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

# FORM SB-2 REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933 Chembio Diagnostics, Inc.

(Name of small business issuer in its charter)

Nevada
State or Jurisdiction of Incorporation

(Primary Standard Industrial Classification Code Number) **88-0425691** (I.R.S. Employer Identification Number)

(State or Jurisdiction of Incorporation or organization)

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)

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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]

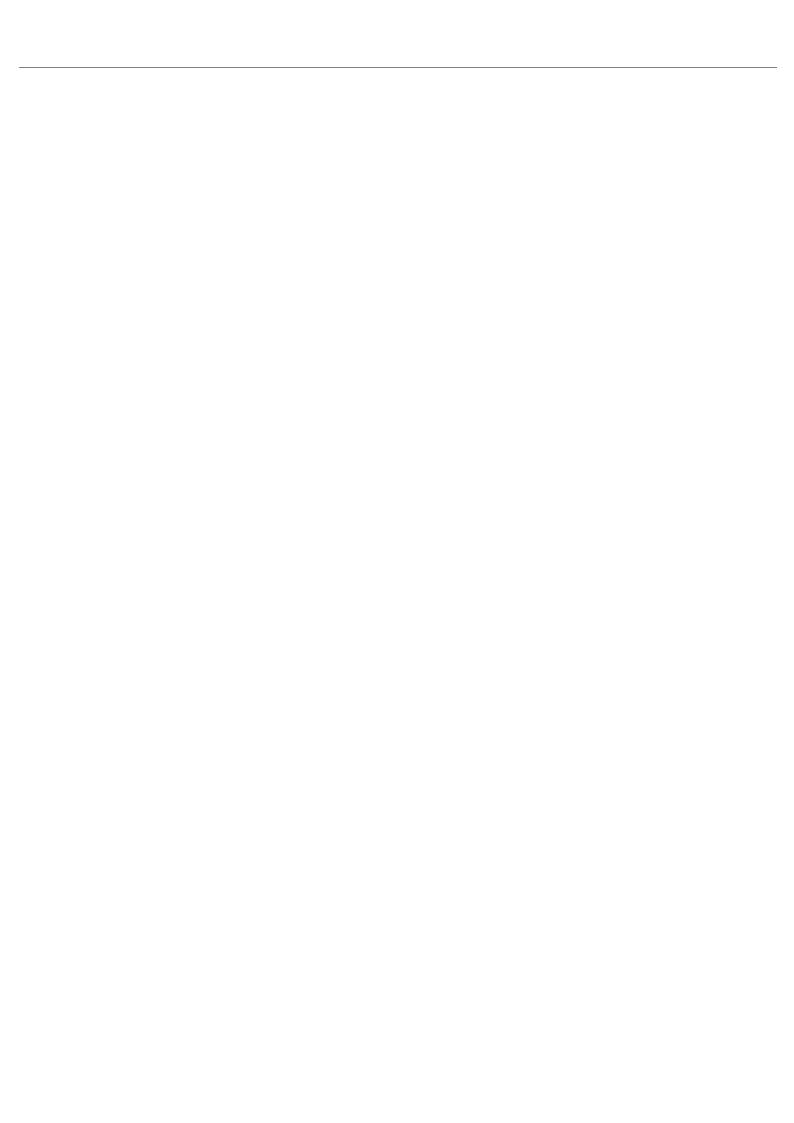
If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. []

CALCULATION OF REGISTRATION FEE							
Title Of Each Amount To Be Proposed Proposed Amount Of Class of Securities Registered Maximum Maximum Registration To Be Registered Offering Price Aggregate Fee Per Unit (1) Offering Price (1)							
common stock (2) 20,826,170 \$1.55 \$32,280,563 \$4,090							

(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.

Includes (i) up to 6,032,032 shares issuable upon the conversion of 120.638 shares of the Registrant's 8% Series A Convertible Preferred Stock, (ii) up to 9,439,025 shares issuable upon the exercise of outstanding warrants and (iii) up to 584,000 shares issuable upon the exercise of outstanding options.

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.



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 JUNE 4, 2004**

# **PROSPECTUS**

# CHEMBIO DIAGNOSTICS, INC.

# 20,826,170 SHARES OF COMMON STOCK

This prospectus relates to the sale by certain stockholders of Chembio Diagnostics, Inc. of up to 20,826,170 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 (the "Series A Preferred") or upon the exercise of warrants and options to purchase shares of our common stock. We are not selling any shares of common stock in this offering and therefore will not receive any proceeds from this offering. All costs associated with this registration will be borne by Chembio.

Preferred") or upon the exercise of warrants and options to purchase shares of our common stock. We are not selling any shares of common stock in this offering and therefore will not receive any proceeds from this offering. All costs associated with this registration will be borne by Chembio.

Chembio's common stock is quoted on the OTC Bulletin Board under the symbol "CEMI"" On June 1, 2004 the closing bid and ask prices for one share of our common stock were \$1.30 and \$1.80, respectively.

THESE SECURITIES ARE SPECULATIVE AND INVOLVE A HIGH DEGREE OF RISK. YOU SHOULD CONSIDER CAREFULLY THE "RISK FACTORS" BEGINNING ON PAGE 3 OF THIS PROSPECTUS BEFORE MAKING A DECISION TO PURCHASE OUR STOCK.

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

The date of this Prospectus is \_\_\_\_\_\_\_\_, 2004

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# PROSPECTUS SUMMARY

This summary is not complete and does not contain all the information that you should consider before investing in our common stock. This summary highlights selected information contained elsewhere in this prospectus. You should read the entire prospectus carefully, including the more detailed information regarding our company, the risks of purchasing our common stock discussed under "Risk Factors," and our financial statements and the accompanying notes, before making an investment decision.

# Overview

Chembio Diagnostic Systems Inc. ("CDS") was formed in 1985. Since its inception, CDS 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 (the "Closing" or the "Effective Time"), CDS completed a merger (the "Merger") through which it became a wholly-owned subsidiary of Trading Solutions.com, Inc. and through which the management and business of CDS 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. ("Chembio").

# **Our Business**

Our near term focus is on obtaining U.S. FDA regulatory approval for and increasing distribution of our rapid HIV tests, and in completing the development of tests for Mad Cow disease, dental bacteria, and Tuberculosis pursuant to various collaborative agreements and grants that are in place with respect to those products. We also have developed the only FDA-cleared and CLIA-waived Lyme disease rapid test, which detects antibodies to the antigen that causes Lyme disease, and which is being distributed by another entity under that entity's brand name.

Our Sure Check<sup>TM</sup> HIV rapid test eliminates the need for a separate sample collection system which improves ease of use and safety. The HIV Stat-Pak product, while not as simple as the Sure-Check®, is value priced, flexible and yet is still as easy to use as the competitive HIV rapid tests (see "Competition" below) that are approved by the Food and Drug Administration ("FDA"). Both of our HIV tests use a standardized test strip that we developed using patented materials that we license from third parties, together with our own know-how, which we believe is proprietary, and trade secrets. Rapid HIV tests address the problem that results from individuals who are tested in public health settings and who do not return or call back for results from laboratory tests, which can take at least several days to process. We expect that FDA approval should occur during 2005 if the various FDA requirements for a Pre-Marketing Approval are met on a timely basis.

Our principal executive offices are located at 3661 Horseblock Road, Medford, New York 11763. Our telephone number is (631) 924-1135.

# The Offering

By means of this prospectus, a number of our stockholders are offering to sell up to 4,771,113 shares of common stock which they own, up to 6,032,032 shares of common stock which they may at a later date acquire upon the conversion of our Series A Preferred, and up to 10,023,025 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 6,333,874 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 and the exercise of options and/or warrants previously issued by Chembio.

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

The purchase of the securities offered by this prospectus involves a high degree of risk. Risk factors include the lack of liquidity of our common stock, our history of operating losses, our need for additional capital, competition from many sources, including those with significantly greater financial resources, and the need to continue to develop technology for our products. See the "Risk Factors" section on page 3 of this prospectus for additional Risk Factors.

#### 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 CDS, as if the Merger transaction between Chembio and CDS had occurred at the beginning of the respective periods presented and therefore assumes that certain proceeds of the financings were expended in the periods presented, and that certain 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	1,392,618	2,744,095	
Net Loss	(1,270,458)	(2,125,140)	
Current Assets	3,402,141	3,410,827	
Total Assets	3,830,857	3,838,225	
Current Liabilities	1,459,039	1,135,984	
<b>Total Liabilities</b>	2,200,341	1,844,460	
Stockholders' Equity	1.630.516	1,993,765	

#### 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. 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. The risks and uncertainties described below are not the only ones we face. There may be additional risks and uncertainties that are not known to us or that we do not consider to be material at this time. If the events described in these risks occur, our business, financial condition and results of operations would likely suffer. Additionally, this prospectus contains forward-looking statements that involve risks and uncertainties. Our actual results may differ significantly from the results discussed in the forward-looking statements. This section discusses the risk factors that might cause those differences.

# **Risks Related To Our Common Stock**

Our common stock is extremely illiquid, and this should be expected to impair your ability to sell or transfer your stock, or to use it as collateral

Our common stock trades on the over-the-counter market. 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 March 31, 2004. The closing price of our common stock ranged from a low of \$0.17 per share to a high of \$3.00 per share during the 12 months ended May 31, 2004, after giving effect to the 1:17 reverse stock split on March 12, 2004. Holders of our common stock may not be able to liquidate it in a short time period or at the market prices that currently exist at the time a holder decides to sell. Because of this limited liquidity, it is unlikely that shares of our common stock will be accepted by lenders as collateral for loans.

There are fewer than 181,000 shares of our common stock currently eligible for trading in the open market, and this could result in an extremely volatile market for our stock.

As of June 1, 2004, there are fewer than 181,000 shares of our common stock eligible for trading in the open market. The balance of our outstanding shares are subject to lock-up agreements or are restricted securities that have not been held long enough to allow resale in the open market. The availability of so few shares for trading could result in an extremely volatile and illiquid market for the shares. There are an additional 10,803,145 shares of common stock (including the common stock underlying the immediately exercisable portion of Series A Preferred but excluding all other convertible securities) that will become tradable if and when this Registration Statement becomes effective. In the absence of an effective registration statement, none of the restricted securities become eligible for resale until May 2005.

At the time of effectiveness of the Registration Statement (the "Registration Statement") of which this Prospectus is a part, there will be a large increase in the number of shares of our common stock that will eligible for trading in the open market, which could result in a significant decrease in the market price for our stock.

At the time of effectiveness of the Registration Statement, the number of shares of our common stock eligible for trading in the open market will increase approximately from 180,0000 to 21,006,965. (This number includes the shares of common stock underlying the immediately exercisable portion of our outstanding Series A Preferred, but excludes the common stock underlying all our other outstanding convertible securities.) Having these additional shares eligible for sale could result in a significant decrease in the market price for our stock.

We will be restricted from paying dividends on our common stock pursuant to the terms of the Certificate of Designation filed in connection with the offering of our Series A Preferred, which will impact the return on your investment.

The Certificate of Designation creating our Series A Preferred that was filed in connection with the private placement of our Series A Preferred contains restrictions on our ability to declare and pay dividends on our common stock at any time that shares of our Series A Preferred are issued and outstanding. Thus, there can be no assurance that the holders of our common stock will ever receive any dividends on the shares of common stock that they hold.

Holders of our common stock own an unsecured equity interest in Chembio, and there can be no assurance that we will be able to make a distribution to the holders of our common stock in the event of our liquidation.

Our common stock will not be secured by any of the assets of Chembio or CDS. Therefore, in the event of the liquidation of Chembio, the holders of our common stock will receive a distribution only after all of our secured and unsecured creditors have been paid in full and the holders of the Series A Preferred have been paid their liquidation preference. There can be no assurance that we will have sufficient assets after paying our secured and unsecured creditors, and the holders of the Series A Preferred, to make any distribution to the holders of our common stock.

The percentage ownership of Chembio evidenced by our common stock is subject to dilution.

We are not prohibited from issuing additional shares of capital stock, or other securities, that rank junior to the Series A Preferred, including additional shares of our common stock. Moreover, to the extent that any additional capital stock is issued by us, a holder of our common stock is not entitled to purchase any part of such issuance of stock. The holders of our common stock do not have statutory "preemptive rights" and therefore are not entitled to maintain a proportionate share of ownership in Chembio by buying additional shares of any new issuance of equity by Chembio before others are given the opportunity to purchase the same. Accordingly, you must be willing to assume the risk that your percentage ownership of Chembio, as a holder of our common stock, is subject to change as a result of the sale of any additional equity interests in Ch embio subsequent to the date that you purchase or acquire your shares of common stock.

Our management will control a significant percentage of our outstanding common stock and their interests may conflict with those of our other stockholders.

Our directors and executive officers and their affiliates beneficially own approximately 54.67% of our outstanding common stock. This concentration of ownership could have the effect of delaying or preventing a change in control of or otherwise discouraging a potential acquirer from attempting to obtain control of Chembio. This could have a material adverse effect on the market price of our common stock or prevent our stockholders from realizing a premium over the then prevailing market prices for their shares of our common stock.

#### Potential issuance and exercise of new warrants and exercise of outstanding warrants could adversely affect the value of our securities.

In connection with our May 5, 2004 private placement of our Series A Preferred, we issued 151.58 shares of Series A Preferred together with warrants to purchase an additional 9,094,784 shares of our common stock at an exercise price of \$.90 per share (the "Private Placement Warrants"). The shares of Series A Preferred are convertible into 7,579,000 shares of our common stock.

In connection with the acquisition of CDS, we assumed warrants (the "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 share.

On May 5, 2004, we issued warrants (the "Placement Agent Warrants") to designees of H.C. Wainwright & Co., Inc. and WellFleet Partners, Inc., our placement agents in the Series A Preferred private placement, to purchase 751,667 shares and 183,333 shares of our common stock, respectively, at an exercise price of \$ 0.72 per share.

On May 5, 2004, we issued warrants (the "MLB Warrants") to Mark L. Baum, our former president and a current member of our board of directors, pursuant to an employment agreement 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.

If and when the Registration Statement becomes effective, and if the Series A Preferred is converted, or if the Private Placement Warrants, the Assumed Warrants, the Placement Agent Warrants or the MLB Warrants are exercised, the common shares issued pursuant to each such conversion or exercise will be freely tradable, increasing the total number of common shares issued and outstanding. If these shares are offered for sale in the public market, the sales could adversely affect the prevailing market price by lowering the bid price of our securities. The exercise of any of these warrants also could materially impair our ability to raise capital through the future sale of equity securities because issuance of the common shares underlying the warrants would cause further dilution of our securities. The Series A Preferred and the warrants are subject to or c ontain certain anti-dilution protection that may result in the issuance of additional shares under some circumstances including, but not limited to, paying of a dividend, subdivision of our outstanding shares into a greater number of shares, combination of our outstanding shares into a smaller number of shares, an issuance of shares of common stock by reclassification or a sale of our common shares, or a security convertible into common shares, for consideration per share less than the conversion price of the Series A Preferred or exercise price of the warrants, as the case may be.

# Potential issuance and exercise of new options and exercise of outstanding options could adversely affect the value of our securities.

In connection with the acquisition of CDS, pursuant to the Merger Agreement, we adopted the 1999 Stock Option Plan of CDS (the "Plan"), and assumed all outstanding options thereunder. As of May 31, 2003, there were 704,000 options issued and outstanding under the Plan and 796,000 options available for issuance under the Plan.

If and when this Registration Statement becomes effective and these options are exercised, the common shares issued will be freely tradable, increasing the total number of common shares issued and outstanding. If these shares are offered for sale in the public market, the sales could adversely affect the prevailing market price by lowering the bid price of our securities. The exercise of any of these options could also materially impair our ability to raise capital through the future sale of equity securities because issuance of the common shares underlying the options would cause further dilution of our securities. The options are subject to or contain certain anti-dilution protection that may result in the issuance of additional shares under some circumstances including, but not limited to, paying of a dividend in common shares, a declaration of a dividend paya ble in a form other than common shares in an amount that has a material effect on the price of common shares, a combination or consolidation of the outstanding common shares (by reclassification or otherwise) into a lesser number of common shares, a recapitalization, a spin-off or a similar occurrence.

# Substantial resale of restricted securities may depress the market price of our securities.

As of June 1, 2004, there are 6,333,874 common shares issued and outstanding, and 19,853,111 shares of common stock underlying our Series A Preferred and our outstanding options and warrants that are (excluding the shares of common stock that were outstanding and freely tradable prior to the Merger) "restricted securities" as that term is defined under the Securities Act of 1933, as amended, (the "Securities Act"). In the future these restricted securities may be sold in compliance with Rule 144 of the Securities Act, or pursuant to this Registration Statement if and when it becomes effective. Rule 144 provides that a person holding restricted securities for a period of one year or more may, in any three

month period, sell those securities in unsolicited brokerage transactions or in transactions with a market maker, in an amount equal to the greater of one percent of our outstanding common shares or the average weekly trading volume for the prior four weeks. Sales of unrestricted shares by affiliates of Chembio are also subject to the same limitation upon the number of shares that may be sold in any three-month period. Investors should be aware that sales under Rule 144 or 144(k), or pursuant to a registration statement filed under the Securities Act, may depress the market price of our securities in any market that may develop for such shares.

# If there are no market makers for our common stock, then the trading market for our common stock may cease.

Our common shares trade on the OTC Bulletin Board under the symbol CEMI. In the event that the market makers cease to function as such, public trading in our securities will be adversely affected or may cease entirely.

Our common stock is a Penny Stock as defined in the Exchange Act and 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.

Our common stock is classified as penny stock, which is traded on the OTCBB. 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 hereby. 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 certain regulations which impose sales practice requirements on broker-dealers. For example, broker-dealers selling such securities must, prior to effecting the transaction, provide their customers with a document that discloses the risks of investing in such securities. Furthermore, if the person purchasing the securities is someone other than an accredited investor or an established customer of the broker-dealer, the broker-dealer must also approve the potential customer 's account by obtaining information concerning the customer's financial situation, investment experience and investment objectives. The broker-dealer must also make a determination whether the transaction is suitable for the customer and whether the customer has sufficient knowledge and experience in financial matters to be reasonably expected to be capable of evaluating the risk of transactions in such securities. Accordingly, the Commission's rules may result in the limitation of the number of potential purchasers of the shares of the common stock.

#### Risks Related To Our Industry, Business and Strategy

The markets we serve are highly competitive and many of our competitors have much greater resources which may make it difficult for us to reach and maintain profitability.

Competition in the markets in which we participate is intense, and we expect competition to increase. This could mean lower prices for our products, reduced demand for our products and a corresponding reduction in our ability to recover development, manufacturing and other costs. Many of our competitors have substantially greater resources than we do.

We are dependent upon key executive and other management personnel, the loss of whom could have an adverse effect on our business.

Our success depends to a significant extent upon the performance of certain key employees, the loss of whom could have an adverse effect on our business. Although we have entered into employment agreements with certain employees, there is no assurance that we will be successful in retaining these or any other key employees.

# Possible inability to hire and retain qualified personnel.

We will need additional skilled, sales and marketing, technical and production personnel to grow the business. If we fail to retain our present staff or hire additional qualified personnel, our business could suffer.

We compete in an industry that continually experiences technological change, and we may have fewer resources than many of our competitors to continue to invest in technological improvements.

The point-of-care diagnostics industry is undergoing rapid technological changes, with frequent introductions of new technology-driven products and services. Our future success will depend, in part, upon our ability to address the needs of our customers by using technology to provide products and services that will satisfy customer demands, as well as to create additional efficiencies in our operations. Many of our competitors have substantially greater 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.

#### If we fail to keep up with technological factors and fail to develop our products, we may be at a competitive disadvantage.

The point of care diagnostic testing market is highly competitive. 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 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. Our success will depend upon new products meeting targeted product costs and performance, in addition to timely introduction into the marketplace. We are subject to all of the risks inherent in product development, which could cause material delays in manufacturing.

Many investors may consider our stock too speculative because of our dependence on products that have a limited market history or that are still being developed.

Although Chembio has been operating continuously since 1985, we have been manufacturing our current HIV products only since 2001, and we are still developing the other products which we believe, together with our HIV tests, will comprise the bulk of our future business. This lack of product market history may result in many investors considering our stock too speculative for investment.

# We have a history of incurring net losses and there is no assurance that we will be able to achieve profitability.

Since the inception of CDS 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. There is no assurance that we will be able to increase our revenues at a rate that is sufficient to achieve profitability. In addition, the success of competing products and technologies, pricing pressures or manufacturing difficulties could further reduce our profitability.

There is no assurance that any of our products will achieve sufficiently widespread market acceptance to reach revenue levels necessary for profitability.

Achieving market acceptance for our rapid HIV tests and other new products pursuant to our collaborations on those products will require substantial marketing efforts and expenditure of significant funds by us and/or our contract partners to inform potential distributors and customers of the distinctive characteristics, benefits and advantages of our test kits. We have no history upon which to base market or customer acceptance of these products, and there is no assurance that it will occur. Introduction of the HIV rapid test kits have required, and may continue to require substantial marketing efforts and expenditure of funds. In certain cases we will be reliant on the marketing efforts and expenditures of our contract partners, and cannot be assured that they will have the expertise and resources to effectively market the products we manufacture.

There is no assurance that we will be able to achieve our intention of participating in large government programs such as the Presidential Emergency Program for Aids Relief (PEPFAR) and similar programs worldwide.

We believe it to be in Chembio's best interests to meaningfully participate in the PEPFAR 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 aligning the Company with the many other players in these programs including the WHO, CDC, USAID, NGOs, and HIV service organizations. While we are making these efforts, there can be no assurance that our efforts will result in participating in these programs in a meaningful way.

Strategic partners may control a specific situation to an extent that it will be difficult for us to receive revenues or profits from those situations.

Although Chembio intends to pursue some product opportunities independently, other products will involve one or more strategic partners such as distributors or other corporate partners, non-governmental organizations, public health entities, non-profit foundations and others. Therefore, the amount and timing of resources to be devoted to these activities will in certain instances be controlled by others. Consequently, there can be no assurance that any revenues or profits will be derived from arrangements with strategic partners.

#### We may not be able to achieve our objective of increasing international sales.

Chembio intends to attempt to increase international sales of its products. A number of factors can slow or prevent international sales, or substantially increase the cost of international sales, including regulatory requirements (including compliance with applicable customs regulations); cultural and political differences; our inexperience in international markets; 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; economic conditions and the absence of available funding sources; and the possibility of long sales cycles, especially sales to foreign governments, quasi-governmental agencies and international public health agencies.

# We are developing and marketing products that are subject to product liability exposure and require product liability insurance.

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 potential liabilities. As we bring new products to market, we may need to increase our product liability coverage. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability or other claims could affect our decision to commercialize products that were developed by us or our strategic partners.

# We are obligated to comply with a settlement agreement with the FTC which may impact our ability to execute our business plan.

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"). The Stipulation is a settlement agreement between Chembio and the United States Federal Trade Commission (the "FTC") arising out of certain events that occurred in 1999. The events resulted in allegations by the FTC that Chembio misrepresented performance claims relating to a previous generation of its HIV test kits. Chembio denied these allegations. Nevertheless, due to the nature of the product and other circumstances, this matter consumed a very substantial amount of Chembio'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 was able to negotiate a settlement that it deemed acceptable and in Chembio's best interest and which would enable Chembio to avoid further litigation, the settlement was concluded. The Stipulation requires Chembio, 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 certain record keeping, notification, and monitoring provisions. Although management believes that it has complied with the Stipulation in every material respect, there can be no assurance that the FTC won't believe otherwise or, for any other reason that Chembio will be able to comply with the requirements of the Stipulation.

Due to the variety and complexity of the environments in which our customers operate, our products may not operate as expected which could adversely affect our business and results from operations.

Due to the variety and complexity of the environments in which our customers operate, our products may not operate as expected. This could result in cancelled orders, delays and increased expenses. In addition, the success of competing products and technologies, pricing pressures or manufacturing difficulties could further reduce our profitability and the price of our securities.

# Our research & development ("R&D") team may not be successful in its product development and/or product enhancement efforts.

Product development and/or enhancement are performed by our R&D team. There can be no assurance that our R&D team can successfully develop and/or complete the enhancement of our current products and/or complete the development of new products. The loss of one or more members of our R&D team could result in the interruption or termination of new product development and/or current product enhancement, affecting our ability to provide new or improved products to the marketplace, which would put us at a competitive disadvantage.

# There is a risk that we may not be able to continue to receive funding from grants and contract research. If that occurs, then we may not be able to fund future R&D.

We derived \$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 (NIH), 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 certain personnel and other costs and expenses for us. As a result of new grants and development contracts awarded to us by the NIH and the World Health Organization, and other entities, these types of revenues are anticipated to increase in 2004; however, there can be no assurance that these awards will be funded in their entirety or that new grants and contracts will be awarded in the future that will be equivalent in amount and/or term to that of recent experience.

# We could incur substantial additional costs if our products are not cost competitive or do not perform to the satisfaction of our customers.

