may hereafter be changed.

"Common Stock Equivalent" means any Convertible Security or warrant, option or other right to subscribe for or purchase any Additional Shares of Common Stock or any Convertible Security.

"Convertible Securities" means evidences of Indebtedness, shares of Capital Stock or other Securities which are or may be at any time convertible into or exchangeable for Additional Shares of Common Stock. The term "Convertible Security" means one of the Convertible Securities.

"Governmental Authority" means any governmental, regulatory or self-regulatory entity, department, body, official, authority, commission, board, agency or instrumentality, whether federal, state or local, and whether domestic or foreign.

"Holders" mean the Persons who shall from time to time own any Warrant. The term "Holder" means one of the Holders.

"Independent Appraiser" means a nationally recognized or major regional investment banking firm or firm of independent certified public accountants of recognized standing (which may be the firm that regularly examines the financial statements of the Issuer) that is regularly engaged in the business of appraising the Capital Stock or assets of corporations or other entities as going concerns, and which is not affiliated with either the Issuer or the Holder of any Warrant.

"Issuer" means Chembio Diagnostics, Inc., a Nevada corporation, and its successors.

"Majority Holders" means at any time the Holders of Warrants exercisable for a majority of the shares of Warrant Stock issuable under the Warrants at the time outstanding.

"Original Issue Date" means May 5, 2004.

"OTC Bulletin Board" means the over-the-counter electronic bulletin board.

"Other Common" means any other Capital Stock of the Issuer of any class which shall be authorized at any time after the date of this Warrant (other than Common Stock) and which shall have the right to participate in the distribution of earnings and assets of the Issuer without limitation as to amount.

"Outstanding Common Stock" means, at any given time, the aggregate amount of outstanding shares of Common Stock, assuming full exercise, conversion or exchange (as applicable) of all options, warrants and other Securities which are convertible into or exercisable or exchangeable for, and any right to subscribe for, shares of Common Stock that are outstanding at such time.

"Person" means an individual, corporation, limited liability company, partnership, joint stock company, trust, unincorporated organization, joint venture, Governmental Authority or other entity of whatever nature.

"Per Share Market Value" means on any particular date (a) the closing bid price for a share of Common Stock in the over-the-counter market, as reported by the OTC Bulletin Board or in the National Quotation Bureau Incorporated or similar organization or agency succeeding to its functions of reporting prices) at the close of business on such date, or (b) if the Common Stock is not then reported by the OTC Bulletin Board or the National Quotation Bureau Incorporated (or similar organization or agency succeeding to its functions of reporting prices), then the average of the "Pink Sheet" quotes for the relevant determination period, or (c) if the Common Stock is not then publicly traded the fair market value of a share of Common Stock as determined by the Board in good faith; provided, however, that the Majority Holders, after receipt of the determination by the Board, shall have the right to select, jointly with the Issuer, an Independent Appraiser, in which case, the fair market value shall be the determination by such Independent Appraiser; and provided, further that all determinations of the Per Share Market Value shall be appropriately adjusted for any stock dividends, stock splits or other similar transactions during such period. The determination of fair market value shall be based upon the fair market value of the Issuer determined on a going concern basis as between a willing buyer and a willing seller and taking into account all relevant facts determinative of value, and shall be final and binding on all parties. In determining the fair market value of any shares of Common Stock, no consideration shall be given to any restrictions on transfer of the Common Stock imposed by agreement or by federal or state securities laws, or to the existence or absence of, or any limitations on, voting rights.

"Purchase Agreement" means the Series A Convertible Preferred Stock and Warrant Purchase Agreement dated as of May 5, 2004 among the Issuer and the investors a party thereto.

"Securities" means any debt or equity securities of the Issuer, whether now or hereafter authorized, any instrument convertible into or exchangeable for Securities or a Security, and any option, warrant or other right to purchase or acquire any Security. "Security" means one of the Securities.

"Securities Act" means the Securities Act of 1933, as amended, or any similar federal statute then in effect.

"Subsidiary" means any corporation at least 50% of whose outstanding Voting Stock shall at the time be owned directly or indirectly by the Issuer or by one or more of its Subsidiaries, or by the Issuer and one or more of its Subsidiaries.

"Term" has the meaning specified in Section 1 hereof.

"Trading Day" means (a) a day on which the Common Stock is traded on the OTC Bulletin Board, or (b) if the Common Stock is not traded on the OTC Bulletin Board, a day on which the Common Stock is quoted in the over-the-counter market as reported by the National Quotation Bureau Incorporated (or any similar organization or agency succeeding its functions of reporting prices); provided, however, that in the event that the Common Stock is not listed or quoted as set forth in (a) or (b) hereof, then Trading Day shall mean any day except Saturday, Sunday and any day which shall be a legal holiday or a day on which banking institutions in the State of New York are authorized or required by law or other government action to close.

"Voting Stock" means, as applied to the Capital Stock of any corporation, Capital Stock of any class or classes (however designated) having ordinary voting power for the election of a majority of the members of the Board of Directors (or other governing body) of such corporation, other than Capital Stock having such power only by reason of the happening of a contingency.

"Warrants" means the Warrants issued and sold pursuant to the Purchase Agreement, including, without limitation, this Warrant, and any other warrants of like tenor issued in substitution or exchange for any thereof pursuant to the provisions of Section 2(c), 2(d) or 2(e) hereof or of any of such other Warrants.

"Warrant Price" initially means U.S. \$.90, as such Warrant Price may be adjusted from time to time as shall result from the adjustments specified in this Warrant, including Section 4 hereto.

"Warrant Share Number" means at any time the aggregate number of shares of Warrant Stock which may at such time be purchased upon exercise of this Warrant, after giving effect to all prior adjustments and increases to such number made or required to be made under the terms hereof.

"Warrant Stock" means Common Stock issuable upon exercise of any Warrant or Warrants or otherwise issuable pursuant to any Warrant or Warrants.