Cost competitiveness and satisfactory product performance are essential for success in the point of care diagnostic testing market. There can be no assurance that new products we may develop will meet projected price or performance objectives. Moreover, there can be no assurance that unanticipated problems will not arise with respect to technologies incorporated into our test kits or that product defects, affecting product performance, will not become apparent after commercial introduction of new products. In the event that we are required to remedy defects in any of our products after commercial introduction, the costs to us could be significant, which could have a material adverse effect on our revenues or earnings.

# We are subject to a number of risks related to regulatory requirements and potential changes in regulatory procedures and requirements.

All of our proposed and existing products are subject to regulation in the United States by the United States Food and Drug Administration ("FDA"), 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, the specific product and 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 it will grant an approval or clearance to market the product. Each authority may impose its own requirements and delay or refuse to grant approval or clearance, even though a product has been approved in another country.

The approval or clearance process for a new product can be complex and lengthy. 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. This time span increases the costs to develop new products and increases the risk that we will not succeed in introducing or selling the subject products. There can be no assurance that these approvals will be granted at all, or that they will be granted in a timely fashion.

Changes in government regulations could also 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. Other changes in government regulations may adversely affect our financial condition and results of operations by requiring that we incur the expense of changing or implementing new manufacturing and control procedures.

Since December 2003, the European Union and other jurisdictions have established a requirement that diagnostic medical devices used to test human biological specimens must receive regulatory approval known as a CE mark or be registered under the ISO 13.485 medical device directive. As such, export to the European and other jurisdictions without the CE or ISO 13.485 mark is not possible. Although we are not currently selling products to countries requiring CE marking, we expect that we will do so in the near future. Although we are in the process of implementing certain quality and documentary procedures in order to obtain CE and 13.485 registration, and we are not aware of any material reason why such approvals will not be granted, there can be no assurance that any CE or ISO 13.485 registration will be granted.

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, there can be no assurance that these regulations will not change in a manner that could adversely impact our ability to export our products.

We own no lateral flow patents, our trade secrets and know-how are difficult to protect, we may not be able to obtain any meaningful protection for our technology, products or services, and the unavailability of licenses to intellectual property owned by others may have a material and adverse effect on our business

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 certain 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<sup>TM</sup> 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. 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 such licenses, which may not be available, may require the payment of upfront 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.

An important factor that will affect the specific countries in which we will be able to sell our rapid HIV tests and therefore the overall sales potential of the test is whether we can arrange a license to patents for detection of the HIV-2 virus. 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 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 certain markets, there can be no assurance that these discussions will continue or will be successful.

# We will need additional funding for our existing and future operations.

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 there can be no assurance that unanticipated costs will not be incurred. Future events, including the problems, delays, expenses and difficulties which may be encountered in obtaining applicable regulatory approvals, establishing and maintaining a substantial market for our products, could make cash on hand insufficient to fund operations for the anticipated period. In any event, we anticipate that we will be required to sell additional equity or debt securities or obtain additional credit

facilities within 10 to 24 months. There can be no assurance that such financing will be available or that we will be able to complete financing on satisfactory terms, if at all. Any financing may result in further dilution to existing shareholders.

# **Cautionary Statement Regarding Forward-Looking Statements**

Some statements in this prospectus contain certain "forward-looking" statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. All statements other than historical or current facts, including, without limitation, statements about our business, financial condition, business strategy, plans and objectives of management and our future prospects, are forward-looking statements. Such forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from these expectations. Forward-looking statements may be identified by the use of forward-looking terminology, such as "may," "shall," "could," "expect," "estimate," "anticipate," "predict," "probable, 48; "possible," "should," "continue," or similar terms, variations of those terms or the negative of those terms. The forward-looking statements specified in the following information have been compiled by our management on the basis of assumptions made by management and considered by management to be reasonable. Our future operating results, however, are impossible to predict and no representation, guarantee, or warranty is to be inferred from those forward-looking statements.

The assumptions used for purposes of the forward-looking statements specified in the following information represent estimates of future events and are subject to uncertainty as to possible changes in economic, legislative, industry, and other circumstances. As a result, the identification and interpretation of data and other information and their use in developing and selecting assumptions from and among reasonable alternatives require the exercise of judgment. To the extent that the assumed events do not occur, the outcome may vary substantially from anticipated or projected results, and, accordingly, no opinion is expressed on the achievability of those forward-looking statements. We cannot guarantee that any of the assumptions relating to the forward-looking statements specified in the following information are accurate, and we assume no obligation to update any such forward-looking statements.

# **USE OF PROCEEDS**

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

#### DILUTION

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

#### SELLING SECURITY HOLDERS

The securities are being offered by certain selling security holders. The selling security holders may from time to time offer and sell pursuant to this prospectus up to an aggregate of 4,771,113 shares of our common shares now owned by them, 6,032,032 shares issuable to them upon the conversion of Series A Preferred that they hold, 9,439,025 shares issuable to them upon the exercise of warrants that they hold and 584,000 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 3, 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. Also named as selling security holders are H.C. Wainwright & Co., Inc. and WellFleet Partners, Inc., each of which received 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, and Patton Boggs LLP, which received 37,319 shares as payment for a past obligation of \$27,989, that we owed.

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. 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 (i) shares of common stock issuable upon conversion of the Series A Preferred issued in the private placement, and (ii) 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: (i) the number of shares of common stock beneficially owned as of May 31, 2004 and prior to the offering contemplated hereby, (ii) the number of shares of common stock eligible for resale (to be offered) by each selling security holder pursuant to this Prospectus, (iii) 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 (iv) 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(1)	Number of Shares To Be Offered(2)	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	117,547	117,547	_	0.00%
Anne Ross	63,236	63,236	_	0.00%
Ari Fuchs	5,058	5,058	_	0.00%
Avi Pelossof	370,329	370,329	_	0.00%
Bill Ledowitz	7,118	7,118	_	0.00%
Bruce J. Ide	496,562	496,562	_	0.00%
Christopher & Lynn Eckert	183,370	183,370	_	0.00%
Chris Phillips	40,471	40,471	_	0.00%
Claudio Beller	143,083	143,083	_	0.00%
Colin Lawrence	7,114	7,114	_	0.00%
Colin Poole	138,600	138,600	_	0.00%
Daniel Gressel	472,500	472,500	_	0.00%
Elior Pelossof	83,160	83,160	_	0.00%
Eduardo Haim	7,114	7,114	_	0.00%
Edwin McGusty	125,000	125,000	_	0.00%
Elaine Klaus	17,241	17,241	_	0.00%
Ellen Siebert Best	42,991	42,991	_	0.00%
Eric Schwartz	5,495	5,495	_	0.00%
Felicia Lew	31,250	31,250	_	0.00%
Frank J. Guzikowski	178,114	178,114	_	0.00%
Gilbert Raker	83,160	83,160	_	0.00%
Gunther Weiss	28,333	28,333		0.00%
Hanka Lew	31,250	31,250	_	0.00%
H.C. Wainwright & Co., Inc.	751,667	751,667		0.00%

AC, Poole   66,365   60,365   - 0,00%     Para Estandiari   92,989   92,880   - 0,00%     Para Paul Calamano   304,583   304,583   - 0,00%     Para Paul Calamano   304,583   304,583   - 0,00%     Para Paul Calamano   304,583   304,583   - 0,00%     Wellfare Partnaris   183,333   183,333   - 0,00%     Wellfare Partnaris   183,333   183,333   - 0,00%     Razer Koiscad Jr.   50,569   30,699   - 0,00%     Karen Koistand Jr.   10,500   10,500   - 0,00%     Korrona Partners LP   73,370   73,370   - 0,00%     Korronan Partners LP   73,370   73,370   - 0,00%     Korronan Partners LP   5,005,021   500,000   4,705,021   40,70%     Alpho Capital AG   1,210,000   1,210,000   - 0,00%     Lewrence Sichert   5,005,021   500,000   4,705,021   40,70%     Alpho Capital AG   1,210,000   1,210,000   - 0,00%     Mark Glass   20,777   20,707   - 0,00%     Mark Staum   1,788,370   1,438,370   350,000   4,11%     Mark Morles   27,720   27,720   - 0,00%     Mark Worles   27,720   27,720   - 0,00%     Mark Worles   27,720   27,720   - 0,00%     Mark Managenola LLC   30,630   36,630   - 0,00%     Mark Managenola LLC   30,630   36,630   - 0,00%     Mike Glassburg   2,374   2,374   - 0,00%     Mike Glassburg   30,942   30,042   - 0,00%     Mike Glassburg   30,942   30,042   - 0,00%     Mike Glassburg   44,44   41,44   - 0,00%     Mike Glassburg   4,444   4,444   - 0,00%     M	J & S Sandler	8,287	8,287	_	0.00%
Dean-Paul Calamarro   304,683   304,583   — 0,00%     Dealmot Lifshitz   132,990   132,990   — 0,00%     Welified Partners   183,333   183,333   — 0,00%     Kaere Kolstad Ir.   50,699   50,599   — 0,00%     Kaere Keskinee   31,578   31,578   — 0,00%     Konstantin Lyashchenko   10,500   10,500   — 0,00%     Kurzuna Portrers, I.P.   73,370   73,370   — 0,00%     Kurzuna Portrers, I.P.   73,370   3,370   — 0,00%     Kurzuna Portrers, I.P.   52,0985   — 0,00%     Lavonne Siebert   5,205,021   500,000   4,705,021   40,78%     Alpha Capital AG   1,210,000   1,210,000   — 0,00%     Marc Giass   20,707   20,707   — 0,00%     Marc Giass   20,707   20,707   — 0,00%     Mark Baum   1,788,370   1,438,370   350,000   4,31%     Mark Wacha   27,720   27,720   — 0,00%     Mark Wacha   27,720   27,720   — 0,00%     Mark Wacha   27,720   36,800   — 0,00%     Mark Wacha   27,720   36,800   — 0,00%     Michael McCarthy   4,144   4,144   — 0,00%     Michael McCarthy   4,144   4,144   — 0,00%     Michael McCarthy   4,144   4,144   — 0,00%     Michael McCarthy   18,378   18,378   — 0,00%     Mark Mayes-Wolf   18,378   18,378   — 0,00%     Mark Mayes-Wolf   18,378   18,378   — 0,00%     Paul & Ellen Knasin   149,800   140,800   — 0,00%     Paul & Ellen Knasin   149,800   140,800   — 0,00%     R. Edward Spilka   300,842   309,842   — 0,00%     R. Edward Spilka   300,842   309,843   — 0,00%     R. Edward Spilka   300,842   309,843   — 0,00%     R. Edward Spilka   300,843   300,843   — 0	J.G. Poole	68,365	68,365	_	0.00%
Deshina Lifehitz	Javan Esfandiari	92,080	92,080	_	0.00%
Weiltleet Partners         183.333         183.333         —         0.00%           Kaizer Kolstad Jr.         50,589         50,589         —         0.00%           Karea Keskinen         31,578         31,578         —         0.00%           Konsantia Lysalchenko         10,500         10,500         —         0.00%           Kurt Horndler         250,955         250,955         —         0.00%           Kurt Horndler         250,5521         500,000         4,705,021         40,708           Alpha Capital AG         1,210,000         12,10,000         —         0.00%           Lon E. Bell         277,200         277,200         —         0.00%           Mark Baum         1,788,370         1,438,370         350,000         4,31%           Mark & Lori Sandler         193,370         193,370         —         0.00%           Mark Wachs         27,720         27,720         —         0.00%           Mark Wachs         27,720         27,720         —         0.00%           Messespola LLC         36,630         36,630         —         0.00%           Mike Gindberg         2,374         2,374         —         0.00%           Mike Mayer	Jean-Paul Calamaro	304,583	304,583	_	0.00%
Kaare Kolatad Æ         50.589         50.589         —         0.00%           Karen Keskinen         31.578         31.578         —         0.00%           Konstantin Lyashchenko         10.500         —         0.00%           Kurzman Patruces, LP         73.370         —         0.00%           Kurt Hoendder         259.955         250.955         —         0.00%           Lawrence Siebert         5.205.021         500.000         4.705.021         40.78%           Alpha Capital AG         1.210.000         1.210.000         —         0.00%           Lon F. Rell         277.200         277.200         —         0.00%           Mark Glass         20,707         20,707         —         0.00%           Mark Baum         1,788,370         1,438,370         350,000         4,31%           Mark Wechs         27,720         27,720         —         0.00%           Mark Wechs         27,720         27,720         —         0.00%           Metasepoia LLC         36,630         36,630         —         0.00%           Michael McCarthy         4,144         4,144         —         0.00%           Mike Mayer-Worf         18,378         18,379<	Joshua Lifshitz	132,990	132,990	_	0.00%
Name   New	Wellfleet Partners	183,333	183,333	_	0.00%
Konstantin Lyashchenko         10,500         10,500         —         0,00%           Kuzman Parmers, I.P         73,370         73,370         —         0,00%           Kurt Haendler         250,955         250,955         —         0,00%           Lawrence Siebert         5,205,021         500,000         4,705,021         40,78%           Alpha Capital AG         1,210,000         1,210,000         —         0,00%           Lon E. Bell         277,200         277,200         —         0,00%           Mark Glass         20,707         20,707         —         0,00%           Mark Baum         1,788,370         1,438,370         350,000         4,31%           Mark & Lori Sandler         183,370         183,370         —         0,00%           Mark Wachs         27,720         27,720         —         0,00%           Mark Wachs         27,720         27,720         —         0,00%           Metasequoia LLC         36,630         36,630         —         0,00%           Mikhael McCarthy         4,144         4,144         —         0,00%           Mikhe Ginsberg         2,374         2,374         —         0,00%           Mike Ginsber	Kaare Kolstad Jr.	50,589	50,589	_	0.00%
Kurman Parmers, LP         73,370         73,370         — 0.00%           Kurt Haendler         250,955         250,955         — 0.00%           Lawrence Siebert         5,205,021         500,000         4,705,021         40.78%           Alpha Capital AG         1,210,000         1,210,000         — 0.00%           Lon E. Bell         277,200         277,200         — 0.00%           Marc Glass         20,707         20,707         — 0.00%           Mark Baum         1,788,370         14,38,370         350,000         4.31%           Mark & Lori Sandler         183,370         183,370         — 0.00%           Mark Wachts         27,720         27,720         — 0.00%           Metasequola LLC         36,630         36,630         — 0.00%           Michael McCarthy         4,144         4,144         — 0.00%           Mike Ginsberg         2,374         2,374         — 0.00%           MSAS Trust         733,370         733,370         — 0.00%           MSAS Trust         733,370         733,370         — 0.00%           Paul & Ellen Knasin         149,809         149,809         — 0.00%           R. Edward Spilka         309,842         309,842         — 0.00% <td>Karen Keskinen</td> <td>31,578</td> <td>31,578</td> <td>_</td> <td>0.00%</td>	Karen Keskinen	31,578	31,578	_	0.00%
Kurt Haendler         250,955         250,955         — 0.00%           Lawrence Siebert         5.205,021         500,000         4,705,021         40,78%           Alpha Capital AG         1,210,000         1,210,000         — 0.00%           Lon E. Bell         277,200         277,200         — 0.00%           Marc Glass         20,707         20,707         — 0.00%           Mark Baum         1,788,370         1,438,370         350,000         4.31%           Mark & Lori Sandler         183,370         183,370         — 0.00%           Mark Wachs         27,720         27,720         — 0.00%           Mark Wachs         27,720         27,720         — 0.00%           Metasequoia LLC         36,630         36,630         — 0.00%           Michael McCarthy         4,144         4,144         — 0.00%           Mike Ginsberg         2,374         2,374         — 0.00%           MSAS Trust         733,370         733,370         — 0.00%           MSAS Trust         733,370         733,370         — 0.00%           Phil Greenblatt         10,346         10,346         — 0.00%           R. Edward Spilka         309,842         309,842         — 0.00%	Konstantin Lyashchenko	10,500	10,500	_	0.00%
Lawrence Siebert   5,205,021   500,000   4,705,021   40,78%	Kurzman Partners, LP	73,370	73,370	_	0.00%
Alpha Capital AG         1,210,000         1,210,000         —         0,00%           Lon E. Bell         277,200         277,200         —         0,00%           Marc Glass         20,707         20,707         —         0,00%           Mark Baum         1,788,370         1,436,370         350,000         4,31%           Mark Wachs         27,720         27,720         —         0,00%           Mark Wachs         27,720         27,720         —         0,00%           Metasequoia LLC         36,630         36,630         —         0,00%           Mike Ginsberg         2,374         2,374         —         0,00%           Mike Mayer-Wolf         18,378         18,378         —         0,00%           MSAS Trust         733,370         733,370         —         0,00%           MSAS Trust         149,809         149,809         —         0,00%           Phil Greenblatt         10,346         10,346         —         0,00%           R. Edward Spilka         309,842         309,842         —         0,00%           R. Lankenau         102,835         102,835         —         0,00%           R. Siderowf         85,874	Kurt Haendler	250,955	250,955	_	0.00%
Lon E. Bell         277,200         277,200         —         0.00%           Marc Glass         20,707         20,707         —         0.00%           Mark Baum         1,788,370         1,436,370         350,000         431%           Mark & Lori Sandler         183,370         183,370         —         0.00%           Mark Wachs         27,720         27,720         —         0.00%           Total M.I.S., Inc.         550,000         550,000         —         0.00%           Metasequoia LLC         36,630         36,630         —         0.00%           Michael McCarthy         4,144         4,144         —         0.00%           Mike Ginsberg         2,374         2,374         —         0.00%           Mike Mayer-Wolf         18,378         18,378         —         0.00%           MSAS Trust         733,370         733,370         —         0.00%           MSAS Trust         149,809         149,809         —         0.00%           Phil Greenblatt         10,346         10,346         —         0.00%           R. Edward Spilka         309,842         309,842         —         0.00%           R. Lankenau         102,835 <td>Lawrence Siebert</td> <td>5,205,021</td> <td>500,000</td> <td>4,705,021</td> <td>40.78%</td>	Lawrence Siebert	5,205,021	500,000	4,705,021	40.78%
Marc Glass         20,707         20,707         — 0,00%           Mark Baum         1,788,370         1,438,370         350,000         4.31%           Mark & Lori Sandler         183,370         183,370         — 0,00%           Mark Wachs         27,720         27,720         — 0,00%           Total M.I.S., Inc.         550,000         550,000         — 0,00%           Metasequoia LLC         36,630         36,630         — 0,00%           Michael McCarthy         4,144         4,144         — 0,00%           Mike Ginsberg         2,374         2,374         — 0,00%           Mike Mayer-Wolf         18,378         18,378         — 0,00%           MSAS Trust         733,370         733,370         — 0,00%           MSAS Trust         149,809         149,809         — 0,00%           Paul & Ellen Knasin         149,809         149,809         — 0,00%           Phil Greenblatt         10,346         10,346         — 0,00%           R. Edward Spilka         309,842         309,842         — 0,00%           R. Lankenau         102,835         102,835         — 0,00%           R. Siderowf         85,874         85,874         — 0,00%           Renata	Alpha Capital AG	1,210,000	1,210,000		0.00%
Mark Baum         1,788,370         1,438,370         350,000         4.31%           Mark & Lori Sandler         183,370         183,370         —         0.00%           Mark Wachs         27,720         27,720         —         0.00%           Total M.I.S., Inc.         550,000         550,000         —         0.00%           Metasequoia LLC         36,630         36,630         —         0.00%           Mike Ginsberg         2,374         2,374         —         0.00%           Mike Mayer-Wolf         18,378         18,378         —         0.00%           MSAS Trust         733,370         733,370         —         0.00%           ME Ellen Knasin         149,809         149,809         —         0.00%           Phil Greenblatt         10,346         10,346         —         0.00%           R. Edward Spilka         309,842         309,842         —         0.00%           R. Lankenau         102,835         102,835         —         0.00%           R. Siderowf         85,874         85,874         —         0.00%           Renata Haendler         44,828         44,828         —         0.00%           Richard Larkin <td< td=""><td>Lon E. Bell</td><td>277,200</td><td>277,200</td><td>_</td><td>0.00%</td></td<>	Lon E. Bell	277,200	277,200	_	0.00%
Mark & Lori Sandler         183,370         183,370         —         0,00%           Mark Wachs         27,720         27,720         —         0,00%           Total M.I.S., Inc.         550,000         550,000         —         0,00%           Metasequoia LLC         36,630         36,630         —         0,00%           Michael McCarthy         4,144         4,144         —         0,00%           Mike Ginsberg         2,374         2,374         —         0,00%           Mike Mayer-Wolf         18,378         18,378         —         0,00%           MSAS Trust         733,370         733,370         —         0,00%           MSAS Trust         149,809         149,809         —         0,00%           Phil Greenblatt         10,346         10,346         —         0,00%           R. Edward Spilka         309,842         309,842         —         0,00%           R. Lankenau         102,835         102,835         —         0,00%           R. Siderowf         85,874         85,874         —         0,00%           Renata Haendler         44,828         44,828         —         0,00%           Richard A. Jacoby         462,675<	Marc Glass	20,707	20,707	_	0.00%
Mark Wachs         27,720         27,720         —         0.00%           Total M.I.S., Inc.         550,000         550,000         —         0.00%           Metasequoia LLC         36,630         36,630         —         0.00%           Michael McCarthy         4,144         4,144         —         0.00%           Mike Ginsberg         2,374         2,374         —         0.00%           Mike Mayer-Wolf         18,378         18,378         —         0.00%           MSAS Trust         733,370         733,370         —         0.00%           Paul & Ellen Knasin         149,809         149,809         —         0.00%           Phil Greenblatt         10,346         10,346         —         0.00%           R. Edward Spilka         309,842         309,842         —         0.00%           R. Lankenau         102,835         102,835         —         0.00%           R. Siderowf         85,874         85,874         —         0.00%           Renata Haendler         44,828         44,828         —         0.00%           Richard A. Jacoby         462,675         462,675         —         0.00%           Richard Larkin         108,	Mark Baum	1,788,370	1,438,370	350,000	4.31%
Total M.I.S., Inc.         550,000         550,000         —         0.00%           Metasequoia LLC         36,630         36,630         —         0.00%           Michael McCarthy         4.144         4.144         —         0.00%           Mike Ginsberg         2,374         2,374         —         0.00%           Mike Mayer-Wolf         18,378         18,378         —         0.00%           MSAS Trust         733,370         733,370         —         0.00%           Paul & Ellen Knasin         149,809         —         0.00%           Phil Greenblatt         10,346         10,346         —         0.00%           R. Edward Spilka         309,842         309,842         —         0.00%           R. Lankenau         102,835         102,835         —         0.00%           R. Siderowf         85,874         85,874         —         0.00%           Renata Haendler         44,828         44,828         —         0.00%           Richard A. Jacoby         462,675         —         0.00%           Richard Bruce         75,500         75,500         —         0.00%           Richard Larkin         108,190         108,190         —	Mark & Lori Sandler	183,370	183,370	_	0.00%
Metasequoia LLC         36,630         36,630         —         0.00%           Michael McCarthy         4,144.         4,144.         —         0.00%           Mike Ginsberg         2,374         2,374         —         0.00%           Mike Mayer-Wolf         18,378         18,378         —         0.00%           MSAS Trust         733,370         733,370         —         0.00%           Paul & Ellen Knasin         149,809         149,809         —         0.00%           Phil Greenblatt         10,346         10,346         —         0.00%           R. Edward Spilka         309,842         309,842         —         0.00%           R. Lankenau         102,835         102,835         —         0.00%           R. Siderowf         85,874         85,874         —         0.00%           Renata Haendler         44,828         44,828         —         0.00%           Richard A. Jacoby         462,675         462,675         —         0.00%           Richard Bruce         75,500         75,500         —         0.00%           Richard Larkin         108,190         —         0.00%           Sam Engel         4,118         4,118	Mark Wachs	27,720	27,720	_	0.00%
Michael McCarthy         4,144.         4,144.         —         0.00%           Mike Ginsberg         2,374         2,374         —         0.00%           Mike Mayer-Wolf         18,378         18,378         —         0.00%           MSAS Trust         733,370         733,370         —         0.00%           Paul & Ellen Knasin         149,809         149,809         —         0.00%           Phil Greenblatt         10,346         10,346         —         0.00%           R. Edward Spilka         309,842         309,842         —         0.00%           R. Lankenau         102,835         102,835         —         0.00%           R. Siderowf         85,874         85,874         —         0.00%           Renata Haendler         44,828         44,828         —         0.00%           Richard A. Jacoby         462,675         462,675         —         0.00%           Richard Bruce         75,500         75,500         —         0.00%           Robin Smith         99,883         99,883         —         0.00%           Sam Engel         4,118         4,118         4,118         —         0.00%	Total M.I.S., Inc.	550,000	550,000	_	0.00%
Mike Ginsberg         2,374         2,374         —         0.00%           Mike Mayer-Wolf         18,378         18,378         —         0.00%           MSAS Trust         733,370         733,370         —         0.00%           Paul & Ellen Knasin         149,809         149,809         —         0.00%           Phil Greenblatt         10,346         10,346         —         0.00%           R. Edward Spilka         309,842         309,842         —         0.00%           R. Lankenau         102,835         102,835         —         0.00%           R. Siderowf         85,874         85,874         —         0.00%           Renata Haendler         44,828         44,828         —         0.00%           Richard A. Jacoby         462,675         —         0.00%           Richard Bruce         75,500         75,500         —         0.00%           Robin Smith         99,883         99,883         —         0.00%           Sam Engel         4,118         4,118         —         0.00%	Metasequoia LLC	36,630	36,630	_	0.00%
Mike Mayer-Wolf         18,378         18,378         —         0.00%           MSAS Trust         733,370         733,370         —         0.00%           Paul & Ellen Knasin         149,809         —         0.00%           Phil Greenblatt         10,346         —         0.00%           R. Edward Spilka         309,842         309,842         —         0.00%           R. Lankenau         102,835         102,835         —         0.00%           R. Siderowf         85,874         85,874         —         0.00%           Renata Haendler         44,828         44,828         —         0.00%           Richard A. Jacoby         462,675         462,675         —         0.00%           Richard Bruce         75,500         75,500         —         0.00%           Richard Larkin         108,190         108,190         —         0.00%           Robin Smith         99,883         99,883         —         0.00%           Sam Engel         4,118         4,118         —         0.00%	Michael McCarthy	4,144.	4,144	_	0.00%
MSAS Trust         733,370         733,370         —         0.00%           Paul & Ellen Knasin         149,809         149,809         —         0.00%           Phil Greenblatt         10,346         10,346         —         0.00%           R. Edward Spilka         309,842         309,842         —         0.00%           R. Lankenau         102,835         102,835         —         0.00%           R. Siderowf         85,874         85,874         —         0.00%           Renata Haendler         44,828         44,828         —         0.00%           Richard A. Jacoby         462,675         462,675         —         0.00%           Richard Bruce         75,500         75,500         —         0.00%           Richard Larkin         108,190         —         0.00%           Robin Smith         99,883         99,883         —         0.00%           Sam Engel         4,118         4,118         —         0.00%	Mike Ginsberg	2,374	2,374	_	0.00%
Paul & Ellen Knasin       149,809       149,809       —       0.00%         Phil Greenblatt       10,346       10,346       —       0.00%         R. Edward Spilka       309,842       309,842       —       0.00%         R. Lankenau       102,835       102,835       —       0.00%         R. Siderowf       85,874       85,874       —       0.00%         Renata Haendler       44,828       44,828       —       0.00%         Richard A. Jacoby       462,675       462,675       —       0.00%         Richard Bruce       75,500       75,500       —       0.00%         Richard Larkin       108,190       108,190       —       0.00%         Robin Smith       99,883       99,883       —       0.00%         Sam Engel       4,118       4,118       —       0.00%	Mike Mayer-Wolf	18,378	18,378	_	0.00%
Phil Greenblatt         10,346         10,346         —         0.00%           R. Edward Spilka         309,842         309,842         —         0.00%           R. Lankenau         102,835         102,835         —         0.00%           R. Siderowf         85,874         85,874         —         0.00%           Renata Haendler         44,828         44,828         —         0.00%           Richard A. Jacoby         462,675         462,675         —         0.00%           Richard Bruce         75,500         75,500         —         0.00%           Richard Larkin         108,190         108,190         —         0.00%           Robin Smith         99,883         99,883         —         0.00%           Sam Engel         4,118         4,118         —         0.00%	MSAS Trust	733,370	733,370	_	0.00%
R. Edward Spilka       309,842       309,842       —       0.00%         R. Lankenau       102,835       102,835       —       0.00%         R. Siderowf       85,874       85,874       —       0.00%         Renata Haendler       44,828       44,828       —       0.00%         Richard A. Jacoby       462,675       462,675       —       0.00%         Richard Bruce       75,500       75,500       —       0.00%         Richard Larkin       108,190       108,190       —       0.00%         Robin Smith       99,883       99,883       —       0.00%         Sam Engel       4,118       4,118       —       0.00%	Paul & Ellen Knasin	149,809	149,809	_	0.00%
R. Lankenau       102,835       102,835       —       0.00%         R. Siderowf       85,874       85,874       —       0.00%         Renata Haendler       44,828       44,828       —       0.00%         Richard A. Jacoby       462,675       462,675       —       0.00%         Richard Bruce       75,500       75,500       —       0.00%         Richard Larkin       108,190       108,190       —       0.00%         Robin Smith       99,883       99,883       —       0.00%         Sam Engel       4,118       4,118       —       0.00%	Phil Greenblatt	10,346	10,346	_	0.00%
R. Siderowf       85,874       85,874       —       0.00%         Renata Haendler       44,828       44,828       —       0.00%         Richard A. Jacoby       462,675       462,675       —       0.00%         Richard Bruce       75,500       75,500       —       0.00%         Richard Larkin       108,190       108,190       —       0.00%         Robin Smith       99,883       99,883       —       0.00%         Sam Engel       4,118       4,118       —       0.00%	R. Edward Spilka	309,842	309,842	_	0.00%
Renata Haendler       44,828       44,828       —       0.00%         Richard A. Jacoby       462,675       462,675       —       0.00%         Richard Bruce       75,500       75,500       —       0.00%         Richard Larkin       108,190       108,190       —       0.00%         Robin Smith       99,883       99,883       —       0.00%         Sam Engel       4,118       4,118       —       0.00%	R. Lankenau	102,835	102,835	_	0.00%
Richard A. Jacoby       462,675       462,675       —       0.00%         Richard Bruce       75,500       75,500       —       0.00%         Richard Larkin       108,190       108,190       —       0.00%         Robin Smith       99,883       99,883       —       0.00%         Sam Engel       4,118       4,118       —       0.00%	R. Siderowf	85,874	85,874		0.00%
Richard Bruce       75,500       75,500       —       0.00%         Richard Larkin       108,190       108,190       —       0.00%         Robin Smith       99,883       99,883       —       0.00%         Sam Engel       4,118       4,118       —       0.00%	Renata Haendler	44,828	44,828	_	0.00%
Richard Larkin     108,190     108,190     —     0.00%       Robin Smith     99,883     99,883     —     0.00%       Sam Engel     4,118     4,118     —     0.00%	Richard A. Jacoby	462,675	462,675	_	0.00%
Robin Smith         99,883         99,883         —         0.00%           Sam Engel         4,118         4,118         —         0.00%	Richard Bruce	75,500	75,500	_	0.00%
Sam Engel 4,118 4,118 — 0.00%	Richard Larkin	108,190	108,190	_	0.00%
	Robin Smith	99,883	99,883		0.00%
Sam Jacob 10,000 10,000 — 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 W. Phillips	50,589	50,589	_	0.00%
Victus Capital	5,500,000	5,500,000	_	0.00%
Sive Paget & Reisel	2,054	2,054	_	0.00%
Spencer Reibman	18,780	18,780	_	0.00%
Stanley Seren	8,287	8,287	_	0.00%
Stephen Feldman	2,054	2,054	_	0.00%
Steve Chrust	127,656	127,656	_	0.00%
Steve Schnipper	199,540	199,540	_	0.00%
Jeffery Benison	91,630	91,630	_	0.00%
Straightline Capital Opp. Fund, LLC	737,088	737,088	_	0.00%
Alan L. Talesnick	238,159	238,159	_	0.00%
Thunderbird Global Corporation	1,011,643	1,011,643	_	0.00%
Tomas Haendler	698,943	698,943	_	0.00%
Truman Bassett	42,526	42,526	_	0.00%
Wendy Joffe	36,901	36,901	_	0.00%
Westbury Diagnostics	141,900	141,900	_	0.00%
Zilma Rojas	5,500	5,500		0.00%
Patton Boggs LLP	37,319	37,319		0.00%
TOTALS	25,881,191	20,826,170	5	,055,021 —