10. Other Notices. In case at any time:

- (A) the Issuer shall make any distributions to the holders of Common Stock; or
- (B) the Issuer shall authorize the granting to all holders of its Common Stock of rights to subscribe for or purchase any shares of Capital Stock of any class or other rights; or
- (C) there shall be any reclassification of the Capital Stock of the Issuer; or
- (D) there shall be any capital reorganization by the Issuer; or
- (E) there shall be any (i) consolidation or merger involving the Issuer or (ii) sale, transfer or other disposition of all or substantially all of the Issuer's property, assets or business (except a merger or other reorganization in which the Issuer shall be the surviving corporation and its shares of Capital Stock shall continue to be outstanding and unchanged and except a consolidation, merger, sale, transfer or other disposition involving a wholly-owned Subsidiary); or
- (F) there shall be a voluntary or involuntary dissolution, liquidation or winding-up of the Issuer or any partial liquidation of the Issuer or distribution to holders of Common Stock;

then, in each of such cases, the Issuer shall give written notice to the Holder of the date on which (i) the books of the Issuer shall close or a record shall be taken for such dividend, distribution or subscription rights or (ii) such reorganization, reclassification, consolidation, merger, disposition, dissolution, liquidation or winding-up, as the case may be, shall take place. Such notice also shall specify the date as of which the holders of Common Stock of record shall participate in such dividend, distribution or subscription rights, or shall be entitled to exchange their certificates for Common Stock for securities or other property deliverable upon such reorganization, reclassification, consolidation, merger, disposition, dissolution, liquidation or winding-up, as the case may be. Such notice shall be given at least twenty (20) days prior to the record date or effective date for the event specified in such notice.

11. Amendment and Waiver. Any term, covenant, agreement or condition in this Warrant may be amended, or compliance therewith may be waived (either generally or in a particular instance and either retroactively or prospectively), by a written instrument or written instruments executed by the Issuer and the Majority Holders; provided, however, that no such amendment or waiver shall reduce the Warrant Share Number, increase the Warrant Price, shorten the period during which this Warrant may be exercised or modify any provision of this Section 11 without the consent of the Holder of this Warrant.

12. Governing Law. **THIS WARRANT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK, WITHOUT GIVING EFFECT TO PRINCIPLES OF CONFLICTS OF LAW.**

13. Notices. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be in writing and shall be deemed given and effective on the earlier of (i) the date of transmission, if such notice or communication is delivered via facsimile at the facsimile telephone number specified for notice prior to 5:00 p.m., eastern time, on a Trading Day, (ii) the Trading Day after the date of transmission, if such notice or communication is delivered via facsimile at the facsimile telephone number specified for notice later than 5:00 p.m., eastern time, on any date and earlier than 11:59 p.m., eastern time, on such date, or (iii) actual receipt by the party to whom such notice is required to be given. The addresses for such communications shall be with respect to the Holder of this Warrant or of Warrant Stock issued pursuant hereto, addressed to such Holder at its last known address or facsimile number appearing on the books of the Issuer maintained for such purposes, or with respect to the Issuer, addressed to:

Chembio Diagnostics, Inc.  
3661 Horseblock Road  
Medford, NY 11763  
Attention: Lawrence A. Siebert, President  
Tel. No.: (631) 924-1135  
Fax No.: (631) 924-6033

Copies of notices to the Issuer shall be sent to Patton Boggs LLP, 1660 Lincoln Street, Suite 1900, Denver, CO 80264, Attention: Alan Talesnick, Tel. No.: (303) 830-1776, Fax No.: (303) 894-9239. Copies of notices to the Holder shall be sent to Jenkins & Gilchrist Parker Chapin LLP, 405 Lexington Avenue, New York, New York 10174, Attention: Christopher S. Auguste, Facsimile No.: (212) 704-6288. Any party hereto may from time to time change its address for notices by giving at least ten (10) days written notice of such changed address to the other party hereto.

14. Warrant Agent. The Issuer may, by written notice to each Holder of this Warrant, appoint an agent for the purpose of issuing shares of Warrant Stock on the exercise of this Warrant pursuant to subsection (b) of Section 2 hereof, exchanging this Warrant pursuant to subsection (d) of Section 2 hereof or replacing this Warrant pursuant to subsection (d) of Section 3 hereof, or any of the foregoing, and thereafter any such issuance, exchange or replacement, as the case may be, shall be made at such office by such agent.

15. Remedies. The Issuer stipulates that the remedies at law of the Holder of this Warrant in the event of any default or threatened default by the Issuer in the performance of or compliance with any of the terms of this Warrant are not and will not be adequate and that, to the fullest extent permitted by law, such terms may be specifically enforced by a decree for the specific performance of any agreement contained herein or by an injunction against a violation of any of the terms hereof or otherwise.

16. Successors and Assigns. This Warrant and the rights evidenced hereby shall inure to the benefit of and be binding upon the successors and assigns of the Issuer, the Holder hereof and (to the extent provided herein) the Holders of Warrant Stock issued pursuant hereto, and shall be enforceable by any such Holder or Holder of Warrant Stock.

17. Modification and Severability. If, in any action before any court or agency legally empowered to enforce any provision contained herein, any provision hereof is found to be unenforceable, then such provision shall be deemed modified to the extent necessary to make it enforceable by such court or agency. If any such provision is not enforceable as set forth in the

preceding sentence, the unenforceability of such provision shall not affect the other provisions of this Warrant, but this Warrant shall be construed as if such unenforceable provision had never been contained herein.

18.       Headings. The headings of the Sections of this Warrant are for convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

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IN WITNESS WHEREOF, the Issuer has executed this Warrant as of the day and year first above written.

**CHEMBIO DIAGNOSTICS, INC.**

By:  
Name:  
Title:

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EXERCISE FORM

**CHEMBIO DIAGNOSTICS, INC.**

The undersigned \_\_\_\_\_, pursuant to the provisions of the within Warrant, hereby elects to purchase \_\_\_\_\_ shares of Common Stock of Chembio Diagnostics, Inc. covered by the within Warrant.

Dated: \_\_\_\_\_ Signature \_\_\_\_\_

Address \_\_\_\_\_  
\_\_\_\_\_

Number of shares of Common Stock beneficially owned or deemed beneficially owned by the Holder on the date of Exercise:  
\_\_\_\_\_

ASSIGNMENT

FOR VALUE RECEIVED, \_\_\_\_\_ hereby sells, assigns and transfers unto \_\_\_\_\_ the within Warrant and all rights evidenced thereby and does irrevocably constitute and appoint \_\_\_\_\_, attorney, to transfer the said Warrant on the books of the within named corporation.