- (1) Includes shares underlying Series A Preferred into which the Series A Preferred 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 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 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 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 Act.

We are required to pay all fees and expenses (excluding commission and other selling 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 have agreed to indemnify certain of the selling security holders against certain losses, claims, damages and liabilities, including liabilities under the Act.

# **LEGAL PROCEEDINGS**

From time to time, we may be involved in litigation relating to claims arising out of its 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.

SDS 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 certain conveniences in terms of ease of use and safety. Until May 2003, Sure Check™ was known as "Hema Strip". Hema Strip was manufactured by CDS pursuant to a manufacturing agreement between CDS and Saliva Diagnostic Systems, Inc. ("SDS"). The contract with SDS was based upon, among other things, a patent that SDS owns (the "'864 Patent") that SDS represented covered the sample collection method employed by the Hema Strip and which patent SDS also represented was valid and enforceable. After SDS unilaterally terminated the contract and alleged patent infringement by CDS, CDS learned that the af orementioned patent did not cover the sample collection method used by the Hema Strip, and that in any case each claim of the '864 patent was not valid due to the existence of previously uncited prior art.. CDS received opinions from its patent counsel, Sterne Kessler Goldstein & Fox PLLC, Washington, DC, to this effect.

On March 17, 2004, further allegations of patent infringement were made against CDS. In connection with the foregoing, CDS filed a complaint against SDS 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 '864 patent, that the '864 patent is invalid, and that the '864 patent is unenforceable due to inequitable procurement. On April 8, 2004, SDS filed its answer and counterclaim, alleging that we were infringing on the '864 Patent. We filed our Reply to Counterclaim on May 3, 2004, denying the allegation of infringement of the '864 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 and a member of our board of directors upon consummation of the Merger. Mr. Siebert has been Chairman of CDS 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 and Siebert Associates, and was a principal investor in a privately held test and measurement company which was sold in 2002. Mr. Siebert received a JD from Case Western Reserve University School of Law in 1981 and a BA with Distinction in Economics from the University of Connecticut in 1978.

Richard J. Larkin (47), Chief Financial Officer. Mr. Larkin was appointed as Chief Financial Officer of Chembio upon consummation of the Merger. Mr. Larkin oversees our financial activities and information systems. Mr. Larkin has been the Chief Financial Officer of CDS since September 2003. Prior to joining CDS, 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 ERP (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 Colle ge 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 CDS in 1996 and has been responsible for developing CDS'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. 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 CDS 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 TB 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 CDS 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. Rick 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 SmallCap and MicroCap 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" (as defined below the table) and all of our directors and executive officers as a group as of May 31, 2004.

Name of Beneficial Owner	Amount of Owner	Percent of Class	
Victus Capital (1)	5,500,000	46.48%	
Lawrence Siebert(2)	5,205,021	45.11%	
Mark Baum(3)	1,788,370	22.02%	
Alpha Capital AG(4)	1,210,000	16.04%	
H.C. Wainwright & Co., Inc.(5)	751,667	10.61%	
Straightline Capital Opp. Fund, LLC(6)	737,088	10.42%	
MSAS Trust(7)	733,370	10.38%	
Tomas Haendler(8)	698,943	9.94%	
Thunderbird Global Corporation(9)	1,011,643	13.77%	
Total M.I.S., Inc.(10)	550,000	7.99%	
Bruce J. Ide(11)	496,562	7.27%	
Ami Dabush(12)	494,694	7.24%	
Daniel Gressel(13)	472,500	6.94%	
Richard A. Jacoby(14)	462,675	6.81%	
Avi Pelossof(15)	370,329	5.52%	
Richard Bruce(16)	75,500	1.18%	
All officers and directors as a group	7,639,491	54.67%	

<sup>\*</sup> Represents less than 1%

Beneficial ownership is determined in accordance with the Rule 13d-3(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), 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 includes convertible securities which, due to contractual restrictions, are not exercisable within 60 days of the date of this Prospectus.

- (1) Includes 2,500,000 shares issuable upon conversion of Series A Preferred and 3,000,000 shares issuable upon exercise of warrants
- (2) Includes 1,547,100 shares issuable upon conversion of Series A Preferred, 120,000 shares issuable upon exercise of options exercisable within 60 days and 2,130,954 shares issuable upon exercise of warrants.
- (3) Includes 108,350 shares issuable upon conversion of Series A Preferred and 980,020 shares issuable upon exercise of
- (4) Includes 550,000 shares issuable upon conversion of Series A Preferred and 660,000 shares issuable upon exercise of warrants.
- (5) Includes 751,667 shares issuable upon exercise of warrants.
- (6) Includes 326,950 shares issuable upon conversion of Series A Preferred and 410,138 shares issuable upon exercise of warrants.
- (7) Includes 233,350 shares issuable upon conversion of Series A Preferred and 300,020 shares issuable upon exercise of warrants.
- (8) Includes 44,450 shares issuable upon conversion of Series A Preferred, 160,000 shares issuable upon exercise of options exercisable within 60 days and 91,536 shares issuable upon exercise of warrants.

- (9) Includes 251,950 shares issuable upon conversion of Series A Preferred and 302,340 shares issuable upon exercise of warrants.
- (10) Includes 250,000 shares issuable upon conversion of Series A Preferred and 300,000 shares issuable upon exercise of warrants.
- (11) Includes 113,100 shares issuable upon conversion of Series A Preferred, 10,000 shares issuable upon exercise of options exercisable within 60 days and 165,423 shares issuable upon exercise of warrants.
- (12) Includes 200,000 shares issuable upon conversion of Series A Preferred and 294,694 shares issuable upon exercise of warrants.
- (13) Includes 10,000 shares issuable upon exercise of options exercisable within 60 days and 42,045 shares issuable upon exercise of warrants.
- (14) Includes 171,750 shares issuable upon conversion of Series A Preferred and 213,811 shares issuable upon exercise of warrants.
- (15) Includes 10,100 shares issuable upon conversion of Series A Preferred and 100,000 shares issuable upon exercise of options exercisable within 60 days and 34,675 shares issuable upon exercise of warrants.
- (16) Includes 70,000 shares issuable upon exercise of options exercisable within 60 days and 500 shares issuable upon exercise of warrants.

#### **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 Chembio's preferred stock.

#### **Common Stock**

Holders of the common stock are entitled to one vote for each share held by them of record on the books of Chembio in all matters to be voted on by the stockholders. Holders of common stock are entitled to receive such dividends as may be declared from time to time by the board of directors out of funds legally available, and in the event of liquidation, dissolution or winding up of Chembio, 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 the future earnings, capital requirements and financial condition of Chembio. Chembio has not declared dividends on its common stock in the past and the management currently anticipates that retained earnings, if any, in the future will be applied to the expans ion and development of Chembio rather than the payment of dividends. Additionally, pursuant to the Certificate of Designation authorizing and creating the Series A Preferred, Chembio is restricted from paying dividends on the common stock without the approval of holders of at least three-fourths (¾) of the then outstanding shares of Series A Preferred.

The holders of common stock have no preemptive or conversion rights and are not subject to further calls or assessments by Chembio. There are no redemption or sinking fund provisions applicable to the common stock. The Articles of Incorporation require the approval of the holders of a majority of Chembio's common stock for the election of directors and for certain fundamental corporate actions, such as mergers and sales of substantial assets, or for an amendment to the Articles of Incorporation. There exists no provision in the Articles of Incorporation or Chembio's Bylaws that would delay, defer or prevent a change in control of Chembio.

Action Stock Transfer (www.actionstocktransfer.com) acts as our transfer agent and registrar

# **Preferred Stock**

*Dividends*. Holders of Series A Preferred are entitled to an 8% per annum dividend per share. The dividend accrues and is payable semi-annually in cash, in shares of Series A Preferred or in shares of common stock (at the option of Chembio). Accrued but unpaid dividends are also payable upon the conversion or redemption of the shares of Series A Preferred and upon a liquidation event.

*Voting Rights.* As long as any shares of Series A Preferred are outstanding, Chembio cannot take any of the following actions without the separate class vote or written consent of at least three-fourths (¾) of the then outstanding shares of Series A Preferred:

- amend, alter or repeal the provisions of the Series A Preferred so as to adversely affect any right, preference, privilege or voting power of the Series A Preferred;
- repurchase, redeem or pay dividends on, shares of common stock or any other shares of Chembio's equity securities that by its terms does not rank senior to the Series A Preferred ("Junior Stock") (other than de minimus repurchases from employees of Chembio in certain circumstances);
- amend the Articles of Incorporation or By-Laws of Chembio so as to affect materially and adversely any right, preference, privilege or voting power of the Series A Preferred;
- effect any distribution with respect to Junior Stock;
- reclassify Chembio's outstanding securities;
- voluntarily file for bankruptcy, liquidate Chembio's assets or make an assignment for the benefit of Chembio's creditors; or
- change the nature of Chembio's business.

In addition, as long as at least \$1,000,000 of Series A Preferred is outstanding, Chembio cannot, without the affirmative vote or consent of the holders of at least three-fourths (¾) of the shares of the Series A Preferred outstanding at the time, authorize, create, issue or increase the authorized or issued amount of any class or series of stock, including but not limited to the issuance of any more shares of previously authorized common stock or preferred stock, ranking pari passu or senior to the Series A Preferred (except for the issuance of shares of Series A Preferred with respect to the payment of dividends on such shares of Series A Preferred).

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

*Conversion.* The Series A Preferred 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 is initially convertible into 50,000 shares of common stock. The Series A Preferred is issuable in fractional shares. The Series A Preferred 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 cannot convert more than twenty percent (20%) of the shares of Series A Preferred that the holder owns into shares of common stock until the earlier to occur of (i) six (6) months following the effective date of this Registration Statement or (ii) March 5, 2005.

Each share of the Series A Preferred will automatically convert into common stock on the date that the closing bid price for Chembio's common stock exceeds \$1.50 for a period of ten (10) consecutive trading days, if the following conditions are satisfied: (i) such date is at least one hundred eighty (180) days following the effective date of this Registration Statement, and (ii) 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 is convertible can be freely traded pursuant to Rule 144(k) under the Securities Act of 1933, as amended).

Redemption. In the event of (i) a consolidation, merger, or other business combination involving Chembio, (ii) the sale of more than 50% of Chembio's assets, or (iii) the closing of a purchase, tender or exchange offer made to holders of more than 50% of the outstanding shares of Chembio's common stock, each holder of Series A Preferred has the right to require Chembio to redeem all or a portion of such holder's shares of Series A Preferred at a price per share of Series A Preferred equal to 100% of the then current liquidation preference amount for the Series A Preferred, plus any accrued and unpaid dividends; provided that Chembio will have the sole option to pay the redemption price in cash or shares of common stock. If Chembio elects to pay the redemption price in shares of common stock, the price per share will be based upon the lesser of (i) the conversion price for the Series A Preferred or (ii) 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 Chembio elects to pay the redemption price in shares of common stock, demand registration rights will be granted on those additional shares.

In the event of certain specified triggering events (involving (i) the lapse or unavailability of the Registration Statement, (ii) the suspension from listing of the common stock for a period of seven (7) consecutive days, (iii) Chembio's failure or inability to comply with a conversion request from a holder of Series A Preferred, or (iii) the breach by Chembio of any of its representations or warranties contained in the Series A Preferred documentation (except to the extent that such breach would not have a material adverse effect) that continues uncured for a period of ten (10) days), each holder of Series A Preferred has the right to require Chembio to redeem all or a portion of that holder's shares of Series A Preferred at a price per share of Series A Preferred equal to 120% of the then current liquidation preference amount for the Series A Preferred, plus any accrued and unpaid dividends; provided that with respect to certain of the triggering events referenced above, Chembio will have the sole option to pay the redemption price in cash or shares of common stock. If Chembio elects to pay the redemption price in shares of common stock, the price per share will be based upon the lesser of (i) the conversion price for the Series A Preferred or (ii) 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 Chembio elects 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 Series A Preferred rank prior to the holders of Chembio's common stock and, unless otherwise consented to by the holders of Series A Preferred, prior to all other classes of capital stock that Chembio 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 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 the financial statements of Chembio Diagnostic Systems, Inc. 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 certain 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 (which are convertible into 72.350 shares of common stock) and a warrant to purchase 96,023 shares of our common stock, all of which are being registered as part of this Registration Statement. Patton Boggs LLP owns 37,319 shares of common stock, all of which are being registered as part of this Registration Statement.

#### DISCLOSURE OF COMMISSION POSITION OF INDEMNIFICATIONFOR SECURITIES ACT LIABILITIES

Our directors and officers are indemnified by our Bylaws and Articles of Incorporation to the fullest extent permitted by the Nevada Revised Statutes. Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended (the "Act"), 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 Act and is, therefore, unenforceable.

In the event that a claim for indemnification against such liabilities (other than the payment by Chembio 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 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 CDS 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, CDS completed the Merger through which it became our wholly-owned subsidiary, and through which the management and business of CDS became our management and business. As part of this transaction, we changed our name to Chembio Diagnostics, Inc.

# **Our Business following the Merger**

# General

Our near term focus is on obtaining US FDA regulatory approval for and increasing distribution of our rapid HIV tests, and in completing the development of tests for Mad Cow disease, Dental bacteria, and Tuberculosis pursuant to various collaborative agreements and grants that are in place with respect to those products. Our Sure Check<sup>TM</sup> HIV rapid test eliminates the need for a separate sample collection system which improves ease of use and safety. Our HIV Stat-Pak product, while not as simple as the Sure-Check®, is value priced, flexible and yet is still as easy to use as the competitive HIV rapid tests (see Competition below) that are Food and Drug Administration ("FDA") approved. Both of our HIV tests use a standardized test strip which we developed using patented materials licensed from third parties and proprietary know-how and trade secrets. Rapid HIV tests 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 which can take at least several days to process. This group comprises a significant amount of all new infections. We expect that FDA approval should occur during 2005 if the various FDA requirements for a Pre-Marketing Approval are met on a timely basis.

Our TB rapid tests are being designed to significantly increase the accuracy of existing TB screening methods. Studies of our serological test for active pulmonary TB in humans have shown that sensitivity can increase from 45% to 82% when used in combination with the sputum smear method (the current standard in high incidence settings), and from 82% to 91% when used with the two- step confirmatory combination of sputum smear and culture testing. Our strategy is to, at least initially, forego U.S. FDA approval and to instead have the product evaluated in developing countries, by the CDC, and by the World Health Organization "WHO." Nearer term, we are moving forward with completing a serological test for non-human primates that is being funded in part by a Phase II NIH SBIRR grant. We plan to have a product in this niche market in 2005.

Product development and manufacturing agreements are now in place with strategic partners in the fields of BSE (mad cow disease) and dental disease. We also have developed the only FDA – cleared and CLIA – waived Lyme disease rapid test, which detects antibodies to the antigen that causes Lyme disease, and which is being marketed and distributed by another entity under that entity's brand name.

We also manufacture pregnancy tests sold under private label for the OTC market. Although pregnancy tests have constituted the majority of our historical revenues, we are de-emphasizing this product due to its highly competitive nature.

# **Lateral Flow Technology**

Lateral flow point of care tests are used for in vitro diagnosis of human and veterinary diseases. These immunodiagnostic tests (see below) analyze constituents of blood, urine and other body fluids for the presence of specific substances or markers of infectious diseases or other conditions. These tests are "in vitro" tests as they are performed outside the body, in contrast to "in vivo" tests, which are performed directly on or within the body. Lateral flow technology was developed in the 1980s initially as a simple way for detecting pregnancy based on the HCG hormone. The technology has become a standard method for the point of care diagnostics industry and has been applied in a multitude of designs, formats, enhancements, etc.

The substance or marker that a diagnostic test is intended to detect is generally referred to as an analyte. Immunodiagnostic tests, of which the lateral flow tests developed at Chembio are a sub-category, are based on the ability of an antibody to bind with a specific antigen or vice versa. The body produces antibodies in response to an infectious disease caused by pathogens, such as bacteria, viruses, fungi, etc. An antibody binds specifically with an antigen in a lock-and-key fashion that initiates a biochemical reaction to attempt to neutralize and, ultimately, eliminate the antigen. The binding that occurs is captured by use of a visual label, such as colloidal gold, thereby producing a colored line to indicate that the binding has occurred (the test line) in the case of a reactive result (eg, a "positive"), and that the test result is valid (the c ontrol line).

The specific methodology and design used in a particular lateral flow test to achieve this result will vary based upon many factors depending on the test objective, the analytes being used, etc.

The lateral-flow technology employed at Chembio allows the development of easy-to-perform, single-use diagnostic tests for rapid, visual detection of specific antigen-antibody complexes on a nitrocellulose 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 < 20 min), safe (minimizes handling of specimens potentially infected), non-invasive (requires 5-20 ml of serum or whole blood easily obtained with a finger prick), stable (at least 12 months without refrigeration), and highly reproducible.

# **Proprietary Applications of Lateral Flow Technology**

There are a number of proprietary technologies in the area of test formulation and manufacture, and in the reagents used in them, which we have developed or obtained license rights for use in our products. This intellectual property is summarized as follows:

# Lateral Flow Technology Know-How & Trade Secrets

We develop our rapid tests using colloidal gold or colored latex, and we can develop and produce tests that are used in qualitative (yes/no), semi-quantitative, and multiple parameter (e.g., HIV/TB) applications. 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.

# **Proprietary Device Formats**

We have extensive experience with a variety of lateral flow device hardware including the barrel device used in our Sure Check<sup>TM</sup> HIV rapid test which we believe is easier to use than other finger-stick whole blood point of care devices. Sure Check<sup>TM</sup> eliminates the need for transferring finger-stick whole blood samples from the finger-tip onto a test device, as the collection of the sample is performed within a closed capillary tube and the sample is absorbed directly onto the test strip by means of a capillary tip and absorbent pad. We have also developed new features for the barrel device that will provide additional user advantages and features. *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<sup>TM</sup>.* 

# **Reagent Licenses**

We own licenses (exclusive and non-exclusive) to patented reagents used in the following tests: HIV, TB, Lyme Disease, Mad Cow, Dental Bacteria, Chagas, among others. In our TB serology research and development, we have identified and developed proprietary combinations and fusions of antigens used to develop our human and animal rapid TB tests. We also have developed a proprietary methodology for screening antigens in our development work.

# **Target Market**

We believe that the point of care diagnostic testing market is growing at a faster pace than the overall diagnostics market. Although market growth in the developed markets of the US, Europe and Japan in the field of point of care diagnostics is primarily driven by the need to control healthcare costs, advances in technology, and consumer awareness of personal health issues, market growth in the demand for rapid testing for HIV and TB in the high burden developing countries is largely dictated by the availability of donor funds such as those funds administered and distributed by President Bush's Presidential Emergency Program for Aids Relief ("PEPFAR"), and other governmental and non-governmental programs that fund testing for infectious diseases around the world.

# **Distribution Channels**

Chembio's core competency is in the development and manufacture of lateral flow rapid diagnostic tests. Our business model has been evolutionary and opportunistic, resulting in a diversity of products that serve different markets; consequently we are orienting increasingly toward collaborating with leading companies and agencies that are best positioned to identify market needs and provide distribution within

their field(s) of expertise. These are the types of opportunities that we have pursued in establishing the product development and exclusive or co-exclusive manufacturing contracts we have in the dental disease and mad cow disease fields. In HIV and TB, we are focused on building strategic relationships with public health agencies and companies that are positioned to access these markets in the developing countries as well as the developed markets of the US, Europe and Japan.

We are also seeking to access the national and international public health markets by participating in programs being established by the CDC, WHO and other public health agencies in order to build product acceptance, recognition and distribution opportunities.

We are also engaged in and actively seeking new collaborations for the local assembly and even local production of our HIV tests, other tests under development, and/or tests that we develop or co-develop at the customer's request. We believe that this is a sound business strategy, as it provides our customers with a more cost effective means of establishing widespread rapid testing programs in their countries, while also contributing to controlling the HIV and potentially other epidemics.

For example, in February CDS signed a technology transfer and supply agreement with Bio-Manguinhos, which is the largest Brazilian manufacturer of vaccines and is an affiliated entity of the Brazilian Ministry of Health. This collaboration will provide Bio-Manguinhos with our support to have a Brazilian-made product to serve its population, which is what the Brazilian Health Ministry and National Aids Control Organization in Brazil requested of Bio-Manguinhos. Chembio's participation over the last few years in several of the rapid testing evaluations that have been conducted by the CDC in countries now beginning to receive funding from the Bush administration's PEPFAR (Presidential Emergency Program for Aids Relief) has been crucial to the opportunities that are now beginning to unfold. Chembio's near term prospects rely largely on the success of the program in Brazil, our ability to meaningfully participate in the PEPFAR program, in obtaining other distribution opportunities for our HIV tests, and in obtaining FDA regulatory approval of our HIV rapid tests. Completion of our non-human primate TB test and our mad cow disease test is also important to our growth plans.

#### Competition

The diagnostic 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.

Important competitive factors for our products include product quality, price, ease of use, customer service, and reputation. Industry competition 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., good manufacturing practices);
- Access to adequate capital;
- The ability to attract and retain qualified personnel; and
- The availability of patent protection.

A few large corporations produce a wide variety of diagnostic tests and other medical devices and equipment. A larger number of mid-size companies generally compete only in the diagnostic industry, and a significant number of small companies produce only a few diagnostic products. As a result, the diagnostic test industry is highly fragmented and segmented.

The future market for diagnostic tests is expected to be characterized by consolidation, greater cost consciousness, and tighter reimbursement policies. The purchasers of diagnostic products are expected to place increased emphasis on lowering costs, reducing inventory levels, automation, service, and volume discounts. The increased complexity of the market is expected to force many competitors to enter into joint ventures or license certain products or technologies.

We expect competition to intensify as technological advances are made and become more widely known, and as new products reach the market. Furthermore, new testing methodologies could be developed in the future that render our products impractical, uneconomical or obsolete. There can be no assurance that our competitors will not succeed in developing or marketing technologies and products that are more effective than those we develop or that would render our technologies and products obsolete or otherwise commercially unattractive. In addition, there can be no assurance that our competitors will not succeed in obtaining regulatory approval for these products, or introduce or commercialize them before we can do so. These developments could have a material adverse effect on our business, financial condition and results of operations. Competition in the market for HIV testing is intense and is expected to increase. We believe that the principal competition will come from existing laboratory-based blood tests, point-of-care whole blood rapid tests, laboratory-based urine assays, and oral fluid-based tests. Our competitors include specialized biotechnology firms as well as pharmaceutical companies with biotechnology divisions and other medical diagnostic companies.

Significant direct competitors for our Sure Check<sup>TM</sup> 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. Although management believes that each of these companies represent varying levels of competition, it nevertheless believes that its HIV rapid tests compare favorably on the basis of performance, availability, price, ease of use, and other criteria. Abbott and Trinity manufacture their products outside the USA.

Our whole blood rapid test for active pulmonary TB has not yet been sufficiently evaluated to begin marketing. However, we believe that Chembio is in a leadership position as it relates to TB serology in humans and animals. 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 TB countries. We are also not aware of any rapid whole blood test to detect active pulmonary TB in non-human primates and/or other animals for which Chembio is developing rapid TB tests.

# **Research and Development**

During 2003 and 2002, approximately \$313,891 and \$378,089 respectively was spent on research and development activities. Our R&D activities consist both of basic research in identifying, screening and optimizing reagents to be used in tests under development as well as in developing lateral flow applications of reagents that have been provided to us by our collaborative partners. In 2003 we received several contracts and grants for research and development activities, several of which are still ongoing. These include the following: (i) a contract to develop key components for the rapid test for Mad Cow disease which we will be manufacturing for our contract partner, (ii) a multi-phase contract to develop the dental bacteria disease rapid test that we are developing for our contract partner, (iii) a grant from the World Health

Organization to develop an antigen detection test for Tuberculosis, (iv) a Phase II grant (as a sub-contractor) to develop the Tuberculosis test for non-human primates, and (v) other research and development contracts and grants for TB serology in animals. Through these activities, we have in certain cases outsourced certain aspects of our development efforts and in the process we have identified some new technologies, leveraging our internal capabilities. In some cases we have identified proprietary technologies that could enhance our current technology platform which we could acquire or license.

# **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 R&D. 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, USDA, certain state and local agencies, and/or comparable regulatory bodies in other countries. This regulation governs almost all aspects of development, production, and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing, and record keeping. All of Chembio's FDA and USDA 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 mu st submit a 510(k) application at least 90 days before marketing of the affected product commences. Although FDA clearance may be granted within that 90-day period, in some cases as much as a year or more may be required before clearance is obtained, if at all.

If the medical device does not qualify for the 510(k) procedure (either because it is not substantially equivalent to a legally marketed device or because it is required by statute and the FDA's implementing regulations to have an approved application), the FDA must approve a pre-market approval ("PMA") application before marketing can begin. PMAs must demonstrate, among other matters, that the medical device provides a reasonable assurance of safety and effectiveness. A PMA is typically a complex submission, including the results of preclinical and clinical studies. Preparing a PMA is a detailed and time-consuming process. Once a PMA 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 required ests for additional data.

Biologic products must be the subject of an approved biologics license application ("BLA") before they can be marketed. The FDA approval process for a biologic product is similar to the PMA 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 ("QSRs"). These regulations govern the manufacturing process, including design, manufacture, testing, release, packaging, distribution, documentation, and purchasing. Compliance with QSRs 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 QSRs and other post-approval requirements. Failure to comply with statutory requirements and the FDA's regulations can lead to substantial penalties, including monetary penalties, injunctions, product recalls, seizure of products, and criminal prosecution.

The Clinical Laboratory Improvement Act of 1988 ("CLIA") prohibits laboratories from performing in vitro tests for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of, the health of human beings unless there is in effect for such laboratories a certificate issued by the U.S. Department of Health and Human Services 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 CLIA in the design and development of its products. A CLIA 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 diagnost ics market.

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.

At the present time, Chembio has received FDA 510(K) clearances and CLIA waivers for its pregnancy tests, ovulation test, and B. Burgdoferi (Lyme Disease) test. Chembio also has a laboratory test for sickle cell anemia that is FDA-cleared. 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 (IDE) to begin clinical trials for the Sure Check<sup>TM</sup> 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**

Trade Secrets & Know-How

The test strips used in our lateral flow products were developed by us using trade secrets, know-how, and technological innovations together with reagents (antibodies, recombinant antigens, synthetic peptides) which are in certain cases patented materials licensed to Chembio 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, including how to maximize speed to result and to sensitivity while minimizing the impact on specificity.

# Lateral Flow Technology Patents

We own no patents covering lateral flow technology. As a result of extensive research and analysis, our patent counsel believes that our HIV tests are outside the claims of most of the lateral flow patents held by other companies. However, certain patents have been issued and have been brought to our attention by the patent holders that contain very broad claims which could require us to enter into additional licenses or redesign at least some of our products. CDS has been offered licenses from certain of these patent holders. We believe that cross-licensing or other business strategies, of which there is no assurance of availability, could minimize the possibility of any adverse developments in this regard, and we intend to pursue one or more of these strategies.

# Reagent Licenses

Beyond further licenses, trade secrets, and know-how within the area of lateral flow technology, our IP strategy is to acquire proprietary positions in reagents and hardware platforms which can provide us with exclusive, co-exclusive or non-exclusive rights to manufacture and/or market rapid diagnostic tests utilizing these materials. The peptides used in our HIV rapid tests are patented by Adaltis Inc. under US patent #5,241,047 and related patents in certain foreign jurisdictions. This IP is licensed to us under a 10-year license agreement dated August 30, 2002. We also have licenses to other patented antigens used in our TB, Chagas, Lyme, Mad Cow, H. Pylori and Dental Bacteria tests.

# **Legal Issues**

FTC Matter

CDS entered into a settlement agreement with the Federal Trade Commission on January 16, 2001 that was entered in the United States District Court on February 27, 2001. See "Risk Factors – Risk Related to Our Industry, Business and Strategy." The settlement agreement provides that CDS must provide all of its principals, officers, directors, managers and all other employees of CDS having responsibilities related to CDS'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 CDS 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 RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2004 AS COMPARED WITH THE THREE MONTHS ENDED MARCH 31, 2003

The following management discussion and analysis relates to the business of Chembio Diagnostic Systems, Inc. ("Chembio"), a 100% wholly-owned subsidiary of the Company. Prior to the merger between Chembio and the Company, there were no assets or liabilities of the Company and no operations. Chembio is de-emphasizing the manufacturing of private label pregnancy tests and is 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. Chembio has and/or is pursuing collaborative agreements that may include distribution arrangements in each of these areas. Management believes that the amount of research and development, manufacturing overhead, selling, marketing and general and administrative costs will increase as it creates the necessary infras tructure to focus in these new areas.

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 Chembio's 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 which 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.

Research and development ("R&D") 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.

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.

# 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 unit pricing decreases and to reduced sales of Chembio's midstream pregnancy tests to its distributor in Japan. 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 Chembio's eventual decision to not pursue or contest the claim of infringement due to the volume of the business and, more important, the Company 's 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 ("R&D") 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 in R&D expense is due primarily to subcontractor 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 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 million from \$989,000 for the twelve months ended December 31, 2002.

# LIQUIDITY AND CAPITAL RESOURCES

Chembio began to improve its liquidity and capital resources position during the first quarter of 2004 as a result of the completion of the \$1MM Convertible Note Offering in March. As a result of the completion of the Series A Financing, \$328,000 of the \$1MM 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 33.838 shares of the Series A Preferred Stock. Simultaneous to that conversion, 73.334 shares of Series A Preferred Stock were issued for \$2.2MM in cash and an additional \$1,332,292 of debt to Chembio note holders was converted into 44.441 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 Dec ember 31, 2003. However, the March 31, 2004 unaudited balance reflects only the Convertible Note Offering which had been completed during the month of March 2004.

During the three months ended March 31, 2004, Chembio 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 primarily funded from the \$1 million of Convertible Notes issued during March, the accrual of interest on all debt due to holders of Chembio term debt and convertible debt, and the funding of \$64,229 of compensation expense by the issuance of common stock to certain key employees. All of 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, as 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, Chembio 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. Chembio's 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 to 28% to \$4.535 million. The increase in long term liabilities is attributable to the completion of the \$1 million 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 debt and any other contractual obligations of Chembio 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
Operating Leases	\$97,688	\$86,688	\$11,000	-	-
Other Long Term Obligations(2)	\$151,162	\$61,162	\$63,252	\$26,748	-
Total Obligations	\$2,924,701	\$147,850	\$74,252	\$26,748	\$2,693,851
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- (1) This represents convertible as well as existing 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 represent Capital Leases used to purchase capital equipment.

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

Chembio's near term focus is its rapid HIV tests. Clinical trials for its HIV rapid tests have begun, and Management believes that they will be completed during the third quarter. The trials will be used to support a Pre-Marketing Approval application to the United States Food & Drug Administration. Simultaneous with this regulatory approval process, Chembio is actively involved in increasing distribution of its HIV rapid tests through a variety of distribution channels and partners. Chembio has 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), prenatal testin g for mother to child transmission, and other programs that are taking root globally. A significant portion of the capital currently available to Chembio is being used to obtain US regulatory approval of its HIV rapid tests and to provide the marketing and business development resources to achieve wider distribution of its products in the global market.

Chembio is also working on completing the development of the Mad Cow, Dental bacteria and TB rapid tests that are under product development agreements and/or research grants. Management believes that these products will begin to produce revenues in 2005.

Chembio's cash requirements depend on numerous factors, including product development activities, penetration of the direct sales market, market acceptance of its new products, and effective management of inventory levels in response to sales forecasts. Chembio expects to devote capital resources to continue its product development, expand manufacturing capacity and continue research and development activities. Chembio will examine other growth opportunities including strategic alliances and expects such activities will be funded from existing cash and cash equivalents, issuance of additional equity or additional borrowings, subject to market and other conditions. Management believes that its 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 Chembio's working capital and capital expenditure requirements, Chembio may be required to sell additional equity or obtain additional credit facilities. There is no assurance that such financing will be available or that Chembio will be able to complete financing on satisfactory terms, if at all.

# DESCRIPTION OF PROPERTY

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

#### **Certain Relationships and Related Transactions**

Mark L. Baum, our former president prior to the Merger and a current director of Chembio, entered into a nine-month employment agreement with Chembio (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 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 , pursuant to which he received 2.167 shares of Series A Preferred (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.

Lawrence A. Siebert, the president and chairman of the board of directors of Chembio beginning at the time of and after the Merger, and the president and chairman of CDS since May 2002, holds two promissory notes issued by CDS. 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's Series A Preferred (together with warrants to acquire 1,800,000 shares of common stock at \$.90 per share) pursuant to Chembio's private placement of its Series A Preferred on May 5, 2004. The shares of Series&nb sp;A Preferred held by Mr. Siebert are convertible into 1,547,100 shares of Chembio'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 on or before December 31, 2004 or, at the option of Chembio, converted into shares of its Series A Preferred as of December 31, 2004.

Mr. Siebert also invested \$18,700 in CDS 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's Series A Preferred (together with warrants to acquire 56,520 shares of common stock at \$.90 per share) pursuant to Chembio's private placement of its Series A Preferred on May 5, 2004.

Richard J. Larkin, the Chief Financial Officer of Chembio, invested \$10,000 in CDS 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's Series A Preferred (together with warrants to acquire 30,240 shares of common stock at \$.90 per share) pursuant to Chembio's private placement of its Series A Preferred on May 5, 2004.

Avi Pelossof, the vice president of sales and marketing of Chembio, invested \$4,000 in CDS 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's Series A Preferred (together with warrants to acquire 22,555 shares of common stock at \$.90 per share) pursuant to Chembio's private placement of its Series A Preferred 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
First Quarter	\$3.00	\$0.34
FI 1 1 2 2000	W 1 W 1	
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 15g-9 of the Securities and Exchange Commission, which rule imposes certain 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 require a broker/ dealer, prior to a transaction in a pennystock 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'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 preferred stock instruments, and our credit arrangements then impose.

# **EXECUTIVE COMPENSATION**

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

		Annual Comp	Long-Term Compensation Awards— Securities Underlying
Name and Position	Year	Salary	Stock Options
Lawrence A. Siebert, President, CEO, Chairman of Board of CDS(1)	2003 2002 2001	103,846 63,000 50,462	  10,000
Rick Bruce, Vice President of CDS(2)	2003 2002 2001	110,326 106,240 101,500	
Mark L. Baum, President, Secretary and Director of Chembio(3)	2003 2002	Ξ	

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

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. ("Madsen"), certified public accountants and to retain Lazar, Levine & Felix LLP as our principal accountant. Lazar, Levine & Felix LLP had been the principal accountant of CDS 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.

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#### **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

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

#### —ASSETS (Note 5)—

	Mar. 31, 2004	Dec. 31, 2003
CURRENT ASSETS:	(unaudited)	
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
-		
TOTAL CURRENT ASSETS	1,277,450	772,680
FIXED ASSETS—(Notes 4 and 6)	244,997	249,247
OTHER ASSETS:		
Deposits	55,290	55,723
Other assets	134,206	9,095
	44.744.040	44 000 = 4=
	\$1,711,943	\$1,086,745
—LIABILITIES AND STOCKHOLDERS' EQUIT	v (Deelciency)	
	I (DEFICIENCI)—	
URRENT LIABILITIES:		
Bank overdraft	<b>\$</b> —	\$67,434
Accounts payable and accrued liabilities (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
TOTAL CURRENT LIABILITIES	1,461,449	1,503,418
	, , ,	,
OTHER LIABILITIES:		
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
TOTAL LIABILITIES	4,535,043	3,544,186
•		
COMMITMENTS AND CONTINGENCIES (NOTES 2(n) AND 11)		
TOCKHOLDERS' 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,	40	39
2003, respectively	4.004.400	4 500 000
Additional paid-in capital	4,664,190	4,599,962
Accumulated deficit	(7,487,330)	(7,057,442)
	(2,823,100)	(2,457,441)
	\$1,711,943	\$1,086,745
	Ψ19/1119 <b>J+J</b>	ψ1,000,743
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# CHEMBIO DIAGNOSTIC SYSTEMS, INC. AND SUBSIDIARY CONSOLIDATED STATEMENTS OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2004 AND 2003 (UNAUDITED)

	2004	2003
REVENUES:		
Net sales (Notes 2(n) and 11) Research grants and development income (Note 7)	\$493,970 91,342	\$72 <b>0,0</b> 77 —
	585,312	720,077
Cost of sales (Note 11)	445,923	616,766
GROSS PROFIT	139,389	103,311
OVERHEAD COSTS:		
Research and development expenses	112,095	85,262
Selling, general and administrative expenses	401,436	304,362
LOSS FROM OPERATIONS	(374,142)	(286,313)
OTHER INCOME (EXPENSES):		
Interest income (expense)—net	(55,746)	(47,223)
LOSS BEFORE INCOME TAXES	(429,888)	(333,536)
Income taxes (Note 8)		_
NET LOSS	\$(429,888)	\$(333,536)
Pro forma basic and diluted loss per share	(11.04)	(8.69)
Weighted number of shares outstanding	38,930	38,395
Page F-		

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

	2003	2002
REVENUES:		
Net sales (Notes 2(n) and 11)	\$2,542,621	\$2,810,852
Research grants and development income(Note 7)	275,730	324,287
	2,818,351	3,135,139
Cost of sales (Note 11)	2,153,454	2,458,596
GROSS PROFIT	664,897	676,543
OVERHEAD COSTS:		
Research and development expenses	313,891	378,089
Selling, general and administrative expenses	1,202,185	1,154,799
LOSS FROM OPERATIONS	(851,179)	(856,345)
OTHER INCOME (EXPENSES):		
Interest income (expense) - net	(208,525)	(132,626)
LOSS BEFORE INCOME TAXES	(1,059,704)	(988,971)
Income taxes (Note 8)		-
NEW YORK	#/4 0F0 F0 A)	#(000 074)
NET LOSS	\$(1,059,704)	\$(988,971)
Pro forma basic and diluted loss per share	(27.60)	(29.45)
Weighted number of shares outstanding	38,395	33,581

# 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

	Commo	n Stock	Additional	Treasury	y stock	Accumulated	Total
	Shares	Amount	paid-in capital Shares =		Amount	Deficit	
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	- \$	i -	\$(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
	CASH FLOWS FROM OPERATING ACTIVITIES:				
	Net loss	\$(429	,888)	\$(333,53	36)
	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
	Net cash used in operating activities		(452,854)		(194,129)
A CITY	EL OLIGINATED IN INVESTING A CITA VIEW				
ASH	FLOWS USED IN INVESTING ACTIVITIES:				
	Acquisition of fixed assets		(13,900)		-
	Net cash used in investing activities		(13,900)		-
ASH 1	FLOWS FROM FINANCING ACTIVITIES:				
	Bank overdraft		(67,434)		43,728
	Repayment of capital lease obligation		(18,512)		(2,770)
	Proceeds from loans		1,000,000		125,000
	Net cash provided by financing activities		914,054	-	165,958
ET IN	ICREASE (DECREASE) IN CASH		447,300		(28,171)
151 119	RCKEASE (DECKEASE) IN CASH		447,300		(20,1/1)
	Cash—beginning of the period	_	-		28,171
ASH-	end of the period	\$447,3	300	\$	-
	Supplemental disclosure of cash flow information:				
	Cash paid during the period for interest	\$	-	\$	-
	Supplemental disclosures for non-cash investing and financing activities:				
	Fixed assets acquired under capital leases	\$	-	\$28,897	
	Page F-				

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

	2003	2002
CASH FLOWS FROM OPERATING ACTIVITIES:		
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:		
-	(150,000)	107.250
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) 523,668	(30,625)
Accounts payable and accrued expenses  Grant and other current liabilities	•	(44,199)
Grant and other current naturates	549 	(142,628)
Net cash used in operating activities	(423,947)	(805,194)
CASH FLOWS USED IN INVESTING ACTIVITIES:		
Acquisition of fixed assets	<u> </u>	(60,527)
Net cash used in investing activities	-	(60,527)
CASH FLOWS FROM FINANCING ACTIVITIES:		
		E2E 12E
Net proceeds from sale of common stock Bank overdraft	67,434	535,125
Repayment of capital lease obligation	(36,931)	(37,834)
Proceeds from shareholder loans	365,273	385,603
Net cash provided by financing activities	395,776	882,894
Net cash provided by imancing activities		
IET DECREASE IN CASH	(28,171)	17,173
Cash—beginning of the year	28,171	10,998
CASH—end of the year	<b>\$</b> -	\$28,171
Supplemental disclosure of cash flow information:		
Cash paid during the year for interest	<b>\$</b> -	\$63,491
Supplemental disclosures for non—cash investing and financing activities:		
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'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 at the point of passage of title, which is generally at the time of shipment.

#### (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.

#### (1)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's consolidated fina ncial 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'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'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.

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 Dece	mber 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
	\$493,970	\$720,077	\$2,542,621	\$2,810,852

#### (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.

#### 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
	\$499,820	\$466,498

#### 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

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

- 1. \$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 spongeform encephalitis (BSE or Mad Cow Disease) for development of a rapid test for BSE.
- 3. \$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.
- **4.** \$89,000 from a research foundation focused on tuberculosis vaccines and diagnostics in connection with the commencement of a Phase II NIH 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.
- 5. 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 realizability of these deferred tax assets.

Deferred tax assets consist of the following at:

\$2,870,000 214,000 7,000	)	\$2,791,000 214,000 6,200
3,091,000	)	3,011,200
(3,091,000)	(	3,011,200)
\$	-	\$—
		3,091,000 (3,091,000) (

#### 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  $3\frac{1}{2}$  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
Granted	240	60
Canceled	_	_
Exercised	_	_
Options outstanding at March 31, 2004	3,890	\$262
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	Deceml	ner 31
1 Cai	chung	Decem	JCI JI,

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

Rent expense associated with these leases for the following periods:

	Three Months E	Three Months Ended March 31,		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 Co nvertible 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 c losing 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 certificate 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. ("SDS"). SDS 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<sup>TM</sup> 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 SDS, the Company developed, manufactured and sold an HIV rapid test that SDS had represented incorporates the sample collection method described in the '864 patent. SDS also represented that the '864 patent is valid. During 2001-2003, the Company paid royalties to SDS and took several other actions based upon SDS' representations. In 2003, SDS 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.