Dated: \_\_\_\_\_ Signature \_\_\_\_\_

Address \_\_\_\_\_  
\_\_\_\_\_

PARTIAL ASSIGNMENT

FOR VALUE RECEIVED, \_\_\_\_\_ hereby sells, assigns and transfers unto \_\_\_\_\_ the right to purchase \_\_\_\_\_ shares of Warrant Stock evidenced by the within Warrant together with all rights therein, and does irrevocably constitute and appoint \_\_\_\_\_, attorney, to transfer that part of the said Warrant on the books of the within named corporation.

Dated: \_\_\_\_\_ Signature \_\_\_\_\_

Address \_\_\_\_\_  
\_\_\_\_\_

FOR USE BY THE ISSUER ONLY:

This Warrant No. W-\_\_\_\_ canceled (or transferred or exchanged) this \_\_\_\_\_ day of \_\_\_\_\_, \_\_\_\_\_, shares of Common Stock issued therefor in the name of \_\_\_\_\_, Warrant No. W-\_\_\_\_ issued for \_\_\_\_\_ shares of Common Stock in the name of \_\_\_\_\_.

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**TECHNO-SCIENTIFIC CO-OPERATION: CONTRACT  
FOR TRANSFER OF TECHNOLOGY AND MATERIALS**

This Agreement effective as of \_\_\_\_\_, 2004, between

**(1)CHEMBIO DIAGNOSTIC SYSTEM, Inc.** a company constituted under the laws of the state of Delaware, USA and with its headquarters at 3661 Horseblock Road, Medford, New York 11763, USA, represented in this act by its Director, hereinafter referred to as CHEMBIO;

**AND**

**(2)FUNDAÇÃO OSWALDO CRUZ**, a public foundation agency of the Brazilian Ministry of Health, organized in accordance with the laws of Brazil, having its main office at Avenida Brasil 4365, Manguinhos, Rio de Janeiro, RJ, CEP 21045-900, Brazil, CGC NI 33.781.055/0001-35, represented in this document by its President Dr. Paulo Marchiori Buss, hereinafter referred to as FIOCRUZ.

**AND**

**(3)INSTITUTE OF IMMUNOBIOLOGICAL TECHNOLOGY**, the FIOCRUZ unit producing vaccines and diagnostic kits, with headquarters at Avenida Brasil 4365, Manguinhos, Rio de Janeiro, RJ, Cep 21045-900, Brazil, represented by its Director Akira Homma, hereafter referred to as BIO-MANGUINHOS;

**WHERE THE FOLLOWING HAS BEEN AGREED:**

**Considering that** CHEMBIO is a company having as its main purpose the production of lateral flow rapid diagnostic test kits including but not limited to “HIV ½ Stat-Pak”, (hereinafter referred to as PRODUCT);

**Considering that** the parties signed, on the 10<sup>th</sup> of June, 2002, a Memorandum of Understanding, with the purpose of combining their efforts with the aim transferring the production of HIV ½ Stat-Pak and associated kit components thereof to FIOCRUZ;

**Considering that** CHEMBIO provided Bio Manguinhos, a FIOCRUZ unit, around 500 (five hundred) units of the PRODUCT as free samples, as well as the necessary technical documentation for a technical and operational evaluation of the PRODUCT, with BIO-MANGUINHOS having tested and approved the PRODUCT;

**Considering that** CHEMBIO possesses the confidential technical information\_for the Production of the rapid Test Kit based on immuno-chromatography and lateral flow, including, but not limited to, the STAT-PAK HIV-1/2.

**THE PARTIES AGREE TO SIGN THE PRESENT CONTRACT, AS STIPULATED BELOW:**



## **DEFINITIONS**

**FINAL PRODUCT** - Rapid test kit for HIV ½ produced by FIOCRUZ termed HIV ½Stat - Pak composed of tests based on immunochromatography and lateral flow, adapted to rapid supports for use with serum, plasma or whole blood, sealed in individual laminated foil pouches containing also, lancets, transfer loops, band-aids and dessicants. Product insert and vials of buffer solution complete the final product.

**BUFFER SOLUTION** - Buffer solution as provided in the Product Specifications (Exhibit B) necessary for the tests to aid in routing the serum, plasma or whole blood.

**INTERMEDIATE PRODUCT 0** - Bulk buffer and plastic support adapted to a test strip sensitized with synthetic peptides of the HIV 1/2, together with colloidal gold, a membrane for retaining cells and hemoglobin and a liquid absorbent membrane, in a manner as to function perfectly within the principles of immunochromatography and lateral flow, packaged in individual laminated foil pouches, , containing dessinants, having as accessories lancets, transfer loops capable of collecting 5uL and band aids dressing. BIO-MANGUINHOS dispences the buffer, inserts, labels and packages of the product, as well as performs storage and Quality Control

**INTERMEDIATE PRODUCT I**- Plastic support adapted to a test strip sensitized with synthetic peptides of the HIV 1/2, together with colloidal gold, a membrane for retaining cells and hemoglobin and a liquid absorbent membrane, in a manner as to function perfectly within the principles of immunochromatography and lateral flow, packaged in individual laminated foil pouches containing dessinants, having as accessories lancets, transfer loops capable of collecting 5uL and band aids dressing. BIO-MANGUINHOS produces the buffer, inserts, labels and packages of the product, as well as performs storage and Quality Control.

**INTERMEDIATE PRODUCT II** - Test membrane sensitized with synthetic peptides of the HIV 1/2 having as accessories the materials necessary for the production of the test supports, lancets, transfer loops capable of collecting 5uL and band aid. BIO-MANGUINHOS produces the plastic support adapted to a test strip sensitized with synthetic peptides of the HIV 1/2, together with colloidal gold, a membrane for retaining cells and haemoglobin and a liquid absorbent membrane, in a manner as to function perfectly within the principles of immunochromatography and lateral flow, packaged in individual laminated foil pouches containing dessicants, buffer, inserts, labels and packages the product, as well as performs storage and Quality Control.

**PRODUCTS** – includes mention of all or any PRODUCT, including the FINAL PRODUCT, INTERMEDIATE PRODUCT 0, INTERMEDIATE PRODUCT I and INTERMEDIATE PRODUCT II.

**NET SALES** – includes the sales undertaken by FIOCRUZ of the PRODUCT, excluding the industrial and commercial taxes, insurance, freight and packaging.