CHEMBIO DIAGNOSTIC SYSTEMS, INC. AND SUBSIDIARYNOTES TO CONSOLIDATED STATEMENTS(INFORMATION AS OF AND FOR THE THREE MONTHS ENDED MARCH 31, 2004 AND 2003 IS UNAUDITED

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

The following unaudited pro forma consolidated balance sheets as of March 31, 2004 and December 31, 2003 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 ("CDS") after giving effect to the merger of CDS into a subsidiary of TSLU formed exclusively for the merger. The result of the combination will have CDS 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 CDS 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)

	HISTORICA	L	PROFORMA ADJUST		s	
	Trading Solutions.Com,			Debit	Credit	Consolidated Proforma
	Inc.	System	s, Inc.			
CURRENT ASSETS:						
Cash	<b>\$</b> —	\$447,300		\$2,200,000 (g)	300,000 (h)	\$2,345,32
					1,976 (j)	
Accounts receivable	_					278,20
Inventories	_		ĺ			499,82
Prepaid expenses and other current assets	_		5	226,667 (n)		278,79
TOTAL CURRENT ASSETS	_					3,402,14
FIXED ASSETS	_					244,99
OTHER ASSETS	_		189,496	113,333 (n)	119,110 (j)	
				220,000 (1.)	===,=== ()	
	<b>\$</b> —	\$				\$3,830,85
CURRENT LIABILITIES:	ĺ					
Accounts payable and accrued liabilities	_					\$1,387,639
Current portion of obligations under capital leases	_					61,16
Other current liabilities	_			11,781 (j)	9,371 (j)	10,23
TOTAL CURRENT LIABILITIES	_					1,459,03
OTHER LIABILITIES:						
Notes payable	_			1,332,292 (k)		361,55
				1,000,000 (j)		
Accrued interest			289,743			289,74
Obligations under capital leases—net of current portion	_					90,00
TOTAL LIABILITIES	_					2,200,34
STOCKHOLDERS' EQUITY (DEFICIENCY):						
Series A Preferred Stock					2,200,000 (g)	
					679,107 (j)	
					1,332,292 (k)	
Common stock	10,632			40 (c)	40,000 (c)	62,96
					67 (h)	
					8,267 (j)	
					4,000 (m)	
A 11', 1 - 11 - 1 - 2	270.000			20.000 ( )	202 121 ***	F 040 07
Additional paid-in capital	378,980			39,960 (c)	322,431 (j)	
				300,067 (h)	156,000 (m)	
				119,110 (j)	340,000 (n)	

			389,612 (l)		
Accumulated deficit	(389,612)	(7,487,330)	160,000 (m)	389,612 (l)	(7,656,701)
			9,371 (j)		
Total Equity (Deficit)	_	(2,823,100)			1,630,516
	<b>\$</b> —	\$	5,902,233	5,902,233	\$3,830,857

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#### CHEMBIO DIAGNOSTICS, INC.

#### (formerly Trading Solutions.com)

#### CONDENSED CONSOLIDATED PRO FORMA STATEMENTS OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2004

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	Trading				
	Solutions.Com, Inc.	Chembio Diagnostic Systems, Inc.	Debit	Credit	Consolidated Pro forma
REVENUES:					<b></b>
Net sales	<b>\$</b> —	\$			\$493,970
Grant income	_				91,342
	_	44= 004			585,312
Cost of sales	_	445,924			445,924
GROSS PROFIT		139,388			139,388
OVERHEAD COSTS:					
Research and development expenses	_	112,095			112,095
Clinical Trials			200,000 (f)		600,000
Camera Francis			400,000 (i)		300,000
Selling, general and			160,000 (m)	680,523	
administrative expenses			56,667 (n)		
	19,920	401,436	42,500 (q)		680,523
LOSS FROM OPERATIONS	(19,920)				(1,253,230)
OTHER INCOME (EXPENSES)					
OTHER INCOME (EXPENSES):  Gain from debt settlement	_				
Interest(expense)	_			38,518 (o)	(17,228)
LOSS BEFORE INCOME TAXES  Income taxes	(19,920)				(1,270,458)
micome taxes					
NET LOSS	\$(19,920)	\$			\$(1,270,458)
	, , ,				
PRO FORMA DIVIDEND PAYABLE	2				\$(90,948)(p)
NET LOSS AVAILABLE TO					\$(1,361,406)
COMMON SHAREHOLDERS					
Basic and Diluted Loss per share					\$(.22)

(Shares used for calculation 6,296,555)			

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# CHEMBIO DIAGNOSTICS, INC. (formerly Trading Solutions.com) CONDENSED CONSOLIDATED PRO FORMA BALANCE SHEET AS OF DECEMBER 31, 2003 (Unaudited)

	HISTORICAL		PROFORMA AI		
	Trading Solutions.Com, Inc.	Chembio Diagnostic Systems, Inc.	Debit	Credit	Consolidated Pro forma
CURRENT ASSETS:					
Cash	\$ <u></u>	\$—	\$1,000,000 (d)	367.434 (f)	\$2,411,480
Cuon		Ψ	\$1,000,000 (a)	119,110 (e)	
			2,200,000 (g)	300,000 (h)	
				1,976 (j)	
Accounts receivable	_				282,734
Inventories	_				466,498
Prepaid expenses and other current assets			226,667(n)		250,115
TOTAL CURRENT ASSETS					3,410,827
FIXED ASSETS	_				249,247
OTHER ASSETS	_	64,818	113,333 (n)		178,151
		5 1,020	220,000 (1.)		
	<b>\$</b> —	\$			\$3,838,225
CURRENT LIABILITIES:					
Overdraft	\$—	\$	67,434 (f)		
Accounts payable and accrued liabilities	_		300,000 (f)		\$1,061,547
Current portion of obligations under capital leases	_				61,789
Other current liabilities	-		11,781 (j)	11,781 (j)	12,648
TOTAL CURRENT LIABILITIES	_				1,135,984
OTHER LIABILITIES:					
Notes payable	_		1,332,292 (k)		361,559
Accrued interest	_	239,032			239,032
Convertible notes	_		1,000,000 (j)	1,000,000 (d)	
Obligations under capital leases— net of current portion	_				107,885
TOTAL LIABILITIES	_				1,844,460
STOCKHOLDERS' EQUITY (DEFICIENCY):					
Series A Preferred Stock				2,200,000 (g)	4,211,399
				679,107(j)	
				1,332,292 (k)	
Common stock	180,735		170,103 (a)	1(b)	
			40 (c)	40,000 (c)	
				67 (h)	
				8,267(j)	
				4,000 (m)	
A 11/2 1 . 1 . 1	100 5==		20.000 (2)	480.400.4	F 040 077
Additional paid-in capital	188,957		39,960 (c)	170,103 (a)	5,012,852

	\$—	\$	7,687,256	7,687,256	\$3,838,225
Total Equity (Deficit)	_				1,993,765
			11,781 (j)		
			160,000 (m)		
Accumulated deficit	(369,692)	(7,057,442)	64,229 (b)	369,692 (l)	(7,293,452)
				340,000 (n)	
			369,692 (1)	156,000(m)	
			300,067 (h)	322,431 (j)	

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#### CHEMBIO DIAGNOSTICS, INC.

#### (formerly Trading Solutions.com)

### CONDENSED CONSOLIDATED PRO FORMA STATEMENTS OF OPERATIONS FOR THE TWELVE MONTHS ENDED DECEMBER 31, 2003

(Unaudited)

Trading Solutions.Com, Inc.	Chembio Diagnostic Systems, Inc.	Debit	Credit	Consolidated Pro forma
<b>\$</b> —	\$			\$2,542,621
_				275,73
_				2,818,35
_	2,153,454			2,153,45
_	664,897			664,89
_	313,891			313,89
		200,000 (f)		600,00
		400,000 (i)		
		64,229 (b)		
		160,000 (m)		
		226,667 (n)		
7,123	1,202,185	170,000 (q)		1,830,20
(7,123)				(2,079,198
8,513				8,51
_			154,070 (o)	(54,455
1,390				(2,125,140
_	_			_
\$1,390	\$			\$(2,125,140)
				\$(363,792) (p)
				\$(2,488,932)
	Solutions.Com, Inc.	Solutions.Com, Inc.    Sample   Systems, Inc.	Solutions.Com, Inc.   Systems, Inc.   Systems, Inc.	Solutions.Com, Inc.  Diagnostic Systems, Inc.  S———————————————————————————————————

Basic and Diluted Loss per share			\$(.40)
(Shares used for calculation 6,296,555)			

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#### 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 CDS closed on a merger agreement, which will result in CDS being a wholly owned subsidiary of TSLU, with CDS as the operating Company. The pro forma Balance Sheets assumes the transaction occurred on the as of date for each statement and the pro forma Statement of Operations assumes the transaction occurred as of the first day of the periods reflected. The pro forma adjustments reflecting this transaction are described below:

- a. Reflects the 1:17 reverse stock split of the existing outstanding pre merger shares of common stock of TSLU. 18,000,000 pre split shares resulting in approximately 1,063,147 post split shares. The split was actually consummated as of March 12, 2004.
- b. Issuance of approximately 1,605 shares of common stock of CDS to employees as compensation prior to the completion of the merger at a price of \$40 per share.
- C. Share exchange of 100 shares of TSLU common stock for each share of issued and outstanding stock of CDS. (4,000,000 shares issued in TSLU in exchange for 40,000 shares of CDS). Existing shareholders of CDS also received an aggregate of 400,000 options as part of this share exchange transaction.
- d. Receipt of \$1,000,000 in March of 2004 by CDS associated with a Convertible Debt offering. The debt is convertible into either (i) such number of shares of common stock of TSLU equal to the principal amount of the convertible debentures plus, if elected, all accrued and unpaid interest divided by the conversion price of \$0.40 or (ii) into the Series A Convertible Preferred Stock (see g below) at an effective 33% discount, such that the amount of Series A received would be equivalent to the amount converted times 1.5.
- e. Fees associated with the offering above (d) including \$48,640 of investment banking fees and \$70,470 of legal and accounting expenses. These fees are considered deferred financing costs, but subsequently charged to Equity. (See (j) below)
- **f.** Use of proceeds from Convertible debt offering to pay \$300,000 of selected accounts payable and accrued expenses, fund an outstanding overdraft of \$67,434 and \$200,000 to fund the start of Clinical trials.
- g. 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.
- h. Investment banking and legal fees associated with the Preferred Stock A offering are anticipated at \$300,000. Also, 6,667 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.
- i. Expected use of proceeds from the Series A Preferred Stock of \$400,000 to fund Clinical trials.
- j. Reflects the conversion of \$672,000 of the convertible debt (see (d) above) along with \$7,107 of accrued unpaid interest into Series A Convertible Preferred stock. The debt would be convertible into 33.837 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.
- k. Reflects the conversion of \$1,332,292 of pre-merger debt into Series A Convertible Preferred Stock. The conversion results in an additional 44.41 shares of Series A Preferred Stock being issued and outstanding.
- l. Elimination of TSLU accumulated deficit.
- m. Issuance of 400,000 shares of common stock, with restrictions as payment of salary to a former Officer of TSLU. Salary costs reflected equaled \$160,000.
- **n.** 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.
- O. 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.
- p. 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.
- **q.** 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	\$4,090
Transfer Agent Fees	\$5,000
Costs of Printing and Engraving	\$2,000
Legal Fees	\$25,000
Accounting Fees	\$10,000
Total	\$46,090

#### 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. ("CDS"), a Delaware corporation, Chembio Diagnostics, Inc. (formerly, Trading Solutions.com, Inc.), a publicly traded Nevada corporation ("the Registrant") and New Trading Solutions, Inc., a wholly owned subsidiary of the Registrant ("Merger Sub"), the Merger Sub merged with and into CDS, with CDS remaining as the surviving corporation (the "Merger"). Pursuant to the Merger, the Registrant 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 CDS in exchange for 100% of their issued and outstanding common stock, options and warrants to purchase CDS's common stock. The Registrant 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 Registrant in the Merger. All of the stockholders of CDS, including the non-accredited investors, were provided with an information statement meeting the informational requirements of Rule 502 (b)(2) of the Securities Act.

At or about the time of the Merger, the Registrant consummated three private placements of its 8% Series A Convertible Preferred Stock (the "Series A Preferred") 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 CDS (the "Existing Debt Exchange Offering"). These placements are described below:

- i. *The Cash Offering*. A total of 73.333 shares of Series A Preferred and warrants to acquire 4,399,980 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 Registrant 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 Registrant 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, CDS 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 Registrant's Series A Preferred (together with warrants to acquire shares of the Registrant's Common Stock) or into shares of the Registrant's Common Stock at the Effective Time. As a result, \$672,000 in principal amount of the Bridge Notes, together with accrued and unpaid interest, was converted into 33.837 shares of the Registrant's Series A Preferred (together with warrants to acquire an additional 2,030,220 shares of the Registrant's Common Stock at \$.90 per share). The balance of the Bridge Financing, or \$328,000, was converted into 826,741 shares of the Registrant [6;s Common Stock. The Registrant 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 Registrant 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 Registrant issued 44.410 shares of Series A Preferred 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 CDS's debt existing on its balance sheet as of December 31, 2003. The Registrant 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 Registrant 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 early June 2004, the Registrant agreed with Patton Boggs LLP, a law firm providing legal services to the Registrant, that the Registrant would pay for \$27,989 of its outstanding bill for previously provided legal services with 37,319 shares of the Registrant's restricted common stock. The Registrant 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**

		EMIDITO .
	2.1	Agreement and Plan of Merger dated as March 3, 2004 (the "Merger Agreement"), by and
among the	_	New Trading Solutions, Inc. ("Merger Sub") and Chembio Diagnostic Systems, Inc. ("CDS") (2)
5	2.2	Amendment No. 1 to the Merger Agreement dated as May 1, 2004, by and among the
Registrant	_	b and CDS (1)
	3.1	Articles of Incorporation (2)
	3.2	Certificate of Amendment to Articles of Incorporation (2)
	3.3	Bylaws (2)
	3.4	Amendment No. 1 to Bylaws dated May 3, 2004 (1)
	4.2	Certificate of Designation of the Relative Rights and Preferences of the Series A Convertible
Preferred	Stock of the	Registrant (1)
Purchaser	4.3 s listed there	Registration Rights Agreement, dated as of May 5, 2004, by and among the Registrant and the
T di ciidoci	4.4	Lock-Up Agreement, dated as of May 5, 2004, by and among the Registrant and the
shareholde		egistrant listed therein (1)
	4.5	Form of Common Stock Warrant issued pursuant to the Stock and Warrant Purchase
Agreemen	nt (1)	•
	4.6	Form of \$.90 Warrant issued to Mark L. Baum pursuant to the Consulting Agreement dated as
of May 5,	2004 betwe	en the Registrant and Mark L. Baum (1)
	4.7	Form of \$.60 Warrant issued to Mark L. Baum pursuant to the Consulting Agreement dated as
of May 5,	2004 betwe	en the Registrant and Mark L. Baum (1)
	4.8	Form of Warrant issued to Placement Agents pursuant to the Series A Convertible Stock
Private Pla	acement	
	5.1	Opinion and Consent of Patton Boggs LLP
	10.1	Employment Agreement between the Registrant and Mark L. Baum dated as of May 5, 2004
(1)		
	10.2	Employment Agreement between the Registrant and Lawrence A. Siebert dated as of May 5,
2004		
	10.3	Employment Agreement between the Registrant and with Avi Pelossof dated as of May 5,
2004		
<b>5</b> 2004	10.4	Employment Agreement between the Registrant and with Javan Esfandiari dated as of May
5, 2004		
T. 7 . 70	10.5	Series A Convertible Preferred Stock and Warrant Purchase Agreement (the "Stock and
Warrant P (1)	urchase Agi	reement"), dated as of May 5, 2004, by and among the Registrant and the Purchasers listed therein
	10.6	License and Supply Agreement dated as of August 30, 2002 by and between CDS and
Adaltis In	С.	
	10.7	License and Supply Agreement dated as of February 3, 2004 by and between CDS and

Statens Serum Institut

23.1

- 21 List of Subsidiaries (1)
  - 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,

Consent of Lazar, Levine & Felix LLP, Independent Accountants

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

#### **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.

#### **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 Registration Statement to be signed on its behalf by the undersigned, in the City of Medford, State of New York, on June 4, 2004.

Chembio Diagnostics, Inc., Nevada corporation By: /s/ Lawrence A. Siebert

Lawrence A. Siebert

Its:
President, Chief Executive Officer
and Chairman of the Board

#### POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each individual whose signature appears below constitutes and appoints Lawrence A. Siebert his true and lawful attorney-in-fact and agent, with full power of substitution, for him an in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, and to sign any registration statement for the same offering covered by this registration statement that is to be effective upon filing pursuant to Rule 462(b) promulgated under the Securities Act of 1933, and all post-effective amendments thereto, and to file the same, with all exhibits thereto and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

In accordance with the requirements of the Securities Act of 1933, this Registration Statement on Form SB-2 has been signed by the following persons in the capacities and on the dates indicated.

By:	June 4, 2004
/s/ Lawrence A. Siebert	
Lawrence A. Siebert	
President, Chief Executive Officer	
and Chairman of the Board	
(Principal Executive Officer)	
By:	- June 4, 2004
/s/ Richard J. Larkin	
Richard J. Larkin	
Secretary, Chief Financial Officer	
(Principal Financial and Accounting	
Officer)	
By:	– June 4, 2004
/s/ Mark L. Baum	
Mark L. Baum	
Director	

#### OPINION OF PATTON BOGGS LLP

June 4, 2004

Chembio Diagnostics, Inc. 3661 Horseblock Road Medford, New York 11763

Re: Chembio Diagnostics, Inc. Registration Statement on Form SB-2 for Resale of 20,826,170 Shares of Common Stock

Ladies and Gentlemen:

We have acted as counsel to Chembio Diagnostics, Inc., a Nevada corporation (the "Company"), in connection with the registration for resale of 20,826,170 shares of the Company's Common Stock (the "Shares"), as described in the Company's Registration Statement on Form SB-2 ("Registration Statement") filed with the Securities and Exchange Commission under the Securities Act of 1933, as amended (the "Act").

This opinion is being furnished in accordance with the requirements of Item 27 of Form SB-2 and Item 601(b)(5)(i) of Regulation S-B.

We have reviewed the Company's charter documents and the corporate proceedings taken by the Company in connection with the original issuance and sale of the Shares. Based on such review, we are of the opinion that (1) the Shares (other than Shares issuable upon the conversion of preferred stock or the exercise of options or warrants) are duly authorized, legally issued, and are fully paid and non-assessable; and (2) the Shares issuable upon conversion of preferred stock or the exercise of options or warrants, if, as and when issued by the Company, are duly authorized and, upon conversion or exercise thereof in the manner and for the consideration expressed in such preferred stock, options or warrants, will be legally issued, fully paid and non-assessable.

We consent to the filing of this opinion as Exhibit 5.1 to the Registration Statement and to the reference to this firm under the caption "Legal Matters" in the prospectus which is part of the Registration Statement. In giving this consent, we do not thereby admit that we are within the category of persons whose consent is required under Section 7 of the Act, the rules and regulations of the Securities and Exchange Commission promulgated thereunder, or Item 509 of Regulation SB-2.

This opinion letter is rendered as of the date first written above and we disclaim any obligation to advise you of facts, circumstances, events or developments which hereafter may be brought to our attention and which may

alter, affect or modify the opinion expressed herein. Our opinion is expressly limited to the matters set forth above and we render no opinion, whether by implication or otherwise, as to any other matters relating to the Company or the Shares.

Very truly yours,

/s/ Patton Boggs LLP PATTON BOGGS LLP

#### **EMPLOYMENT AGREEMENT**

This Employment Agreement (the "Agreement") is entered into as of this 5th day of May, 2004 by and between Chembio Diagnostics, Inc., a Nevada corporation (the "Company"), and Lawrence A. Siebert ("Employee") and to be effective as of May 10, 2004. Employee and Company are sometimes referred to individually as a "Party" and collectively as the "Parties."

In consideration of the mutual covenants, promises and agreements herein contained, the Company and Employee hereby covenant, promise and agree to and with each other as follows:

Employment. The Company shall employ Employee and Employee shall perform services for and on behalf of the Company upon the terms and conditions set forth in this Agreement.

Positions and Duties of Employment. Employee shall be required to devote his full energy, skill and best efforts as required to the furtherance of his managerial duties with the Company as the Company's President & Chief Executive Officer. While serving in such capacity(ies), Employee shall have the responsibilities, duties, obligations, rights, benefits and requisite authority as is customary for his position and as may be determined by the Board of Directors (the "Board") of the Company.

Employee understands that his employment as President and Chief Executive Officer of the Company involves a high degree of trust and confidence, that he is employed for the purpose of furthering the Company's reputation and improving the Company's operations and profitability, and that in executing this Agreement he undertakes the obligations set forth herein to accomplish such objectives. Employee agrees that he shall serve the Company fully, diligently, competently, and to the best of his ability. Employee certifies that he fully understands his right to discuss this Agreement with his attorney, that he has availed himself of this right to the extent that he desires, that he has carefully read and fully understands this entire Agreement, and that he is voluntarily entering into this Agreement.

Duties. Employee shall perform the following services for the Company:

Employee shall serve as President and Chief Executive Officer of the Company, or in such other position as determined by the Board, and in that capacity shall work with the Company to pursue the Company's plans as directed by the Board.

Employee shall perform duties with the functions of an officer of the Company, subject to the direction of the Board Of Directors (the "Board") of the Company.

During the term of this Agreement, Employee shall devote substantially all of Employee's business time to the performance of Employee's duties under this Agreement. Without limiting the foregoing, Employee shall perform services on behalf of the Company for at least 40 hours per week, and Employee shall be available at the request of the Company at other times, including weekends and holidays, to meet the needs and requests of the Company's customers.

During the term of this Agreement, Employee will not engage in any other activities or undertake any other commitments that conflict with or take priority over Employee's responsibilities and obligations to the Company and the Company's customers, including without limitation those responsibilities and obligations incurred pursuant to this Agreement.

Term. Unless terminated earlier as provided for in this Agreement, the term of this Agreement shall be for two years, commencing on the Effective Date and ending on the second anniversary of the effective date (the "Term"). If the employment relationship is terminated by either Party, Employee agrees to cooperate with the Company and with the Company's new management with respect to the transition of the new management in the operations previously performed by Employee. Upon Employee's termination, Employee agrees to return to the Company all Company documents (and all copies thereof), any other Company property in Employee's possession or control, and any materials of any kind that contain or embody any proprietary or confidential material of the Company.

Compensation. Employee shall receive the following as compensation:

A salary at an annual rate of \$150,000, subject to periodic review by the Board or the Compensation Committee of the Board, payable in accordance with the Company's customary payroll practices.

At the discretion of the Board or the Compensation Committee of the Board, a performance-based bonus.

Employer shall include Employee, if otherwise eligible, in any profit sharing plan, executive stock option plan, pension plan, retirement plan, medical and/or hospitalization plan, and/or any and all other benefit plans, except for disability and life insurance, which may be placed in effect by Employer for the benefit of Employer's executives during the Term. Except for the fact that Employer at all times shall provide Employee with all or at least a portion of Employee's medical and/or hospitalization insurance, which shall not be less than that afforded to Employer's other executives, nothing in this Agreement shall limit (i) Employer's ability to exercise the discretion provided to it under any such benefit plan, or (ii) Employer's discretion to adopt, not adopt, amend or terminate any such benefit plan at any time.

The Company shall provide Employee with four weeks vacation leave per each year of Employee's employment (which vacation leave may carry over and accrue up to an aggregate of six weeks at any time), sick leave, medical insurance coverage, and any other benefits consistent with Company plans and policies in effect for executive Employees from time to time. The Company may modify in its sole and absolute discretion such benefits from time to time as it considers necessary or appropriate, provided that any such modification shall not affect or modify Employee's then existing rights with respect to any previously accrued vacation.

Any payments which the Company shall make to Employee pursuant to this Agreement shall be reduced by standard withholding and other applicable payroll deductions, including but not limited to federal, state or local income or other taxes, Social Security and Medicare Taxes, State Unemployment Insurance, State Disability Insurance, and the like.

During the term of his employment, Employee shall be reimbursed for reasonable expenses that are authorized by the Company and that are incurred by Employee for the benefit of the Company in accordance with the standard reimbursement practices of the Company. Any direct payment or reimbursement of expenses shall be made only upon presentation of an itemized accounting conforming in form and content to standards prescribed by the Internal Revenue Service relative to the substantiation of the deductibility of business expenses.

Confidentiality. Employee hereby warrants, covenants and agrees that, without the prior express written approval of Employer or unless required by law or court order, Employee shall hold in the strictest confidence, and shall not disclose to any person, firm, corporation or other entity, any and all of Employer's data, including but not limited to (a) information, drawings, sketches, plans or other documents concerning Employer's business or development plans, customers or suppliers, (b) Employer's development, design, construction or sales and marketing methods or techniques, or (c) Employer's trade secrets and other "know-how" or information not of a public nature, regardless of how such information came to the custody of Employee. For purposes of this Agreement, such information shall include, but not be limited to, information, including a formula, pattern, compilation, program, device, method, technique or process, that (i) derives independent economic value, present or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy. The warranty, covenant and agreement set forth in this paragraph shall not expire, shall survive this Agreement, and shall be binding upon Employee without regard to the passage of time or other events.

Non-Compete. Employee acknowledges and recognizes the highly competitive nature of the Company's business and that Employee's duties hereunder justify restricting Employee's further employment following any termination of employment. The Employee agrees that so long as the Employee is employed by the Company, and (i) for a period of two years following the termination of this Agreement, Employee, except when acting at the request of the Company on behalf of or for the benefit of the Company, will not induce customers, agents or other sources of distribution of the Company's business under contract or doing business with the Company to terminate, reduce, alter or divert business with or from the Company.

Termination. If Employee's employment is terminated by the Company without Cause (as defined below), or if Employee terminates his employment for Reasonable Basis (as defined below), then the Company shall, in exchange for Employee's execution of a general release and waiver of claims against the Company as of the termination date in a form reasonably acceptable to the Company, continue to pay as severance Employee's salary for six months. Such payments shall be made in accordance with the Company's customary payroll practices and shall be subject to applicable withholding and payroll deductions. In the event of any such termination set forth in this section 8(a), Employee will not be entitled to any additional compensation or benefits beyond what is provided in the first sentence of this section 8(a).

For purposes of this Agreement, "Cause" shall mean that the Board, acting in good faith based upon the information then known to the Company, determines that Employee has engaged in or committed any of the following: willful misconduct, gross negligence, theft, fraud, or other illegal conduct; refusal or unwillingness to perform Employee's duties; performance by Employee of Employee's duties determined by the Board to be inadequate in a material respect; breach of any applicable non-competition, confidentiality or other proprietary information or inventions agreement between Employee and the Company; inappropriate conflict of interest; insubordination; failure to follow the directions of the Board or any committee thereof; or any other material breach of this Agreement. Indictment or conviction of any felony, or any entry of a plea of

nolo contendre, u nder the laws of the United States or any State shall also be considered "Cause" hereunder. "Cause" shall be specified in a notice of termination to be delivered by the Company no later than the date as of which termination is effective.

For purposes of this Agreement, "Reasonable Basis" shall mean (A) a material breach of this Agreement by the Company, provided that Employee shall have first given written notice of such default to the Company and if within thirty days after receipt of such notice, the Company has not cured such default; or (B) termination of Employee's employment by the Company without Cause during the term hereof; or (C) a reduction in Employee's salary, except to the extent that a majority of the other executive officers of the Company incur reductions of salary that average no less than the percentage reduction incurred by Employee; or (E) termination of the Employee's employment by the Employee within 12 months after a "Change Of Control," with Change Of Control being defined as follows:

"Change in Control" shall mean any of the following:

- (1) any consolidation or merger of Employer in which Employer is not the continuing or surviving corporation, other than a merger of Employer in which the holders of Employer common stock immediately prior to the merger own a majority of the voting common stock of the surviving corporation immediately after the merger;
- (2) any sale, lease, exchange or other transfer (in one transaction or a series of related transactions) of all or substantially all the assets of Employer;
- (3) any approval by the stockholders of Employer of any plan or proposal for the liquidation or dissolution of Employer;
- (4) the acquisition by any person or entity, or any group of persons and/or entities of a majority of the stock entitled to elect a majority of the directors of the Company; or
- (5) subject to applicable law, in a Chapter 11 bankruptcy proceeding, the appointment of a trustee or the conversion of a case involving Employer to a case under a Chapter 7 bankruptcy proceeding.

In the event that Employee's employment with the Company is terminated for Cause, by reason of Employee's death or disability, or due to Employee's resignation or voluntary termination (other than for Reasonable Basis), then all compensation and benefits will cease as of the effective date of such termination, and Employee shall receive no severance benefits, or any other compensation; provided that Employee shall be entitled to receive all compensation earned and all benefits and reimbursements due through the effective date of termination.

Employee agrees that the payments contemplated by this Agreement shall constitute the exclusive and sole remedy for any termination of employment, and Employee covenants not to assert or pursue any other remedies, at law or in equity, with respect to any termination of employment.

Any party terminating this Agreement shall give prompt written notice ("Notice of Termination") to the other party hereto advising such other party of the termination of this Agreement stating in reasonable detail the basis for such termination. The Notice of Termination shall indicate whether termination is being made for Cause (if Employer has terminated the Agreement) or for Reasonable Basis (if the Employee has terminated the Agreement).

Remedies. If there is a breach or threatened breach of any provision of Section 6 or Section 7 of this Agreement, the Company will suffer irreparable harm and shall be entitled to an injunction restraining Employee from such breach. Nothing herein shall be construed as prohibiting the Company from pursuing any other remedies for such breach or threatened breach.

Severability. It is the clear intention of the Parties to this Agreement that no term, provision or clause of this Agreement shall be deemed to be invalid, illegal or unenforceable in any respect, unless such term, provision or clause cannot be otherwise construed, interpreted, or modified to give effect to the intent of the Parties and to be valid, legal or enforceable. The Parties specifically charge the trier of fact to give effect to the intent of the Parties, even if in doing so, information of a specific provision of this Agreement is required consistent with the foregoing stated intent. In the event that such a term, provision, or clause cannot be so construed, interpreted or modified, the validity, legality and enforceability of the remaining provisions contained herein and other application(s) thereof shall not in any way be affected or impaired thereby and shall remain in full force and effect.

Waiver of Breach. The waiver by the Company or Employee of the breach of any provision of this Agreement by the other Party shall not operate or be construed as a waiver of any subsequent breach by that Party.

Entire Agreement. This document contains the entire agreement between the Parties and supersedes all prior oral or written agreements, if any, concerning the subject matter hereof or otherwise concerning Employee's employment by Employer (except for options to purchase shares of Employer's restricted stock previously granted to Employee). This Agreement may not be changed orally, but only by agreement in writing signed by the Parties.

Governing Law. This Agreement, its validity, interpretation and enforcement, shall be governed by the laws of the State of New York, excluding conflict of laws principles. Employee hereby expressly consents to personal jurisdiction in the state and federal courts located in Long Island, NY for any lawsuit filed there against him by the Company arising from or relating to this Agreement.

Notices. Any notice pursuant to this Agreement shall be validly given or served if that notice is made in writing and delivered personally or sent by certified mail or registered, return receipt requested, postage prepaid, to the following addresses:

If to Company:		
	Attention:	-
If to Employee:	To the address for Employee s	et forth below his signature.
		personal delivery or, if sent by certified or registered mail, five business given, may change the address to which his or its future notices shall be
•		all be binding upon Employee and the Company and shall benefit the nent shall not be assignable by Employee.
Headings. The heading affect its interpretation	_	convenience only; they form no part of this Agreement and shall not
to consult with such le	• •	nd completely understands this Agreement and (b) had an opportunity s desired in connection with this Agreement. This Agreement shall not
Insurance. The Comp of Directors of the Co		d officers' insurance in an amount determined reasonably by the Board
IN WITNESS WHER	REOF, the parties have caused th	is Agreement to be executed the day and year first above written.
EMPLOYEE	Larry Siebert	

<u>/s/Mark Baum</u> Director

By:

Chembio Diagnostics, Inc.

#### **EMPLOYMENT AGREEMENT**

This Employment Agreement (the "Agreement") is entered into as of this 5th day of May, 2004 by and between Chembio Diagnostics, Inc., a Nevada corporation (the "Company"), and Avi Pelossof ("Employee") and to be effective as of May 10, 2004. Employee and Company are sometimes referred to individually as a "Party" and collectively as the "Parties."

In consideration of the mutual covenants, promises and agreements herein contained, the Company and Employee hereby covenant, promise and agree to and with each other as follows:

Employment. The Company shall employ Employee and Employee shall perform services for and on behalf of the Company upon the terms and conditions set forth in this Agreement.

Positions and Duties of Employment. Employee shall be required to devote his full energy, skill and best efforts as required to the furtherance of his managerial duties with the Company as the Company's Vice President of Sales, Marketing and Business Development. While serving in such capacity(ies), Employee shall have the responsibilities, duties, obligations, rights, benefits and requisite authority as is customary for his position and as may be determined by the Board of Directors (the "Board") of the Company.

Employee understands that his employment as Vice President of Sales, Marketing and Business Developmentof the Company involves a high degree of trust and confidence, that he is employed for the purpose of furthering the Company's reputation and improving the Company's operations and profitability, and that in executing this Agreement he undertakes the obligations set forth herein to accomplish such objectives. Employee agrees that he shall serve the Company fully, diligently, competently, and to the best of his ability. Employee certifies that he fully understands his right to discuss this Agreement with his attorney, that he has availed himself of this right to the extent that he desires, that he has carefully read and fully understands this entire Agreement, and that he is voluntarily entering into this Agreement.

Duties. Employee shall perform the following services for the Company:

Employee shall serve as President and Chief Executive Officer of the Company, or in such other position as determined by the Board, and in that capacity shall work with the Company to pursue the Company's plans as directed by the Board.

Employee shall perform duties with the functions of an officer of the Company, subject to the direction of the Board Of Directors (the "Board") of the Company.

During the term of this Agreement, Employee shall devote substantially all of Employee's business time to the performance of Employee's duties under this Agreement. Without limiting the foregoing, Employee shall perform services on behalf of the Company for at least 40 hours per week, and Employee shall be available at the request of the Company at other times, including weekends and holidays, to meet the needs and requests of the Company's customers.

During the term of this Agreement, Employee will not engage in any other activities or undertake any other commitments that conflict with or take priority over Employee's responsibilities and obligations to the Company and the Company's customers, including without limitation those responsibilities and obligations incurred pursuant to this Agreement.

Term. Unless terminated earlier as provided for in this Agreement, the term of this Agreement shall be for two years, commencing on the Effective Date and ending on the second anniversary of the effective date (the "Term"). If the employment relationship is terminated by either Party, Employee agrees to cooperate with the Company and with the Company's new management with respect to the transition of the new management in the operations previously performed by Employee. Upon Employee's termination, Employee agrees to return to the Company all Company documents (and all copies thereof), any other Company property in Employee's possession or control, and any materials of any kind that contain or embody any proprietary or confidential material of the Company.

Compensation. Employee shall receive the following as compensation:

A salary at an annual rate of \$120,000, subject to periodic review by the Board or the Compensation Committee of the Board, payable in accordance with the Company's customary payroll practices. Annual salary increases will be not less than 5%.

At the discretion of the Board or the Compensation Committee of the Board, a performance-based bonus.

Employer shall include Employee, if otherwise eligible, in any profit sharing plan, executive stock option plan, pension plan, retirement plan, medical and/or hospitalization plan, and/or any and all other benefit plans, except for disability and life insurance, which may be placed in effect by Employer for the benefit of Employer's executives during the Term. Except for the fact that Employer at all times shall provide Employee with all or at least a portion of Employee's medical and/or hospitalization insurance, which shall not be less than that afforded to Employer's other executives, nothing in this Agreement shall limit (i) Employer's ability to exercise the discretion provided to it under any such benefit plan, or (ii) Employer's discretion to adopt, not adopt, amend or terminate any such benefit plan at any time.

The Company shall provide Employee with four weeks vacation leave per each year of Employee's employment (which vacation leave may carry over and accrue up to an aggregate of six weeks at any time), sick leave, medical insurance coverage, and any other benefits consistent with Company plans and policies in effect for executive Employees from time to time. The Company may modify in its sole and absolute discretion such benefits from time to time as it considers necessary or appropriate, provided that any such modification shall not affect or modify Employee's then existing rights with respect to any previously accrued vacation.

Any payments which the Company shall make to Employee pursuant to this Agreement shall be reduced by standard withholding and other applicable payroll deductions, including but not limited to federal, state or local income or other taxes, Social Security and Medicare Taxes, State Unemployment Insurance, State Disability Insurance, and the like.

During the term of his employment, Employee shall be reimbursed for reasonable expenses that are authorized by the Company and that are incurred by Employee for the benefit of the Company in accordance with the standard reimbursement practices of the Company. Any direct payment or reimbursement of expenses shall be made only upon presentation of an itemized accounting conforming in form and content to standards prescribed by the Internal Revenue Service relative to the substantiation of the deductibility of business expenses.

Confidentiality. Employee hereby warrants, covenants and agrees that, without the prior express written approval of Employer or unless required by law or court order, Employee shall hold in the strictest confidence, and shall not disclose to any person, firm, corporation or other entity, any and all of Employer's data, including but not limited to (a) information, drawings, sketches, plans or other documents concerning Employer's business or development plans, customers or suppliers, (b) Employer's development, design, construction or sales and marketing methods or techniques, or (c) Employer's trade secrets and other "know-how" or information not of a public nature, regardless of how such information came to the custody of Employee. For purposes of this Agreement, such information shall include, but not be limited to, information, including a formula, pattern, compilation, program, device, method, technique or process, that (i) derives independent economic value, present or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy. The warranty, covenant and agreement set forth in this paragraph shall not expire, shall survive this Agreement, and shall be binding upon Employee without regard to the passage of time or other events.

Non-Compete. Employee acknowledges and recognizes the highly competitive nature of the Company's business and that Employee's duties hereunder justify restricting Employee's further employment following any termination of employment. The Employee agrees that so long as the Employee is employed by the Company, and (i) for a period of two years following the termination of this Agreement, Employee, except when acting at the request of the Company on behalf of or for the benefit of the Company, will not induce customers, agents or other sources of distribution of the Company's business under contract or doing business with the Company to terminate, reduce, alter or divert business with or from the Company.

Termination. If Employee's employment is terminated by the Company without Cause (as defined below), or if Employee terminates his employment for Reasonable Basis (as defined below), then the Company shall, in exchange for Employee's execution of a general release and waiver of claims against the Company as of the termination date in a form reasonably acceptable to the Company, continue to pay as severance Employee's salary for six months. Such payments shall be made in accordance with the Company's customary payroll practices and shall be subject to applicable withholding and payroll deductions. In the event of any such termination set forth in this section 8(a), Employee will not be entitled to any additional compensation or benefits beyond what is provided in the first sentence of this section 8(a).

For purposes of this Agreement, "Cause" shall mean that the Board, acting in good faith based upon the information then known to the Company, determines that Employee has engaged in or committed any of the following: willful misconduct, gross negligence, theft, fraud, or other illegal conduct; refusal or unwillingness to perform Employee's duties; performance by Employee of Employee's duties determined by the Board to be inadequate in a material respect; breach of any applicable non-competition, confidentiality or other proprietary information or inventions agreement between Employee and the Company; inappropriate conflict of interest; insubordination; failure to follow the directions of the Board or any committee

thereof; or any other material breach of this Agreement. Indictment or conviction of any felony, or any entry of a plea of nolo contendre, u nder the laws of the United States or any State shall also be considered "Cause" hereunder. "Cause" shall be specified in a notice of termination to be delivered by the Company no later than the date as of which termination is effective.

For purposes of this Agreement, "Reasonable Basis" shall mean (A) a material breach of this Agreement by the Company, provided that Employee shall have first given written notice of such default to the Company and if within thirty days after receipt of such notice, the Company has not cured such default; or (B) termination of Employee's employment by the Company without Cause during the term hereof; or (C) a reduction in Employee's salary, except to the extent that a majority of the other executive officers of the Company incur reductions of salary that average no less than the percentage reduction incurred by Employee; or (E) termination of the Employee's employment by the Employee within 12 months after a "Change Of Control," with Change Of Control being defined as follows:

"Change in Control" shall mean any of the following:

- (1) any consolidation or merger of Employer in which Employer is not the continuing or surviving corporation, other than a merger of Employer in which the holders of Employer common stock immediately prior to the merger own a majority of the voting common stock of the surviving corporation immediately after the merger;
- (2) any sale, lease, exchange or other transfer (in one transaction or a series of related transactions) of all or substantially all the assets of Employer;
- (3) any approval by the stockholders of Employer of any plan or proposal for the liquidation or dissolution of Employer;
- (4) the acquisition by any person or entity, or any group of persons and/or entities of a majority of the stock entitled to elect a majority of the directors of the Company; or
- (5) subject to applicable law, in a Chapter 11 bankruptcy proceeding, the appointment of a trustee or the conversion of a case involving Employer to a case under a Chapter 7 bankruptcy proceeding.

In the event that Employee's employment with the Company is terminated for Cause, by reason of Employee's death or disability, or due to Employee's resignation or voluntary termination (other than for Reasonable Basis), then all compensation and benefits will cease as of the effective date of such termination, and Employee shall receive no severance benefits, or any other compensation; provided that Employee shall be entitled to receive all compensation earned and all benefits and reimbursements due through the effective date of termination.

Employee agrees that the payments contemplated by this Agreement shall constitute the exclusive and sole remedy for any termination of employment, and Employee covenants not to assert or pursue any other remedies, at law or in equity, with respect to any termination of employment.

Any party terminating this Agreement shall give prompt written notice ("Notice of Termination") to the other party hereto advising such other party of the termination of this Agreement stating in reasonable detail the basis for such termination. The Notice of Termination shall indicate whether termination is being made for Cause (if Employer has terminated the Agreement) or for Reasonable Basis (if the Employee has terminated the Agreement).

Remedies. If there is a breach or threatened breach of any provision of Section 6 or Section 7 of this Agreement, the Company will suffer irreparable harm and shall be entitled to an injunction restraining Employee from such breach. Nothing herein shall be construed as prohibiting the Company from pursuing any other remedies for such breach or threatened breach.

Severability. It is the clear intention of the Parties to this Agreement that no term, provision or clause of this Agreement shall be deemed to be invalid, illegal or unenforceable in any respect, unless such term, provision or clause cannot be otherwise construed, interpreted, or modified to give effect to the intent of the Parties and to be valid, legal or enforceable. The Parties specifically charge the trier of fact to give effect to the intent of the Parties, even if in doing so, information of a specific provision of this Agreement is required consistent with the foregoing stated intent. In the event that such a term, provision, or clause cannot be so construed, interpreted or modified, the validity, legality and enforceability of the remaining provisions contained herein and other application(s) thereof shall not in any way be affected or impaired thereby and shall remain in full force and effect.

Waiver of Breach. The waiver by the Company or Employee of the breach of any provision of this Agreement by the other Party shall not operate or be construed as a waiver of any subsequent breach by that Party.

Entire Agreement. This document contains the entire agreement between the Parties and supersedes all prior oral or written agreements, if any, concerning the subject matter hereof or otherwise concerning Employee's employment by Employer (except for options to purchase shares of Employer's restricted stock previously granted to Employee). This Agreement may not be changed orally, but only by agreement in writing signed by the Parties.

Governing Law. This Agreement, its validity, interpretation and enforcement, shall be governed by the laws of the State of New York, excluding conflict of laws principles. Employee hereby expressly consents to personal jurisdiction in the state and federal courts located in Long Island, NY for any lawsuit filed there against him by the Company arising from or relating to this Agreement.

Notices. Any notice pursuant to this Agreement shall be validly given or served if that notice is made in writing and delivered personally or sent by certified mail or registered, return receipt requested, postage prepaid, to the following addresses:

If to Company:	
	Attention:
If to Employee:	To the address for Employee set forth below his signature.
	hall be deemed effective upon personal delivery or, if sent by certified or registered mail, five business ling. Either party, by notice so given, may change the address to which his or its future notices shall be
•	ling Effect. This Agreement shall be binding upon Employee and the Company and shall benefit the tessors and assigns. This Agreement shall not be assignable by Employee.
Headings. The heading affect its interpretation	ngs in this Agreement are for convenience only; they form no part of this Agreement and shall not n.
	ree represents he has (a) read and completely understands this Agreement and (b) had an opportunity egal and other advisers as he has desired in connection with this Agreement. This Agreement shall not any one of the Parties.
Insurance. The Comp of Directors of the Co	any is to maintain directors' and officers' insurance in an amount determined reasonably by the Board mpany.
IN WITNESS WHER	EOF, the parties have caused this Agreement to be executed the day and year first above written.
EMPLOYEE	
/s/Avi Pelossof Avi Pelossof	

/s/Lawrence A. Siebert President

By:

Chembio Diagnostics, Inc.

### **EMPLOYMENT AGREEMENT**

This Employment Agreement (the "Agreement") is entered into as of this 5th day of May, 2004 by and between Chembio Diagnostics, Inc., a Nevada corporation (the "Company"), and Javan Esfandiari ("Employee") and to be effective as of May 10th, 2004. Employee and Company are sometimes referred to individually as a "Party" and collectively as the "Parties."

In consideration of the mutual covenants, promises and agreements herein contained, the Company and Employee hereby covenant, promise and agree to and with each other as follows:

Employment. The Company shall employ Employee and Employee shall perform services for and on behalf of the Company upon the terms and conditions set forth in this Agreement.

Positions and Duties of Employment. Employee shall be required to devote his full energy, skill and best efforts as required to the furtherance of his managerial duties with the Company as the Company's Director of Research & Development. While serving in such capacity(ies), Employee shall have the responsibilities, duties, obligations, rights, benefits and requisite authority as is customary for his position and as may be determined by the Board of Directors (the "Board") of the Company.

Employee understands that his employment as Director of Research & Director of the Company involves a high degree of trust and confidence, he is employed for the purpose of furthering the Company's reputation and increasing and improving the Company's product portfolio, and that in executing this Agreement he undertakes the obligations set forth herein to accomplish such objectives. Employee agrees that he shall serve the Company fully, diligently, competently, and to the best of his ability. Employee certifies that he fully understands his right to discuss this Agreement with his attorney, he has availed himself of this right to the extent that he desires, that he has carefully read and fully understands this entire Agreement, and that he is voluntarily entering into this Agreement.

Duties. Employee shall perform the following services for the Company:

Employee shall serve as Director of Research & Development of the Company, or in such other position as determined by the Board, and in that capacity shall work with the Company to pursue the Company's plans as directed by the Board.

During the term of this Agreement, Employee shall devote substantially all of Employee's business time to the performance of Employee's duties under this Agreement. Without limiting the foregoing, Employee shall perform services on behalf of the Company for at least 40 hours per week, and Employee shall be available at the request of the Company at other times, including weekends and holidays, to meet the needs and requests of the Company's customers.

During the term of this Agreement, Employee will not engage in any other activities or undertake any other commitments that conflict with or take priority over Employee's responsibilities and obligations to the Company and the Company's customers, including without limitation those responsibilities and obligations incurred pursuant to this Agreement.

Term. Unless terminated earlier as provided for in this Agreement, the term of this Agreement shall be for three years, commencing on the Effective Date and ending on May 10, 2007 (the "Term"). If the employment relationship is terminated by either Party, Employee agrees to cooperate with the Company and with the Company's new management with respect to the transition of the new management in the operations previously performed by Employee. Upon Employee's termination, Employee agrees to return to the Company all Company documents (and all copies thereof), any other Company property in Employee's possession or control, and any materials of any kind that contain or embody any proprietary or confidential material of the Company.

Compensation. Employee shall receive the following as compensation:

A salary at an annual rate of \$115,000 in the first year, \$125,000 in the second year, and \$135,000 in the third year payable in accordance with the Company's customary payroll practices. At the discretion of the Board or the Compensation Committee of the Board, a performance-based bonus.

Employer shall include Employee, if otherwise eligible, in any profit sharing plan, executive stock option plan, pension plan, retirement plan, medical and/or hospitalization plan, and/or any and all other benefit plans, except for disability and life insurance, which may be placed in effect by Employer for the benefit of Employer's executives during the Term. Except for the fact that Employer at all times shall provide Employee with all or at least a portion of Employee's medical and/or hospitalization insurance, which shall not be less than that afforded to Employer's other executives, nothing in this

Agreement shall limit (i) Employer's ability to exercise the discretion provided to it under any such benefit plan, or (ii) Employer's discretion to adopt, not adopt, amend or terminate any such benefit plan at any time.

The Company shall provide Employee with four weeks vacation leave per each year of Employee's employment (which vacation leave may carry over and accrue up to an aggregate of six weeks at any time), sick leave, medical insurance coverage, and any other benefits consistent with Company plans and policies in effect for executive Employees from time to time. The Company may modify in its sole and absolute discretion such benefits from time to time as it considers necessary or appropriate, provided that any such modification shall not affect or modify Employee's then existing rights with respect to any previously accrued vacation.

Any payments which the Company shall make to Employee pursuant to this Agreement shall be reduced by standard withholding and other applicable payroll deductions, including but not limited to federal, state or local income or other taxes, Social Security and Medicare Taxes, State Unemployment Insurance, State Disability Insurance, and the like.

During the term of his employment, Employee shall be reimbursed for reasonable expenses that are authorized by the Company and that are incurred by Employee for the benefit of the Company in accordance with the standard reimbursement practices of the Company. Any direct payment or reimbursement of expenses shall be made only upon presentation of an itemized accounting conforming in form and content to standards prescribed by the Internal Revenue Service relative to the substantiation of the deductibility of business expenses.