**MINISTRY OF HEALTH** – an organism in the administrative structure of Brazil’s Federative Republic which is basically charged with the formulation and execution of public health policy, acting in the following areas:

- a. national health policy;
- b. co-ordination and verification of the Sistema Único de Saude (Single Health System);
- c. environmental health and actions towards the promotion, maintenance and recovery of individual and collective health, including labor and native Indian health issues;
- d. health information;
- e. critical health material;
- f. general preventive measures, sanitary vigilance and control of borders and maritime and fluvial ports and airports;
- g. scientific and technological research in the area of health;

**ANVISA** – Agência Nacional de Vigilância Sanitária (National Sanitary Vigilance Agency) – created by law n. 9.782, of the 26<sup>th</sup> of January, 1999. It is an autarchy under a special regime, as such, a regulatory agency characterized by its administrative independence, stability of its directors during the mandate period and financial autonomy. Its administration is the responsibility of a board of directors having five members.

**FIOCRUZ** – Fundação Oswaldo Cruz – public foundation in public law, linked to the Brazilian Ministry of Health, it develops measures in the area of science and technology related to health, including basic and applied research activities, teaching, formulation of public health policies, health information and its diffusion, training of human resources, production of vaccines, drugs, diagnostic kits and reagents, quality control, development of health related technology and is a

## **SECTION 1 – Objective**

1.1The present Contract for the Transfer of Technology and Material calls for the scientific and technological co-operation between FIOCRUZ and CHEMBIO for the production of the HIV ½ Stat-Pak produced by CHEMBIO DIAGNOSTIC SYSTEMS, INC., hereinafter referred to as the PRODUCT, which is to be produced by FIOCRUZ in its Bio-Manguinhos unit with both Parties estimating that the process for the transfer of technical knowledge for production, shall be completed on or before the third anniversary of the Effective Date of the present Contract. The schedule and process for this technology transfer is set forth in Exhibit A hereto.

1. FIOCRUZ will register the PRODUCT at the ANVISA, in its own name following the Effective Date of this contract, counting for this purpose on the technical assistance of CHEMBIO, if necessary;
2. For the manufacture of the FINAL PRODUCT by FIOCRUZ, CHEMBIO shall provide all the confidential technical information, the necessary materials, as decided and required by FIOCRUZ, included the supplier of the synthetic peptides, as well as providing the technical assistance which may be necessary, including that which may be requested by FIOCRUZ.

1.2. After the conditions of 3.2 (iii) have been met each Party shall forbear, directly or indirectly, from entering any negotiation or contract with third parties for the purpose of development, production and/or commercialization of the PRODUCT (or any other lateral flow HIV rapid test) without the knowledge and consent of the other Party.

## **SECTION 2 – Rights granted**

2.1. CHEMBIO and FIOCRUZ agree that supply of the PRODUCT manufactured in BIO-MANGUINHOS shall, mainly, meet the public market in Brazil and members of Mercosul, as well as, occasionally, multilateral agencies of the United Nations and governments of developing countries, in accordance to the present legislation.

2.2. At the end of the technology transfer process, FIOCRUZ shall make the best efforts to meet, as soon as possible, the demand of the Brazilian Public Market. Only after having regularly met Brazilian public market, FIOCRUZ may offer to other customers, mainly, the countries of Mercosul, in accordance to the present legislation.

2.3. Neither Party has the right to sublicense to third parties the rights granted in this Section, except if formally authorized, in writing, by the other Party.

## **SECTION 3 – Conditions for entering into effect**

3.1. This Contract shall become effective, Effective Date, when the following stages are cumulatively complied with and fulfilled.

- 1) it is examined and considered in accordance with the pertinent legislation by the FIOCRUZ attorney general; and
- 2) after registry at the Instituto Nacional de Propriedade Industrial (INPI-National Institute of Industrial Property), an agency of the Brazilian government, and the notification thereof to FIOCRUZ under the terms of Law n. 9.279, of the 14<sup>th</sup> of May, 1996.

3.2 Any of the Parties shall have the right to cancel this Contract, due to lack of conditions enabling it to become effective, in the occurrence of the following events:

- (i) registration by the INPI is not granted within sixty days after the last date of signature by any of the Parties;
- (ii) the Parties do not reach an agreement for compliance with the requirements made by the INPI within thirty days after notification of the requirement; and
- (iii) in case the PRODUCT is not accepted by the DST/AIDS and for the use by FIOCRUZ , and the Parties did not reach another solution.

3.3. In the case that ANVISA does not register the PRODUCT, both Parties shall automatically consider this contract null and void, and consider this Technical-Scientific Cooperation at an end.

## **SECTION 4 – Transfer of technology**

4.1 The transfer of technology for the local production of the FINAL PRODUCT by FIOCRUZ includes CHEMBIO sending technical production information, quality control, as well as assistance and training of technicians, where this process is described in Exhibit A I, which becoMonth an integral part of this Contract;

4.2 The transfer of technology shall take effect in three phases, and should be complete at the end of the third phase, and at its end FIOCRUZ shall be entirely capable of industrially producing the FINAL PRODUCT, in accordance with article 5, Exhibit A mentioned above.

4.3. Each step specified in the schedule for the transfer of technology (Exhibit A) will result an increasing amounts of the Brazilian local production represented by the achievement of PRODUCTS (IP0,IP1,IP2 IP3) until the completion of the technology process and the production of FINAL PRODUCT.

4.4 The responsibilities for both CHEMBIO and FIOCRUZ towards the completion of each event of the process for the transfer of technology are determined by the headings of the respective columns.

4.5 The transfer of technology (in each phase) shall be considered complete when after it is mutually agreed between the parties that the aims have been fulfilled.

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## **SECTION 5 – Technical Assistance**

5.1. CHEMBIO shall provide the technical assistance and services as specifically set forth in the Technology Transfer Schedule (Exhibit A) which services shall include but not be limited to the following:

- Training for FIOCRUZ technicians to gain an operational knowledge of the CHEMBIO installations, the production of cassettes, preparation of the buffer and package;
- Support towards registering the PRODUCT at the ANVISA;
- Drafting technical specifications of the industrial plans and equipment specifications.
- Training for FIOCRUZ technicians, as requested by BIO-MANGUINHOS, for the production of the immunochromatographic test supports, including the preparation of the Protein A-Gold colloidal, the sensitizing of the membranes with synthetic peptides, and, mainly, the overall revision of all the stages of the production process of the PRODUCT
- Providing data and assistance at the beginning of the Clinical Tests.