Confidentiality. Employee hereby warrants, covenants and agrees that, without the prior express written approval of Employer or unless required by law or court order, Employee shall hold in the strictest confidence, and shall not disclose to any person, firm, corporation or other entity, any and all of Employer's data, including but not limited to (a) information, drawings, sketches, plans or other documents concerning Employer's business or development plans, customers or suppliers, (b) Employer's development, design, construction or sales and marketing methods or techniques, or (c) Employer's trade secrets and other "know-how" or information not of a public nature, regardless of how such information came to the custody of Employee. For purposes of this Agreement, such information shall include, but not be limited to, information, including a formula, pattern, compilation, program, device, method, technique or process, that (i) derives independent economic value, present or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy. The warranty, covenant and agreement set forth in this paragraph shall not expire, shall survive this Agreement, and shall be binding upon Employee without regard to the passage of time or other events.

Non-Compete. Employee acknowledges and recognizes the highly competitive nature of the Company's business and that Employee's duties hereunder justify restricting Employee's further employment following any termination of employment. The Employee agrees that so long as the Employee is employed by the Company, and (i) for a period of two years following the termination of this Agreement, Employee, except when acting at the request of the Company on behalf of or for the benefit of the Company, will not induce customers, agents or other sources of distribution of the Company's business under contract or doing business with the Company to terminate, reduce, alter or divert business with or from the Company, and (ii) for a period of one year following the termination of this Agreement, Employee shall not, directly or indirectly, either as a principal, agent, employee, employer, consultant, partner, member or manager of a limited liability company, shareholder of a company that does not have securities registered under the Securities Exchange Act of 1934 (the "1934 Act"), or shareholder in excess of one percent of a company that has securities registered under the 1934 Act, corporate officer or director, or in any other individual or representative capacity, engage or otherwise participate in any manner or fashion in any business that is in competition in any manner whatsoever with the business activities of Employer, in or about any market in which Employer has, or has publicly announced a plan for doing business. Employee further covenants and agrees that the restrictive covenant set forth in this paragraph is reasonable as to duration, terms, and geographical area and that the same protects the legitimate interests of Employer, imposes no undue hardship on Employee, and is not injurious to the public. The covenant set forth under (ii) above shall n ot apply if Employee's employment is terminated within twelve months of a Change in Control as defined in of this Agreement. Ownership by Employee, for investment purposes only, of less than one percent of any class of securities of a corporation if said securities are listed on a national securities exchange or registered under the 1934 Act shall not constitute a breach of the covenant set forth under (ii) above. It is the desire and intent of the Parties that the provisions of this paragraph be enforced to the fullest extent permissible under the laws and public policies applied in each jurisdiction in which enforcement is sought. Accordingly, if any particular portion of paragraph shall be adjudicated to be invalid or unenforceable, this paragraph shall be deemed amended to apply in the broadest allowable manner and to delete therefrom the portion adjudicated to be invalid or unenforceable, such amendment and deletion to apply only with respect to the operation of paragraph in the particular jurisdic tion in which that adjudication is made.

Key Man Life Insurance - Employee agrees to cooperate with the Company in order that it may procure key man life insurance on Employee naming Company as beneficiary.

### Termination.

If Employee's employment is terminated by the Company without Cause (as defined below), or if Employee terminates his employment for Reasonable Basis (as defined below), then the Company shall, in exchange for Employee's execution of a general release and waiver of claims against the Company as of the termination date in a form reasonably acceptable to the Company, continue to pay as severance Employee's salary for six months. Such payments shall be made in accordance with the Company's customary payroll practices and shall be subject to applicable withholding and payroll deductions. In the event of any such termination set forth in this section 8(a), Employee will not be entitled to any additional compensation or benefits beyond what is provided in the first sentence of this section 8(a).

For purposes of this Agreement, "Cause" shall mean that the Board, acting in good faith based upon the information then known to the Company, determines that Employee has engaged in or committed any of the following: willful misconduct, gross negligence, theft, fraud, or other illegal conduct; refusal or unwillingness to perform Employee's duties; performance by Employee of Employee's duties determined by the Board to be inadequate in a material respect; breach of any applicable non-competition, confidentiality or other proprietary information or inventions agreement between Employee and the Company; inappropriate conflict of interest; insubordination; failure to follow the directions of the Board or any committee thereof; or any other material breach of this Agreement. Indictment or conviction of any felony, or any entry of a plea of nolo contendre, u nder the laws of the United States or any State shall also be considered "Cause" hereunder. "Cause" shall be specified in a notice of termination to be delivered by the Company no later than the date as of which termination is effective.

For purposes of this Agreement, "Reasonable Basis" shall mean (A) a material breach of this Agreement by the Company, provided that Employee shall have first given written notice of such default to the Company and if within thirty days after receipt of such notice, the Company has not cured such default; or (B) termination of Employee's employment by the Company without Cause during the term hereof; or (C) a reduction in Employee's salary, except to the extent that a majority of the other executive officers of the Company incur reductions of salary that average no less than the percentage reduction incurred by Employee; or (E) termination of the Employee's employment by the Employee within 12 months after a "Change Of Control," with Change Of Control being defined as follows:

"Change in Control" shall mean any of the following:

- (1) any consolidation or merger of Employer in which Employer is not the continuing or surviving corporation, other than a merger of Employer in which the holders of Employer common stock immediately prior to the merger own a majority of the voting common stock of the surviving corporation immediately after the merger;
- (2) any sale, lease, exchange or other transfer (in one transaction or a series of related transactions)of all or substantially all the assets of Employer;
- (3) any approval by the stockholders of Employer of any plan or proposal for the liquidation or dissolution of Employer;
- (4) the acquisition by any person or entity, or any group of persons and/or entities of a majority of the stock entitled to elect a majority of the directors of the Company; or
- (5) subject to applicable law, in a Chapter 11 bankruptcy proceeding, the appointment of a trustee or the conversion of a case involving Employer to a case under a Chapter 7 bankruptcy proceeding.

In the event that Employee's employment with the Company is terminated for Cause, by reason of Employee's death or disability, or due to Employee's resignation or voluntary termination (other than for Reasonable Basis), then all compensation and benefits will cease as of the effective date of such termination, and Employee shall receive no severance benefits, or any other compensation; provided that Employee shall be entitled to receive all compensation earned and all benefits and reimbursements due through the effective date of termination.

Employee agrees that the payments contemplated by this Agreement shall constitute the exclusive and sole remedy for any termination of employment, and Employee covenants not to assert or pursue any other remedies, at law or in equity, with respect to any termination of employment.

Any party terminating this Agreement shall give prompt written notice ("Notice of Termination") to the other party hereto advising such other party of the termination of this Agreement stating in reasonable detail the basis for such termination. The Notice of Termination shall indicate whether termination is being made for Cause (if Employer has terminated the Agreement) or for Reasonable Basis (if the Employee has terminated the Agreement).

Remedies. If there is a breach or threatened breach of any provision of Section 6 or Section 7 of this Agreement, the Company will suffer irreparable harm and shall be entitled to an injunction restraining Employee from such breach. Nothing herein shall be construed as prohibiting the Company from pursuing any other remedies for such breach or threatened breach.

Severability. It is the clear intention of the Parties to this Agreement that no term, provision or clause of this Agreement shall be deemed to be invalid, illegal or unenforceable in any respect, unless such term, provision or clause cannot be otherwise construed, interpreted, or modified to give effect to the intent of the Parties and to be valid, legal or enforceable. The Parties specifically charge the trier of fact to give effect to the intent of the Parties, even if in doing so, information of a specific provision of this Agreement is required consistent with the foregoing stated intent. In the event that such a term, provision, or clause cannot be so construed, interpreted or modified, the validity, legality and enforceability of the remaining provisions contained herein and other application(s) thereof shall not in any way be affected or impaired thereby and shall remain in full force and effect.

Waiver of Breach. The waiver by the Company or Employee of the breach of any provision of this Agreement by the other Party shall not operate or be construed as a waiver of any subsequent breach by that Party.

Entire Agreement. This document contains the entire agreement between the Parties and supersedes all prior oral or written agreements, if any, concerning the subject matter hereof or otherwise concerning Employee's employment by Employer (except for options to purchase shares of Employer's restricted stock previously granted to Employee). This Agreement may not be changed orally, but only by agreement in writing signed by the Parties.

Governing Law. This Agreement, its validity, interpretation and enforcement, shall be governed by the laws of the State of New York, excluding conflict of laws principles. Employee hereby expressly consents to personal jurisdiction in the state and federal courts located in Long Island, NY for any lawsuit filed there against him by the Company arising from or relating to this Agreement.

Notices. Any notice pursuant to this Agreement shall be validly given or served if that notice is made in writing and delivered personally or sent by certified mail or registered, return receipt requested, postage prepaid, to the following addresses:

If to Company:		
	Attention:	

If to Employee: To the address for Employee set forth below his signature.

All notices so given shall be deemed effective upon personal delivery or, if sent by certified or registered mail, five business days after date of mailing. Either party, by notice so given, may change the address to which his or its future notices shall be sent.

Assignment and Binding Effect. This Agreement shall be binding upon Employee and the Company and shall benefit the Company and its successors and assigns. This Agreement shall not be assignable by Employee.

Headings. The headings in this Agreement are for convenience only; they form no part of this Agreement and shall not affect its interpretation.

Construction. Employee represents he has (a) read and completely understands this Agreement and (b) had an opportunity to consult with such legal and other advisers as he has desired in connection with this Agreement. This Agreement shall not be construed against any one of the Parties.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed the day and year first above written.

EMPLOYEE /s/ Javan Esfandiari

Chembio Diagnostic , Inc.

By: /s/Lawrence A. Siebert

President

### LICENSE AND SUPPLY AGREEMENT

THIS MUTUAL LICENCE AND SUPPLY AGREEMENT (the "Agreement") is entered into as of this 30<sup>th</sup> day of, August 2002 (the Effective Date), by and between Chembio Diagnostics Systems, Inc., a corporation organized and existing under the law of the State of New York, U.S.A. and having its principal place of business at 3661 Horseblock Rd., Medford, NY 11763 U.S.A. ("Chembio") and Adaltis Inc., a corporation organized and existing under the laws of Canada, and having its principal place of business at 10900 Hamon Street, Montreal, P.Q., Canada H3M 3A2 ("Adaltis") and shall replace any prior agreement between the Parties.

WHEREAS Adaltis has developed Peptides (as hereinafter defined) for use in diagnostic tests;

WHEREAS Chembio is in the business of manufacturing and distributing diagnostic tests and is desirous of manufacturing and selling diagnostic tests using Peptides developed by Adaltis;

WHEREAS Adaltis is willing to licence and supply Peptides to Chembio under the terms and conditions set in this Agreement;

NOW, THEREFORE, in consideration of the mutual covenants set forth herein, the Parties do agree as follows:

- **1. <u>Definitions.</u>** As used in this Agreement, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below:
  - (a)"Affiliate" of a Party shall mean any individual or entity directly or indirectly controlling, controlled by or under common control with, that Party. For purposes of this Agreement, the direct or indirect ownership of over fifty percent (50%) of the outstanding voting securities of an entity, or the right to receive over fifty percent (50%) of the profits or earnings of an entity shall be deemed to constitute control. Such other relationship as in fact gives such individual or entity the power or ability to control the management, business and affairs of an entity shall also be deemed to constitute control.
  - **(b)"Information"** shall mean the proprietary technology, know-how, and information, in whatever form and whether or not subject to any registration in any country or territory in the Territory, owned by, used by or licenced to either Party for the production, sale, and marketing of the diagnostic tests referred to in the Agreement. "Adaltis Information" shall mean Information, in whatever form and whether or not subject to any registration in any country or territory in the Territory, owned by, Adaltis (other than by Chembio) including, without limitation, all proprietary technology, know-how, and information relating to the Peptides. "Chembio Information" shall mean Information, in whatever form and whether or not subject to any registration in any country or territory in the Territory, owned by Chembio (othe r than by Adaltis), including, without limitation, all proprietary technology, know-how, and information relating to the diagnostic tests and components thereof manufactured by or on behalf of Chembio.
  - (c)"Party" shall mean Chembio or Adaltis and when used in the plural, shall mean Chembio and Adaltis.
  - (d)"Third Party" shall mean a Person other than the Parties and their respective Affiliates,
  - (e) "Patent Rights" shall mean the patents and patent applications as specified in Exhibit "A" hereto, any addition, division, continuation, continuation-in-part, or foreign counterpart of such applications, any patent issuing therefrom, any substitution, extension, or reissue thereof, and any other patent hereafter issued to Adaltis covering the Peptides or Licenced Products.
  - **(f)"Peptides"** shall mean the cyclic HIV-1 gp41 peptide BIOTIN-LYS-BCH-408 (BCH-2360), HIV-1 gp120 peptide BIOTIN-LYS-BCH-132 (BCH-2362) and/or HIV-2 gp36 peptide BIOTIN-LYS-BCH-202c[Lys-1] (BVH-2361) which are identified and specified in Exhibit "B" hereto.
  - **(g)**"**Person**" shall mean an individual, partnership, corporation, business, trust, joint venture, or other entity of a similar nature.
  - (h)"Licenced Products" shall mean the HIV peptide sequences licenced to Chembio under this Agreement.
  - i. "Chembio Products" shall mean those rapid in-vitro immuno-diagnostic test that:

- i. are to be used solely for the diagnosis of HIV (or HIV and another disease/condition), manufactured, marketed, distributed, and/or sold by or on behalf of Chembio; and
- ii. contain, incorporate, or employ any of the Peptides.

Chembio Products include, but are not limited to, those products described in Exhibit "C" hereto.

- (j)"**Prime**" means a fluctuation rate of interest per annum equal to the rate published in the *Wall Street Journal* from time to time as the prime or base rate for loans to commercial borrowers. The prime rate will change at the same time and to the full extent of any changes in the prime rate as published in the *Wall Street Journal*.
- **(k)** "Specifications" shall mean, when referring to Peptides, those specifications set forth in Exhibit "D".
- **(l)**"**Territory**" shall mean all countries and territories of the world with the exception of Canada.
- **(m)**"Net Sales" shall mean the gross amount charged by Chembio and/or its Affiliates on sales of Chembio Products, including the gross amount of all revenues, receipts, monies and the fair market value of all other consideration directly or indirectly charged, collected or received, whether by way of cash or credit or nay barter, benefit, advantage or concession, less the following:
  - (i) customary trade, quantity, and/or cash discounts, rebates and/or commissions to non-affiliated brokers or agents to the extent actually allowed and taken;
    - (ii) amounts actually repaid or credited by reason of rejection or return;
    - (iii)to the extent separately stated on purchase orders, invoiced or other documents of sale, any taxes or other governmental charges actually levied on the sale, transportation, delivery, or use of a Chembio Product which is paid by or on behalf of Chembio; and
    - (iv)outbound transportation costs actually prepaid or allowed by Chembio and the actual cost of insurance in transit paid by Chembio, not to exceed ten percent (10%) of the gross amount charged per invoice.

In cases of transfer of a Chembio Product to an Affiliate, Net Sales shall be based on the final sale of the Chembio Product to an independent third Person; it being understood that Net Sales shall not be calculated on any Chembio Products actually used by Chembio and/or its Affiliates in internal research and development, clinical trial and regulatory filing, to the extent Chembio and/or its Affiliates do not receive any consideration for such Chembio Products. In the event that Chembio or an Affiliate receives non-monetary consideration for any Chembio Product or otherwise transfers a Chembio Product for consideration that is less than fair market value, Net Sales shall be calculated based on the fair market value of such consideration. "Net Sales" shall also include any and all consideration received by Chembio in consideration for the grant of distribution rights in Chembio Products, which consideration shall include, without limitation, equity in a third Person (the value of which was not otherwise paid for by Chembio), distribution, fees, milestone fees, or other payments, regardless of how characterized. Any non-monetary compensation shall be afforded a net present value as a the time of receipt of such compensation, as calculated by the Parties, acting reasonably and in good faith, for the purpose of determining Net Sales hereunder. Without limiting the generality of the foregoing, consideration received by Chembio or its Affiliates from a distributor of Chembio Products shall include:

- i. the actual sale price of the Chembio Product (i.e., the price charged by Chembio or its Affiliate to the distributor, less the deductions provided for above): and
- ii. any distribution fee or other direct or indirect payments paid by the distributor to Chembio or its Affiliates for the right to distribute any Chembio Product.

**(n)**"**Dollars**" shall mean (and any reference to "\$" herein shall be to) lawful currency of the United States of America.

## 2. Grant.

(a) Adaltis hereby grants to Chembio a non-exclusive licence during the term of this Agreement, to possess and use the Peptides in order to make, have made, use, and sell Chembio Products throughout Chembio's Territory,

namely all countries and territories of the world with the exception of Canada. Chembio shall not have the right to sell or allow its distributors to sell Chembio Products in Canada, with Chembio's label or any other label.

(b)Except as provided in Subsection 2(c), Chembio shall not have the right to extend or sublicence any rights granted hereunder, nor to possess or use the Peptides and/or Patent Rights for any reason other than as specifically granted hereunder in Subsection 2 (a).

(c)Chembio shall have the right to sublicence such rights solely to its Affiliates, if prior approved in writing by Adaltis, on a country-by-country basis. In case Chembio desired to grant a sublicence to any of its Affiliates, which has been previously approved in writing by Adaltis, the respective sublicencee will report separately to Adaltis and pay the royalty due directly to Adaltis.

(d)It is understood that Chembio bears sole and complete responsibility for proper product registration with regulatory authorities within any jurisdiction where it intends to manufacture, sell, distribute or appoint distributors. In obtaining such registration or in any promotion of its own products, Chembio will refrain from referring in any fashion to Adaltis product.

## **3. Supply and Purchase.** During the term of this Agreement,

(a) Adaltis shall supply the Peptides to Chembio on a continuous basis and Chembio shall purchase the Peptides from Adaltis under the terms and conditions set forth herein:

(b)Subject to Subsection 6 (b) and to Section 7 hereof, Chembio shall purchase exclusively from Adaltis its total requirement of Peptides for use in Chembio Products, manufactured by or on behalf of Chembio. The Peptide purchase prices are stated in Exhibit "E" and may vary from time to time as provided for in such Exhibit "E".

(c)The Parties hereto acknowledge that money damages would be an inadequate remedy for any breach of Subsection 3 (b) and that such a breach may cause irreparable harm to the other Party. Therefore, in the event of a breach or threatened breach of this Subsection 3(b), a Party may, in addition to other rights and remedies that may be available to it under this Agreement, apply to any court of competent jurisdiction to obtain equitable and injunctive relief in order to enforce, or prevent any violations of, the provisions of this Subsection 3(b);

## 4. Forecast of Demand/Firm Order.

Within thirty (30) days after the Effective Date, Chembio shall provide Adaltis with its first non-binding annual forecast for Peptides. Subject to Subsection 7 (a) hereof, any order for Peptides hereunder shall be placed by Chembio at least three (3) months in advance of the desired delivery date for such Peptides. Once accepted by Adaltis, any order given hereunder shall become firm and binding on the Parties (an "Order"). The first Order of Peptides shall be accompanied by a rolling forecast for the following six (6) months, to be updated by Chembio on a quarterly basis. All Orders for Peptides shall be in writing and shall be subject to the terms hereof, and may not be altered by any additional or differing terms in Chembio's purchase order or otherwise, without the prior written consent of the Parties.

<u>5. Specifications</u>, <u>Testing Methods and Packaging</u>. The Peptides shall be prepared, tested, and packaged in accordance with the Specifications as set forth in Exhibits "D" (1), (2) and (3).

## 6. Payments and Reporting.

(a)Chembio will pay in full for Orders via wire transfer within forty-five (45) days of shipment by Adaltis. Payment shall be made by Chembio to the bank account designated herein by Adaltis, to wit:

Royal Bank of Canada 3100, Boulevard Le Carrefour Laval (Quebec) Canada H7T 2K7 Bank #: 003 Acct. No. 407-881-2 Transit No.: 02301

Chase Manhattan Bank New York

Aba # : 021000021 Swift No.: ROYCCAT2

or to such other account as may be designated in writing by Adaltis from time to time. All Payments to be made pursuant to this Agreement shall be made by Chembio to Adaltis in US dollars in accordance with the procedures established in this Section 6. Late payments shall bear interest at Prime plus three percent (Prime +3%).

(b)Chembio acknowledges that the price of Peptides is subject to fluctuation and that consequently, the price set in Exhibit "E" may be adjusted from time to time. Any increase to Adaltis in the cost of the Peptides in comparison of such cost at the Effective date will be passed along to Chembio and translates into an equivalent increase in the price per milligram set in Exhibit "E". It is understood that this increase is limited to direct cost increase and shall not include additional profit or administrative charges in favor of Adaltis. Such price adjustment will take effect immediately upon written notice given by Adaltis to Chembio and will apply to any Order placed by Chembio after such notice of price adjustment.

- 1. During the 10 year term of this Agreement, Chembio shall pay to Adaltis a royalty of ten percent (10%) of Net sales realized throughout the Territory.
- 2. The royalty due hereunder shall be payable to Adaltis within sixty (60) days from the end of December and the end of June of each calendar year. Together with each royalty payment Chembio shall submit to Adaltis a written statement indicating for each royalty period the Net Sales of Chembio Products and the royalty payable thereon to Adaltis.
- 3. Chembio shall keep such records as are required to accurately determine under generally accepted accounting principles the Net Sales of Chembio Products and the royalty due to Adaltis under this Agreement. In addition, Chembio shall maintain adequate records enabling the reconciliation of the sales records (in terms of units sold) of Chembio Products to the purchase from Adaltis (in terms of units of Peptides purchases) of the Licenced Products. Such records that relate to the Net Sales of Chembio Products shall be retained by Chembio and shall be made available for reasonable review and/or audit during business hours by Adaltis in accordance with the provisions of Section 8, by an independent certified public accountant appointed by Adaltis and reasonably acceptable to Chembio; for the purposes of verifying Chembio's accounting reports hereunder and determining the correctness of such reports and payments to Adaltis. Said accountant shall protect the confidentiality of Chembio's Information, execute any confidentiality agreement reasonably requested by Chembio, and abide by Chembio's reasonable security regulations while on Chembio premises. Such records need not be retained more than one (1) year after the completion of an audit, nor more than five (5) years from the date of their origin, nor more than one (1) year after the date of termination of this Agreement. Royalty payments not audited within five (5) years shall be conclusively deemed correct and not subject to audit or adjustment.
- 4. All royalties and payments to be made pursuant to this Agreement shall be paid by Chembio to Adaltis in Dollars in accordance with the procedures established in this Section 6. Monetary conversions into US Dollars shall be made at the exchange rate in force on the last business day of the period for which the royalties are being paid as reported by the *Wall Street Journal*, or on another basis mutually agreed upon by the Parties in writing.
- 5. USA withholding taxes (if any) levied on account of royalties accruing under this Agreement shall be deducted from such royalty and shall be paid by Chembio to the proper taxing authority, with proof of payment being sent by Chembio to Adaltis. No other withholding payments for tax purposes or otherwise shall be made by Chembio.

### 7. Delivery.

- (a) All sales of Peptides shall be FOB (Incoterms, ICC ed. 2000) Adaltis' Montreal location, or such alternative site of principal manufacture, located in Canada or the continental United States, as notified to Chembio by Adaltis in writing. Should Adaltis ship Peptides from any site outside the continental United States or Canada, Adaltis shall pay the difference in such shipping costs above and beyond the current shipping costs of the same volume of Peptides from the site of principal manufacture in the continental United States or Canada. Adaltis shall ship any Orders for quantities of Peptides that are less than or equal to twenty milligrams (20mg) within ninety (90) days of Adaltis' acceptance of such Order. Adaltis shall ship any Order of Peptides that are greater than twenty milligrams (20mg) within ninety (90) to one hundred twenty (120) days of Adaltis' acceptance of such Order.
  - 1. If Adaltis cannot deliver any Order in full within the stipulated period, then it shall so notify Chembio and the Parties shall meet to negotiate a mutually satisfactory solution provided that Chembio may elect, if the stipulated delivery period has been exceeded by ten (10) days and if prior written notice is given to Adaltis, to purchase peptides from third Persons, or to use Chembio peptides, in each case, to make up any shortfall between the original, unfulfilled Order and the part of that original Order that was fulfilled for use in the

- Chembio Products. Adaltis shall not bring any infringement action against Chembio for any purchase, manufacture, or use of Chembio or third-party peptides provided that the purchase, manufacture, or use of the peptides is in accordance with this Subsection 7(b).
- 2. Adaltis shall make the shipment of the Peptides in packaging suitable for transportation of products such as the Peptides.

(d)At the time of delivery of the Peptides, Adaltis shall provide Chembio with a certificate of analysis in the form set forth in Exhibit "F" hereto.