## **SECTION 6 – Confidentiality**

6.1. CHEMBIO will provide FIOCRUZ, phase by phase, all the technical information necessary to the execution of the phase and all the stages of industrial production, during the course of this Contract.

6.2. CHEMBIO shall also provide FIOCRUZ all the technical information for the improvement of the production process of the FINAL PRODUCT, while this Contract remains in force.

6.3. FIOCRUZ will provide CHEMBIO the information concerning this Contract, with the intent of facilitating the technology transfer process.

6.4. All information received by one of the Parties from the other Party, during the course of this Contract, shall be kept confidential and shall not be disclosed to any third party, without the prior consent of the furnishing party, except when the information:

- a) is to the knowledge of the receiving party before being disclosed by the furnishing party;
- b) is obtained by the receiving party in a legal manner from a source other than the furnishing party, and such source did not require confidentiality of the receiving party, or did not limit or restrict the use of this fact by the receiving party;
- c) is of public knowledge without the receiving party being responsible for this fact;
- d) has been developed by the party independent of the information received, corroborated by written records;
- e) has disclosure required by the receiving party (i) due to the necessity of obtaining government authorisations for use of the process and/or commercialisation of the PRODUCT, (ii) by legal requirement

6.5. The confidentiality obligations established in this Section will remain in force for a period of 5 years after the Effective Date or the cancellation of this Contract, whichever later.

## **SECTION 7 – Technical Information and Samples**

7.1 CHEMBIO shall deliver to BIO-MANGUINHOS, within 30 (thirty) days after the sanction of this Contract by the INPI or immediately after signature of this contract, at the criteria of CHEMBIO:

1. the technical information and documents necessary to register the PRODUCT at the ANVISA, in the name of BIO-MANGUINHOS; and
2. samples of the PRODUCT necessary for prior analysis to be undertaken by the Instituto Nacional de Controle de Qualidade em Saude (National Institute for Quality Control in Health).

## **SECTION 8 - Delivery of Intermediary Products 0, I, and II**

8.1 FIOCRUZ shall make its best efforts to buy from CHEMBIO the PRODUCTS mentioned below, being accepted that all and any acquisition will ruled by terms and conditions of the Law no. 8.666/93, Law no. 4.320/64, Decree no. 93.872/86 and and the annual budget::

Year 1: SeMonthter 1: 150.000 unit of the INTERMEDIATE PRODUCT 0  
Year 1: SeMonthter 2: 150.000 unit of the INTERMEDIATE PRODUCT I  
Year 2: SeMonthter 1: 150.000 unit of the INTERMEDIATE PRODUCT I  
Year 2: SeMonthter 2: 150.000 unit of the INTERMEDIATE PRODUCT II  
Year 3: SeMonthter 1: 150.000 unit of the INTERMEDIATE PRODUCT II  
Year 3: SeMonthter 2: 150.000 unit of the INTERMEDIATE PRODUCT II  
Year 4 and after: All the phases of the technology transfer are finished and the production of the FINAL PRODUCT is started at plant of BIO-MAMGUINHOS.

The previous quantities must be considered cumulative provided that at least the quantities established above are purchased in accordance to the schedule above.

8.2. The prices per unit to be paid by FIOCRUZ to CHEMBIO will be the following stipulated below:

Prices US\$			
US\$/Qts.(10 <sup>3</sup> )			
1º seMonthter Prod. 0		2 e 3º seMonthter Prod. I	4 a 6º seMonthter Prod. II
Until 300 tests	2,40	2,35	1,70
From 301 to 500 tests	2,35	2,30	1,55
From 501 to 750 tests	2,20	2,15	1,31
From 750 to 1.000 tests	2,15	2,10	1,21
Over 1.000 test-s	2,10	2,00	1,16

The prices established are to be applied on a cumulative basis as each product is being supplied by CHEMBIO accordance to Exhibit A.

The Parties agree that in case the products used in the tests procedures in Brazil are being sold for a price that prevents Bio-Manguinhos from manufacturing the PRODUCT for a competitive price, they shall discuss this matter in good faith and try to negotiate a different price. Such a negotiation shall regard mainly the Brazilian Public market price, progress of the technology transfer program, and number of products bought from CHEMBIO so far.

## SECTION 9 – Orders, Delivery, Supply and Inspection

9.1 Orders and Forecast - Within thirty (30) days after the Effective Date, FIOCRUZ shall provide CHEMBIO with its first non-binding annual forecast estimated for PRODUCTS whereby these estimates for the annual period shall be reviewed and revised if necessary quarterly. Any order for PRODUCTS, shall be placed by FIOCRUZ at least two (2) months in advance of the desired delivery date for such PRODUCTS, whereby any order given hereunder shall become firm and binding on the Parties. All Orders for PRODUCTS I, shall be in writing and shall be subject to the terms hereof, and may not be altered by any additional or differing terms in FIOCRUZ's purchase order or otherwise, without the prior written consent of the Parties.

9.2 Specifications, Testing Methods and Packaging. The PRODUCTS shall be prepared, tested, and packaged in accordance with the Product Specifications as set forth in Exhibit B.

9.3 Delivery - All sales of PRODUCTS shall be ex-works Medford, NY or such alternative site of principal manufacture located in the continental United States, as notified to FIOCRUZ by CHEMBIO in writing. CHEMBIO shall ship any Orders for quantities of PRODUCT that are less than or equal to FIFTY THOUSAND units within sixty (60) days of CHEMBIO'S acceptance of such Order. CHEMBIO shall ship any Order of PRODUCTS that are greater than FIFTY THOUSAND units within ninety (90) to one hundred twenty (120) days of CHEMBIO'S acceptance of such Order. CHEMBIO shall make the shipment of the PRODUCTS in packaging suitable for transportation of products. At the time of delivery of the PRODUCTS, CHEMBIO shall provide FIOCRUZ with a Certificate of Analysis in the form set forth in Exhibit C of this CONTRACT .

### 9.4. Inspection and Testing; Records

- Each shipment of PRODUCTS shall be subjected to a quality control inspection by CHEMBIO, as standard and customary for the industry. CHEMBIO shall number each shipment with a CHEMBIO lot number that is traceable to raw materials and/or components used in the manufacture of PRODUCTS.
- Upon receipt of the PRODUCT, FIOCRUZ shall inspect the quantity and appearance of said PRODUCTS. Should FIOCRUZ find any defect in the appearance of the PRODUCTS and/or quantity of the PRODUCTS between the ordered and the delivered PRODUCTS, FIOCRUZ shall notify CHEMBIO, in writing, within ten (10) days after FIOCRUZ's receipt of such PRODUCTS. If CHEMBIO receives FIOCRUZ'S notice with regard to a shortage in quantities, weight or with regard to defects in Specifications, CHEMBIO shall promptly take measures to remedy the situation by, as the case may be, supplementing the initial shipment with sufficient PRODUCTS so as to satisfy that initial order or substituting the non-conforming PRODUCTS with PRODUCTS that meet the Specifications, without any additional expenses to FIOCRUZ. CHEMBIO shall maintain adequate records of PRODUCTS manufacture by batch and lot, including test and laboratory observation data, and will provide copies of such records to FIOCRUZ as requested, as reasonably necessary in connection with any FIOCRUZ Product recall.

## SECTION 10 – Prices and Payments

10.1. Payment by FIOCRUZ for all orders of the PRODUCTS shall be via thirty days irrevocable letter of credit confirmed by a US bank and otherwise containing terms reasonably acceptable to CHEMBIO. Such letter of credit shall be issued to CHEMBIO prior to acceptance of the orders.

10.2. For the rights granted by CHEMBIO to FIOCRUZ for the intangible technical information for the production of the FINAL PRODUCT and the other obligations of CHEMBIO contained in this Contract, FIOCRUZ shall pay CHEMBIO a royalty of 5% (five per cent) of Selling Price of the Units.

10.2.1. 10.2.1 For royalties calculations, NET SALES of FINAL PRODUCT shall be regarded as the greatest potentially possible to be obtained by FIOCRUZ, considering the price to be charged similar to that one in arms length negotiations, or between non related parties, as well as the prices of similar and/or replacing products.

10.2.2 For royalties calculation purposes, NET SALES are defined as gross income of the FINAL PRODUCT undertaken by FIOCRUZ, taking commercial and industrial taxes, insurance, freight and packaging, as well as income of any import directly or indirectly carried out by CHEMBIO.

10.3. FIOCRUZ shall maintain a register of the sales and the royalties to be paid and already paid to CHEMBIO, having to inform CHEMBIO and quarterly the total amount to be paid.

10.4. CHEMBIO may assign a technician to confirm the accuracy of the accounting registers referred to in this in this Section 10, and FIOCRUZ will allow this technician complete access to this accounting data.

10.5. All royalty payments due to the paragraph 10.2 shall be made by FIOCRUZ to CHEMBIO quarterly, within a 30 days period, counted from the date FIOCRUZ is obliged to notify CHEMBIO the amount owed. The payments shall be deposited in a bank account to be designated by CHEMBIO.

10.6. Technical Assistance Services - The payments for the assistance services are included in the payments for the Technology, as determined in paragraph 10.2, but FIOCRUZ being responsible for paying the airline tickets, executive class, normal lodging and other travel expenses and a daily service fee in Real currency corresponding of U.S.\$ 150.00 per person.

## **SECTION 11 – Government authorizations**

11.1. FIOCRUZ shall be responsible for registering the PRODUCTS at ANVISA, as well as at the other government authorities of the MERCOSUL countries, although FIOCRUZ will have full support from CHEMBIO in providing the necessary information.

11.2. In the event ANVISA denies registry for the PRODUCTS, this Contract will be canceled and all its obligations will become null, except those determined in Section 6 of this Contract.

## **SECTION 12 – Term and Termination**

12.1. This Contract will come into force between the Parties as of the Effective Date (i) for a period estimated in 3 years for the transfer of technology, and, (ii) at the end of this period, will remain in force for a period of 5 years as of the date of the first act in the market with the FINAL PRODUCT by FIOCRUZ, and (iii) shall be automatically renewed for a period of 5 (five) years, if INPI authorizes the renewal

12.2. This Contract may be terminated in the failure by any of the Parties to fulfil their obligations as determined in this Contract, which must be notified by the Party considered injured, with the violating Party having to make amends for the violation in a period of not more than 30 days counted as of the notification, without which the Contract may be terminated, whereby the injured Party may further seek remedial action.

## **SECTION 13 – Effects of termination**

13.1. In the case this Contract should be rescinded, through the fault or unjustified initiative of FIOCRUZ, it shall hand over to CHEMBIO all and any documents (including any copy of such document) and all and any record, of any type and done by any means, that contains or concerns the technical information and any other technical information of a confidential nature provided by FIOCRUZ to CHEMBIO and any apparatus, substance or model that may, in some form, constitute a physical form or represent any such technical information or any such technical information of a confidential nature in the possession or in the power of FIOCRUZ at the moment of terminating this Contract.

13.1.1. FIOCRUZ will cease all and any use of the technical information or any other technical information of a confidential nature provided by CHEMBIO to FIOCRUZ for any purpose.

13.1.2. FIOCRUZ will cease production of the PRODUCT and, will negotiate the sale of the PRODUCT that remain stored in accordance with the Decree no. 99.658/90.

13.2. In the case this Contract becoMonth extinct through the expiry of its term or earlier, by fault or unjustified initiative of CHEMBIO, FIOCRUZ will not hand over any document (including any copy of such document) or any record, of any type and done by any means, that contains or concerns the technical information and any other technical information of a confidential nature provided by FIOCRUZ to CHEMBIO and any apparatus, substance or model that may, in some form, constitute a physical form or represent any such technical information or any such technical information of a confidential nature in the possession or in the power of FIOCRUZ at the moment of terminating this Contract.

13.2.1. FIOCRUZ will not cease all and any use of the technical information or any other technical information of a confidential nature provided by CHEMBIO to FIOCRUZ for any purpose.

13.2.2. FIOCRUZ will not cease production of the PRODUCT, and the payment of royalties will no longer be appropriate.

## **SECTION 14 - Controversies and disputes**

14.1 The Parties agree that this CONTRACT shall be governed by the laws of Brazil and its courts shall have jurisdiction over any dispute that may occur from or related to this CONTRACT. Both CHEMBIO and FIOCRUZ recognize they shall not be considered excluded from adjudication and compliance with their obligations under this CONTRACT concerning countries other than Brazil (including, but not limited to the compliance with any restriction of one of the Parties outside the TERRITORY) by courts outside Brazil.

## **SECTION 15 - Obligations**

15.1. CHEMBIO has the following obligations, in particular:

1. that the PRODUCTS delivered to FIOCRUZ conform to the Specifications at the time of delivery and for the duration of the shelf life as stipulated in the Specifications, within the time frame allotted and if handled and stored in accordance with the Specifications and other instructions provided by CHEMBIO.
2. to provide FIOCRUZ with all the intangible technical information necessary for the manufacture, quality control and commercialization of PRODUCT.
3. to provide FIOCRUZ a list of installations, equipment and personnel necessary to comply with the all phases of the technology transfer as the schedule of Exhibit A and render free technical assistance, in accordance with the provisions of Section 5.

15.2. FIOCRUZ has the following obligations, in particular:

1. to register the PRODUCT at ANVISA
2. to assume responsibility for all the expenses of buying the equipment and installations, as well as for all the employment, training and supervision of the agreed services to be provided by CHEMBIO concerning the technology transfer.
3. To attend the DST/AIDS Program demand as estimated set forth in Section 8.1.

15.3. If FIOCRUZ does not satisfy Section 15.2.3, the Parties in good faith will discuss methods to cure the breach of this situation. This shall not prohibit CHEMBIO's right to suspend or terminate the Agreement according to the Section 12.2.

## **SECTION 16 – Intellectual Property Rights and Improvements**

16.1. CHEMBIO guarantees that no right of intellectual property belongs to Parties or third parties, which might prevent the product from being manufactured. If any technical information disclosed by CHEMBIO to BIO-MANGUINHOS should violate the rights of intellectual property of third parties, CHEMBIO shall be responsible for any costs and indemnification incurred, and BIO-MANGUINHOS shall help advocating for CHEMBIO, giving notice of the related matters.

16.2. Should any improvement be made by any of the Parties concerning the PRODUCT, during the term of this Contract, that Party shall promptly disclose the improvement to the other Party, and both Parties will negotiate and reach an agreement concerning the treatment of such improvement. The legal right of the Party that developed the improvement will be respected. Except in the case of improvements that alter substantially the Product, the improvements will be used by both of the Parties without any remuneration to the other Party, and, in this event, the permitted use shall be done without any new contract or addendum to this CONTRACT.

## **SECTION 17 – Informing of adverse experiences and recall of the PRODUCT**

17.1. Each Party will provide the other with the name, position and fax and telephone numbers of a designated safety representative to whom all reports governed by this Section shall be addressed to.

Dr. Avi Pelossof  
Vice President – Sales and Marketing  
CHEMBIO DIAGNOSTIC SYSTEM, Inc.  
3661 Horseblock Rd., Medford  
New York 11763  
USA

and

Dr. Akira Homma  
Diretor  
Fundação Oswaldo Cruz – FIOCRUZ  
Instituto de Tecnologia em Imunobiológicos – BIO-MANGUINHOS  
Pavilhão Rocha Lima  
Av. Brasil 4365 – Mangueiras  
21.045-900 Rio de Janeiro, RJ  
Brasil

17.2. If any of the Parties receives a report of any adverse experience concerning the Product, such Party will notify the problem to the regulatory authority of the country in which the occurrence was reported, observing the laws and regulations of such country. A copy of each such report will simultaneously be forwarded to the other Party.

17.3. Each Party will inform the other by telephone, fax, e-mail or any other means, with notification by registered mail being indispensable:

- a. within a business day as of receipt by the central safety department/committee of the Party, of any unexpected serious and fatal or life threatening adverse experience;
- b. within 5 business days as of receipt by the central safety department/committee of the Party, of all other serious adverse experiences.

17.4. A monthly summary of all the adverse experiences will be undertaken in writing by any of the Parties to the other Party, indicating which cases previously reported in accordance with this Section.

17.5. Any other additional information received by a Party about any serious adverse experience, or any information that renders an adverse experience into a serious adverse experience, will also be informed by telephone, fax, e-mail or any other means, with notification to the other Party by registered mail being indispensable within one or five business days as of receipt by the first Party (as appropriate, in accordance with the criteria defined in paragraph 17.3.).

17.6. The Party that receives the notification of an adverse experience shall employ reasonable efforts to follow the case and inform the other Party.

17.7. The Parties, as soon as they have knowledge of an occurrence with the PRODUCT, will take all the measures necessary to recall the PRODUCT from the circulation, as well as promptly seeking to comply with the national legislation of the country in question.

## **SECTION 18 - Limited Warranty and Indemnification**

18.1. In the event that the PRODUCTS do not conform to the Specifications and such failure does not result from the fault, negligence or wilful misconduct of FIOCRUZ or any of its Affiliates or their directors, officers, agents or employees, CHEMBIO shall replace them immediately upon written request by FIOCRUZ, as set forth in Section 8.4 above. In the event that there is a disagreement between the Parties as to the conformity of the PRODUCTS to the Specifications, a neutral third Person, mutually agreed upon, shall test the PRODUCTS. The Party whose assertion as to the conformity or non-conformity of the PRODUCTS is not confirmed by such neutral review shall bear the costs of carrying out such review. FIOCRUZ shall return the non-conforming PRODUCTS at its own cost, unless it is determined that the non-conforming PRODUCTS do not meet Specifications. In such event, in addition to replacing the non-conforming PRODUCTS, CHEMBIO will reimburse FIOCRUZ for the costs of returning the non-conforming PRODUCTS.

18.2. FIOCRUZ has the expertise and skill in the commercialization and use of the PRODUCT and has made its own evaluation of the capabilities, safety, utility and commercial application of the product. CHEMBIO makes no representation and extends no condition or warranty of any kind, either express or implied, with respect to the suitability of the product, for use by fiocruz other than as specifically provided in the immediately preceding paragraph; and expressly disclaims any warranties of merchantability, satisfactory quality, fitness for a particular purpose and any other implied warranties with respect to the capabilities safety, utility or commercial application of the product FIOCRUZ shall indemnify and hold CHEMBIO, its directors, officers, agents or employees, or any of its Affiliates or their directors , officers, agents or employees (collectively, the “CHEMBIO Parties”; individually, a “CHEMBIO Party”) harmless from any and all liability, damage, loss, cost or expense resulting from any claims or suits brought against any FIOCRUZ Party by any third person which arise solely from FIOCRUZ’s use of the PRODUCT and/or FIOCRUZ’s manufacture, handling or sale of PRODUCTS, unless such liability, damage, loss, cost or expense is directly attributable to any fault, negligence, or wilful misconduct of a CHEMBIO Party or to the failure of the PRODUCT to conform to Specifications or the warranties made in this Agreement.

18.3. In the event that the use of any PRODUCTS infringes or would infringe any third Person patent rights, the Party first becoming aware of same shall notify the other and the Parties shall discuss the matter and decide on a course of action. Should any such infringement claim or suit be made with regard to the PRODUCTS, CHEMBIO may

- I. change the PRODUCTS so as to make them non-infringing ;
- II. obtain rights to the third Person PRODUCTS and make such rights available to FIOCRUZ; or
- III. if neither of the foregoing options is commercially feasible, terminate this Contract without any indemnity to FIOCRUZ.

Despite the agreement above, in the eventuality of the occurrence of an indemnity to be made to the owner of the patent, such indemnity shall be the entire responsibility of CHEMBIO, considering that FIOCRUZ is not party to the intangible confidential information to be furnished by CHEMBIO under the obligations of this Contract.

## **SECTION 19 - Assignment of Rights:**

19.1. No rights or obligations under this Contract may be assigned or transferred by any of the Parties in this Contract to any third party, including the successor of any of the Parties, without prior consent in writing by the other Party, and any attempt to cede or transfer without such consent will be considered null and void.

## **SECTION 20 – Notification**

20.1. Any notification to be furnished in accordance with this CONTRACT shall be by registered airmail, even after prior notification by any other means, sent to the addresses of the headquarters of each of the Parties contained in the beginning of this document. A Party may change such address for purposes of notification, by notification sent to the other Party, in accordance with the determinations of this Section.

20.1.1. Any notification to CHEMBIO shall be addressed as follows:

Dr. Avi Pelossof  
CHEMBIO DIAGNOSTIC SYSTEM, Inc.  
Horseblock St. 3661, Medford  
New York 11763  
USA

20.1.2. Any notification to FIOCRUZ shall be addressed as follows:

Dr. Akira Homma  
Diretor  
Fundação Oswaldo Cruz – FIOCRUZ  
Instituto de Tecnologia em Imunobiológicos – BIO-MANGUINHOS  
Pabilhão Rocha Lima  
Av. Brasil 4365 – Manguinhos  
Rio de Janeiro, RJ 21.045-900  
Brasil

## SECTION 21 – Duplicates of this Contract

21.1. This Contract is executed with two duplicated originals in the Portuguese language and two duplicated originals in the English language. The texts in Portuguese and English are true and faithful translations, one of the other, but in the case of difference between the two texts, the text in Portuguese shall prevail.

## SECTION 22 – Exclusions

22.1. In the event any of the dispositions of this Contract should come to be considered invalid or impossible to enforce due to being in violation of any law or regulation, the remaining dispositions of this Contract shall remain valid and in force, as if the disposition being invalid or impossible to enforce were not part of the Contract. Both Parties agree to substitute such disposition with a new valid and applicable disposition capable of attaining the purposes of this Contract and the original intentions of the Parties, wherever possible under the applicable laws.

## SECTION 23 – Entire content

23.1. This Contract represents the entire content and agreement between the Parties concerning the subject of the Contract, as of the Effective Date of this Contract, and supercedes all and any Contract, negotiation, understanding, representation, request or prior document made and exchanged between the Parties concerning such subject. No amendment, modification or alteration to any of the terms and conditions of this Contract or renouncement concerning these shall be considered valid and in force by the Parties, unless done in writing and signed by both the Parties considered here.

## SECTION 24 – Non-competition

24.1. During the term of the Contract, CHEMBIO shall not transfer the technology for the manufacture of the PRODUCT in Brazil to any third party in Brazil, without prior written consent from FIOCRUZ.

24.2. During the term of the Contract, FIOCRUZ shall not transfer the technology for the manufacture of the PRODUCT to any third party without prior written consent from CHEMBIO.

## SECTION 25 – Force majeure

25.1. Neither of the Parties can be held responsible to the other Party for any impossibility to comply with its obligations in this Contract, provided they are the result of war, revolution, strike, acts of God, official acts by the government or any other event that is beyond reasonable control of that Party; however, in the occurrence of an event of force majeure, the Party whose compliance with its obligations was affected shall immediately inform the other Party, aiming to jointly encounter measures that may circumvent the problem.

**AND, BEING IN AGREEMENT AFTER HAVING BEEN READ AND FOUND IN ACCORDANCE, THE PARTIES SIGN THE PRESENT INSTRUMENT, IN FOUR PARTS, WITH TWO IN THE ENGLISH LANGUAGE AND TWO IN THE PORTUGUESE LANGUAGE, ALL HAVING THE SAME CONTENT AND FORM, WITH ONE SINGLE EFFECT, IN THE PRESENCE OF THE WITNESSES BELOW.**

<b>Local:</b>	<b>Local:</b>
<b>Data:</b>	<b>Data:</b>
<b>Chembio Diagnostic System, Inc.</b>	<b>Fundação Oswaldo Cruz</b>
<b>Lawrence A. Siebert</b>	<b>Paulo Buss</b>
<b>Presidente</b>	<b>Presidente</b>
	<b>Instituto de Tecnologia em Imunobiológicos</b>
	<b>Akira Homma</b>



Testemunhado por:

**CONSENT OF INDEPENDENT ACCOUNTANTS**

We hereby consent to the incorporation by reference in this Registration Statement on Form SB-2 Amendment # 1 of our report dated February 27, 2004 except as to Note 12 which is as of March 19, 2004, relating to the financial statements of Chembio Diagnostic Systems, Inc. and subsidiary which appears in Chembio Diagnostics, Inc. Form 8-K, as filed with the Securities and Exchange Commission on May 14, 2004. We also consent to the references to us under the headings “Experts” in such Registration Statement.

Lazar Levine & Felix LLP  
/s/ Lazar Levine & Felix LLP

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August 2, 2004