**8. Audit.** Chembio shall maintain complete and accurate record to support and document the use of Peptides. Such records shall be retained for a period of at least five (5) years. Adaltis shall have the right to conduct, upon reasonable advance notice and during normal business hours, an audit of the appropriate records of Chembio to verify Chembio's compliance with this Agreement. Said auditors shall protect the confidentiality of Chembio's information. Such audit shall be conducted at Adaltis' cost, unless any such audit indicated an underpayment equaling or exceeding ten percent (10%) of the payments due in respect of any given reporting period under the terms of Section 6, in which case Adaltis' out-of-pocket costs of such inspection, a long with the full amount of the underpayments and interest thereon at an annual rate of Prime plus three percent (Prime+3%), accruing from the date the payment was first due, shall be promptly paid by Chembio to Adaltis; provided however, that if Chembio objects to the results of the audit, the matter shall be resolved in the manner described in Section 25 of this Agreement.

# 1. Inspection and Testing; Records: Recall.

- 2. Each shipment of Peptides shall be subjected to a quality control inspection by Adaltis, as standard and customary for the industry. Adaltis shall number each shipment with an Adaltis lot number that is traceable to raw materials and/or components used in the manufacture of Peptides.
- 3. Upon receipt of the Peptides, Chembio shall inspect the quantity and appearance of said Peptides. Should Chembio find any defect in the appearance of the Peptides and/or quantity of the Peptides between the ordered and the delivered Peptides, Chembio shall notify Adaltis thereof, in writing, within ten (10) days after Chembio's receipt of such Peptides. If Adaltis receives Chembio's notice with regard to a shortage in quantities, weight or with regard to defects in Specifications, Adaltis shall promptly take measures to remedy the situation by, as the case may be, supplementing the initial shipment with sufficient Peptides so as to satisfy that initial order or substituting the non-conforming Peptides with Peptides that meet the Specifications.
- 1. Adaltis shall maintain adequate records of Peptide manufacture by batch and lot, including test and laboratory observation data, and will provide copies of such records to Chembio as requested, as reasonably necessary in connection with any Chembio Product recall.

# 2. Limited Warranty; Indemnification; etc.

- 3. Adaltis warrants that the Peptides delivered to Chembio 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 Adaltis.
- ii. In the event that the Peptides do not conform to such Specifications and such failure does not result from the fault, negligence or wilful misconduct of Chembio or any of its Affiliates or their directors, officers, agents or employees, Adaltis shall replace them immediately upon written request by Chembio, as set forth in Section 9 above. In the event that there is a disagreement between the Parties as to the conformity of the Peptides to the Specifications, a neutral third Person, mutually agreed upon, shall test the Peptides. If the Parties are not able to agree on a neutral third Person within fifteen (15) days, such third Person shall be selected by the presiding judge of the trial court in the jurisdiction selected by the first Party to file an action requesting such selection. The Party whose assertion as to the conformity or non-conformity of the Peptides is not confirmed by such neutral review shall bear the costs of carrying out such review. Chembio shall return the non-conforming Peptides at its own cost, unless, upon review as outlined in the Subsection 10 (a), it is determined that the non-conforming Peptides do not meet Specifications. In such event, in addition to replacing the non-conforming Peptides Adaltis will reimburse Chembio for the costs of returning the non-conforming Peptides.
- iii. Chembio has the expertise and skill in the technical areas with respect to the Chembio Products to make (and has made) its own evaluation of the capabilities, safety, utility and commercial application of the Peptides in the Chembio Products. Accordingly, ADALTIS MAKES NO REPRESENTATION AND EXTENDS NO CONDITION OR WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO THE SUITABILITY OF THE PEPTIDES, FOR USE IN THE CHEMBIO PRODUCTS, OTHER THAN AS SPECIFICALLY PROVIDED IN THE IMMEDIATELY PRECEDING PARAGRAPH; AND EXPRESSLY DISCLAIMS ANY WARRANTIES OF MERCHANTABILITY, SATISFACTORY QUALITY, FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT OF THE INTELLLECTUAL PROPERTY RIGHTS OF THIRD PERSONS AND ANY OTHER IMPLIED WARRANTIES WITH RESPECT TO THE CAPABILITIES SAFETY, UTILITY OR

COMMERCIAL APPLICATION OF THE PEPTIDES AND/OR THE PATENT RIGHTS. Without limiting the generality of the foregoing Adaltis does not warrant that any of the Patent Rights is or will be valid or that manufacture or dealing in the Peptides or the Chembio Products is not or will not in the future constitute an infringement of the proprietary rights of third Persons. Chembio shall not grant any warranty to any other Person that exceeds the warranty for the Peptides that Adaltis grants to Chembio hereunder without indemnifying Adaltis for such additional warranty.

- iv. Chembio shall indemnify and hold Adaltis, its directors, officers, agents or employees, or any of its Affiliates or their directors, officers, agents or employees (collectively, the "Adaltis Parties"; individually, a "Adaltis Party") harmless from any and all liability, damage, loss, cost or expense resulting from any claims or suits brought against any Adaltis Party by any third person which arise solely from Chembio's use of the Peptides and/or Chembio's manufacture, handling or sale of Chembio Products incorporating the Peptides, unless such liability, damage, loss, cost or expense is directly attributable to any fault, negligence, or wilful misconduct of a Adaltis Party or to the failure of the Peptides to conform to Specifications or the warranties made in this Agreement.
- v. In the event that the use of any Peptides in the Chembio Products infringes or would infringe any third Person patent rights, the Party first becoming aware of same shall notify the other and, subject to Subsection 10(c), 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 Peptides, Adaltis shall repurchase from Chembio, at the Chembio' peptide cost, all the Peptides currently in Chembio's stock that have not been used in Chembio Products. Adaltis may then, at its sole discretion, elect to
  - (i) change the Peptides so as to make them non-infringing;
  - (ii) obtain rights to the third Person peptides and make such rights available to Chembio; or
  - (iii) if neither of the foregoing options is commercially feasible, terminate this Agreement.
- 1. In the event that either Party determines that a third Person (other than a permitted licencee, transferee or distributor of either Party) is making, using, or selling a product or process that may infringe a Patent Right, it will promptly notify the other Party in writing.
- 2. Adaltis shall be responsible for, in its sole discretion, obtaining a discontinuance of any infringement or bringing suit against a third Person infringer with respect to any Patent Rights. Notwithstanding anything contained herein to the contrary, Adaltis shall have the right, but not the obligation, to bring such a suit. Adaltis shall bear all the expenses of any such suit brought by it and shall retain any and all recovery and damages therefrom. Chembio agrees to be named as a co-plaintiff if Adaltis brings suit and shall cooperate with Adaltis (with any reasonable, receipted out-of-pocket expenses being reimbursed to Chembio by Adaltis to the extent of such expenses to be previously approved in writing by Adaltis) in any such suit for infringement of a Patent Right brought by Adaltis against a third Person (which shall include providing any necessary assistance and executing any necessary documents), and shall have the right to consult with Adaltis and to participate in and be represented by independent counsel in such litigation at its own expense. Except as otherwise specifically provided herein, Adaltis shall have control over any such suit, and decisions as to settlement, methods and/or terms and conditions for resolving the suit shall be made by Adaltis (after consultation with Chembio, should Chembio be joined as a party to such suit). Adaltis shall incur no liability to Chembio as a consequence of such litigation or any unfavorable decision resulting therefrom. In the event Adaltis chooses not to prosecute an infringement as aforesaid within ninety (90) days after learning of the infringement. Chembio shall have the right to do so. In such event, Adaltis shall cooperate with Chembio (which shall include providing any necessary assistance and executing any necessary documents, with any reasonable, receipted out-ofpocket expenses being reimbursed to Adaltis by Chembio to the extent of such expenses to be previously approved in writing by Chembio) and Chembio shall retain any and all recovery and damages from such suit. No settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the prior written consent of Adaltis.
- 3. With respect to any claim by a Party for indemnification, the Parties expressly agree that the liability of such Party to the other Party shall be limited by this Agreement or otherwise at law or equity to direct damages only and in no event shall a Party be liable for lost profits, cover damages, punitive, exemplary or consequential damages.
- 11. Insurance. The Parties shall each procure and maintain in full force and effect during the Initial Term of this Agreement and any Renewal Term thereto, as defined in Section 13 hereof, a product liability insurance policy with a minimum coverage of five million dollars (\$5,000,000 US) (a "Policy") insuring against liability and claims for injury, death or property damage which arise out of or relate to the manufacture for sale to Chembio of Peptides (in the case of Adaltis) and which arise out of or relate to the manufacture and sale of Chembio Products by Chembio (in the case of Chembio). Proper evidence, in the form of an insurance certificate, clearly indicating terms and conditions of the Policy, shall be sent by each of the Party's ins urer and/or insurance broker, to the other Party. If the Policy of a Party is not renewed nor replaced within 30 days after the expiration or termination of such Policy, the Party whose Policy is not

replaced nor renewed shall communicate, within 15 days after the 30 days previously mentioned, such event to the other Party, who will have the option of immediately terminating this Agreement.

## 12. Confidentiality.

- (a) The Parties acknowledge that, as the result of their performance of this Agreement, they will exchange Information as defined in Section 1 (b) herein. Each Party agrees that it shall hold confidential all such Information, in whatever form and whenever received, and whether or not the subject of any issued or pending patent, copyright or other registration, and shall use the Information solely to perform its obligations under this Agreement. Each party shall not otherwise use in any manner whatsoever or disclose to any third Persons the Information, with the exception of those employees, agents or third Persons who have a need to use the Information perform this Agreement, and then only after receiving a signed confidentiality agreement from said employees, agents or third Persons to keep the Information confidential to the same extent as required of each P arty herein. Each Party shall take reasonable actions to insure that its employees or agents or any third Persons to whom such Information is disclosed do not breach their confidentiality agreements and that the Information is not otherwise used or disclosed in any manner inconsistent with its obligations pursuant to this Section 12. Each Party shall remain ultimately liable for any breach of this Section 12 by any of its employees or agents or third Persons to whom it discloses any Information, including any breach by any such employee, agent or third Person of its signed confidentiality agreement.
- (b) The obligations imposed by this Section 12 shall not apply with respect to any Information received by either Party from the other which (i) was in the receiving Party's possession prior to the execution of this Agreement and was not subject to an existing confidentiality obligation owed to a third Person; (ii) was publicly available prior to the execution of this Agreement or otherwise becomes publicly available thereafter through no fault of the receiving Party; (iii) is disclosed to the receiving Party in good faith by third Person who has the right to make such disclosure and who is not bound to keep such information confidential; (iv) is independently developed by an employee officer or agent of the receiving Party and who, prior to such development, did not have access to and did not receive the Information; provided that the Party claiming indep endent development shall have the burden of establishing such claim by clear and convincing evidence; or (v) the receiving Party is required by a court or other governmental authority of competent jurisdiction to disclose.
- (c) Disclosure of certain of the Information in a publication, such as a patent, or by otherwise placing it in the public domain, shall not relieve either Party of its obligations hereunder with respect to any other portion of the Information not otherwise specifically disclosed in or fairly ascertainable from such publication or disclosure.
- (d) This Section 12 shall survive the expiration or earlier termination of this Agreement and thereafter shall be binding upon the Parties to the maximum extent permitted by applicable law, until such time as the Information falls within one of the exceptions enumerated in Subsection 12 (b).

## 13.Term and Termination.

- a. This Agreement shall commence as of the Effective Date and shall remain in effect for a period of the (10) years thereafter unless earlier terminated by either Party pursuant to this Section 13. This Agreement shall thereafter be renewed automatically for additional terms of 10 years each (the "Renewal Term" or "Terms"), unless either Party gives the other a least ninety (90) days prior written notice of its intent not to renew the Agreement upon the expiration of the Initial Term or any Renewal Term, as the case may be. Each Renewal Term shall be subject to the termination provisions of this Section 13.
- b. Either Party may terminate this Agreement during the Initial Term or any Renewal Term for "cause". Cause shall include, but shall not be limited to (i) a material breach of this Agreement which remains uncorrected for a period of thirty (30) days from the receipt by the breaching Party of written notice of such breach, said notice to contain details of the alleged breach; (ii) the insolvency of either Party, the filing of a voluntary or involuntary petition in bankruptcy or the assignment of substantially all of the assets of either Party for the benefit of its creditors; or (iii) a good faith decision by Chembio that the continued use of the peptides will violate a third Person's patent or other intellectual property rights. Subject to Section 16, Adaltis may, at its sole discretion and upon simple notice, terminate this Agreement upon: (I) the "change of control" of Chembio as the term "control" is defined in Subsection 1 (a) where the change of control is effected between Chembio and a competitor of Adaltis; (II) the sale of all or substantially all of the assets of Chembio where such sale is effected between Chembio and a competitor of Adaltis. For purposes of this Subsection 13 (b), "competitor" shall mean a third Person whose commercial activities consist of the manufacturing, marketing and distribution of infectious disease in-vitro immuno-diagnostic test currently sold by Adaltis.

**14. Effect of Termination.** Upon expiration or termination of this Agreement pursuant to Section 13 hereof, all licences granted herein shall terminate immediately; provided that:

- (a) Chembio may complete the manufacture and distribution of products that have been partially manufactured as of the date of termination;
- (b) Chembio may continue to sell from inventory any products in which the Peptides are incorporated, contained or employed as of the date of termination;
  - (c)Chembio shall return all unused Peptides not required for the purpose of Subsection 14 (a), as well as all copies of Adaltis Information, in whatever form, in Chembio's possession or under its control, including any copies made after receipt of such Information. Adaltis shall refund the purchase price of such unused Peptides to Chembio provided that they have been properly stored by Chembio, are not damaged and have a remaining shelf life equivalent to at least fifty percent (50%) of the shelf life indicated in the Specifications. Chembio may retain one (1) copy of Adaltis Information for its legal advisors for the purpose of determining the extent of its continuing obligations and to complete the manufacture and distribution of any Chembio Products which were partially manufactured at the date of termination;
- 15. Relationship of the Parties. This Agreement shall not be construed to make either Party (or its principals, officers, employees or agents) an agent of or joint venturer with the other Party. Neither Party shall have any right or authority whatsoever to incur any liability, obligation (express or implied) or otherwise act in any manner in the name or on behalf of the other, or to make any promise, warranty or representation binding on the other except as specifically permitted herein.
- **16. Assignment.** Except as otherwise specifically provided for herein, neither Party may assign its rights or delegate its duties hereunder without the express prior written approval of the other Party, and any attempted assignment of rights or delegation of duties in contradiction to this Section 16 shall be void and of no effect. Notwithstanding the foregoing, either Party may, without the consent of the other Party, assign any of its rights or delegate any of its duties pursuant to this Agreement, in whole or in part, to an Affiliate if:
  - a. in connection with the transfer or sale of all or substantially all of its assets related to the division or the subject business relation hereto, or
  - b. in the event of a change in control of the said Party, as the term "control" is defined in Subsection 1(a),

except, in all cases, where such assignment or delegation would be from Chembio to a "competitor" of Adaltis, as such term is defined and qualified in Subsection 13(b) hereof. This Agreement shall be binding upon and inure to the benefit of each Party and its permitted successors and assigns.

#### 17. No Amendment; No Waiver.

- a. This Agreement may not be amended, modified or otherwise changed in any respect whatsoever without the prior written approval of both Parties hereto.
- b. No delay or omission or failure to exercise any right or remedy provided for herein shall be deemed to be a waiver thereof or acquiescence in the event giving rise to such right or remedy, but every such right and remedy may be exercised from time to time and so often as may be deemed expedient by the Parties exercising such right or remedy.
- **18. Headings**. The Section headings herein are for convenience only and shall not be deemed to affect in any way the language of the provisions to which they refer.
- **19. Severability.** In the event that any of the terms of this Agreement are in conflict with any rule or law or statutory provision or otherwise are unenforceable under the laws or regulations of the government or subdivision thereof having jurisdiction over matters related to this Agreement, such terms shall be deemed stricken from this Agreement. Such invalidity or unenforceability, under reserve of Subsection 13 (c), shall not invalidate any of the other terms of this Agreement and this Agreement shall continue in full force and effect.
- **20. Notice.** Any notice or communication given under the provisions of this Agreement shall be made in writing by registered airmail, facsimile (fax) or hand delivery. Such notice shall be deemed given upon reception of a mailing or a facsimile, or when personally delivered in the case of hand delivery. Any notices and communications shall be given as follows:

If to Chembio: Larry Siebert

President & CEO

Chembio Diagnostic Systems, Inc.

3661 Horseblock Road

Medford, NY 11763

If to Adaltis: Paulo Bouça

Corporate VP Business Development Adaltis Inc 10900, Hamon Street Montreal (Quebec), Canada H3M 3A2 Fax: (514) 335-9919

- **21. Entirety.** This Agreement and the Exhibits hereto shall supersede and take the place of all other understandings and agreements if any, between the Parties with respect to the subject matter hereof.
- **22. Force Majeure.** Failure of any party to perform its obligations under this Agreement (except the obligation to make payments when properly due) shall not subject such Party to any liability or place it in breach of any term or condition of this Agreement to the Party if such failure is caused by any cause beyond the reasonable control of such non-performing Party, including without limitation acts of God, fire, explosion, flood, drought, war, riot, sabotage, embargo, strikes or other labor trouble, failure in whole or in part of suppliers to deliver materials, equipment or machinery, interruption of or delay in transportation, a national health emergency or compliance with any order or regulation of any government en tity acting with color of right; provided however, that the Party affected shall promptly notify the other Party for the condition constituting *force majeure* as defined herein and shall exert reasonable efforts to eliminate, cure and overcome any such causes and to resume performance of its obligations with all possible diligence. If a condition constituting *force majeure* as defined herein exists for more than ninety (90) consecutive days, the Parties shall meet to negotiate a mutually satisfactory solution to the problem, if practicable.
- **23. Continuing Obligations**. Termination of this Agreement shall not affect the rights or obligations of any Party that have accrued prior to the effective date of such termination. The provisions of Sections 6 (Payments and Reporting), 10 (Limited Warranty; Indemnification), 11 (Insurance), 12 (Confidentiality), 14 (Effect of Termination), 16 (Assignment) and this Section 23 shall survive termination of this Agreement.
- **24. Governing Law**. Subject to Section 25 hereof, this Agreement shall be governed by and construed in accordance with the laws of the Province of Quebec and the laws of Canada applicable therein.
- 25. Disputes. The Parties shall mutually consult in good faith in an attempt to settle amicably in the spirit of cooperation any and all disputes arising out of or in connection with this Agreement or questions regarding the interpretation of the provisions hereof. Each dispute arising out of or in connection with this Agreement or question regarding the interpretation hereof which cannot be settled amicably within two (2) months from the date of notification of either Party to the other of such dispute or question, which notice shall specify the details of such dispute or question, shall be finally settled by binding arbitration, in English, in accordance with the Rules of the American Arbitration Association, by one (1) arbitrator appointed in accordance with such Rules. If the Parties cannot agree on the arbitrator to be so appointed, each Party shall be entitled to appoint one (1) arbitrator, and the two (2) arbitrators so appointed shall agree upon a third. The arbitrator(s) shall have the technical expertise required to understand and arbitrate the dispute. Such arbitration shall be held in Montreal, Quebec, if initiated by Chembio, and in Medford, New York, if initiated by Adaltis. The costs of any arbitration, including administrative and arbitrators' fees, shall be shared equally by the Parties and each Party shall bear its own costs and attorneys' and witness' fees, provided however, that the prevailing Party, if determined by the arbitrator(s), shall be entitled to an award against the other Party in the amount of the prevailing Party's costs (including arbitration costs) and reasonable attorneys' fees. The arbitration carried out hereunder shall apply to the exclusion of regular legal means, provided that the rights of the Parties in urgent situations in which time is of the essence to obtain proper remedies in courts of Law or equity shall remain unimpaired. There shall be no appeal from the decision or findings of the arbitrator(s), which shall be final and binding upon the Parties and may be entered in any court having proper jurisdiction.
- **26. Language.** The Parties have expressly required that this Agreement, all ancillary documents and all disclosures hereunder shall be in the English language. *Les Parties aux présentes ont expressément demandé que ce contrat ainsi que tout document accessoire y afférant ainsi que toute divulgation de renseignements confidentiels soient rédigés en langue anglaise.*
- **27. Publicity.** Neither Party shall issue any press release or other public announcement relating to this Agreement or any activities related hereto without the prior written consent of the other Party, except where such press release or public announcement may be required by law, in which event the Parties shall promptly co-operate in preparing and drafting such press release or public announcement to meet statutory requirements.
- **28. Counterparts.** This Agreement may be executed in counterparts. Delivery of a signed copy by fax will be deemed equivalent to delivery of a signed original.

IN WITNESS WHEREOF, the Parties have caused as of the day and year first above written.	this Agreement to be executed by their duly authorized representatives
CHEMBIO DIAGNOSTIC SYSTEMS, INC	ADALTIS INC.

By:	By:
Larry Siebert	Paulo Bouça
President & CEO	Corporate VP Business Development

#### LICENSE AND SUPPLY AGREEMENT

This License and Supply Agreement (this "Agreement") is entered into as of February 3<sup>rd</sup>,, 2004 (the "Effective Date") by and between Chembio Diagnostics Systems, Inc., and its Affiliates ("Chembio") a corporation incorporated under the laws of Delaware and having its registered address at 3661 Horseblock Road, Medford, NY 11763, USA and Statens Serum Institut ("SSI"), a governmental enterprise under the laws of the Kingdom of Denmark with offices at 5, Artillerivej, 2300 Copenhagen S, Denmark.

#### RECITALS

WHEREAS, SSI possesses intellectual property rights to and has considerable know-how in the development and production of certain antigens to be used for the diagnosis of human and certain veterinary Tuberculosis;

WHEREAS, SSI is a manufacturer of biologicals and certain recombinant proteins to be used for diagnosis of human and certain veterinary Tuberculosis;

WHEREAS, Chembio wishes to further develop its Lateral Flow Immunoassay for the diagnosis of human and certain veterinary Tuberculosis;

WHEREAS, SSI desires to license certain intellectual property rights and know-how to Chembio, and Chembio is willing to receive and undertakes to utilize such license, for use in the diagnosis of human and certain veterinary Tuberculosis, on the terms and conditions set forth below;

WHEREAS, SSI desires to supply certain antigens to Chembio, and Chembio is willing to receive and undertakes to utilize such antigens for use in the diagnosis of human and certain veterinary Tuberculosis, on the terms and conditions set forth below;

WHEREAS, for reasons of quality assurance of Licensed Products, it is desirable that Chembio purchase said SSI antigens exclusively from SSI for use therein:

WHEREAS, for reasons of quality assurance of Licensed Products, it is essential that SSI manufacture and supply to Chembio alpha-crystallin\_MPT83, for use therein;

NOW, THEREFORE, for and in consideration of the mutual observance of the covenants hereinafter set forth and other good and valuable consideration, the receipt of which is hereby acknowledged, SSI and Chembio agree in good faith as follows:

#### 1.DEFINITIONS

- 1.1. "Affiliate" shall mean any business entity that Controls, is controlled by, or is under common control with another corporation or other business entity. The direct or indirect ownership of at least fifty percent (50%) or, if smaller, the maximum allowed by applicable law, of the voting securities or an interest in the assets, profits or earnings of any such business entity, or the ability to dominate or direct decisions through management or directors or otherwise in any such business entity shall be deemed to constitute "Control" thereof.
- 1.2. "Field" shall mean in vitro diagnosis of Tuberculosis in humans, deer, badgers, and primates using a serological method as the diagnostic assay provided, however, that Field does not include any right by Chembio to undertake any form of composition of matter research or development related to any vaccine use of the Licensed Material known as CFP-10, or any right to undertake any composition of matter modification to CFP-10's nucleic acid sequence or amino acid sequence.
- 1.3. "Governmental Approval" shall mean any approvals, licenses, registrations or authorizations of any inter- or supranational, national, regional, state or local regulatory agency, department, bureau or other government entity, foreign or domestic and CE-marking in the European Union, necessary for the use, development, testing, production, marketing, sale or distribution of the Licensed Materials or Licensed Product in a regulatory jurisdiction.
- 1.4. "SSI Know-How" shall mean all non-patented technical and other practical information, resulting from experience and testing, owned and/or controlled with the right to grant sublicenses, by SSI at any time during the term of this Agreement, that directly relates to the Licensed Material, and/or Licensed Patents, including but not limited to biotechnological, pharmacological, toxicological, clinical, assay, and quality control information regarding the Licensed Material and information necessary for the effective development and commercialisation of Licensed Products.
  - $1.5. ``Licensed Material" shall mean SSI's proprietary hybrids and alpha\_crystallin\_MPT83 as listed in Annex A.$
- 1.6. "Licensed Patents" shall mean (a) the patents and patent applications that are identified in Annex A, and (b) all other existing or future patents and patent applications owned or controlled by SSI, or licensed to SSI, with the right to grant sublicenses, at any time during the term of this Agreement covering the Licensed Material. Included within the definition of Licensed Patents are all continuations, continuations-in-part, divisions, patents of addition, reissues, renewals, extensions or governmental extensions of any of the patents and patent applications included in (a) and (b).
- 1.7. "Licensed Product" shall mean the Lateral Flow Immunoassay diagnostic technology used by Chembio in the Field incorporating the Licensed Material or part of the Licensed Material for serological-based detection of Tuberculosis.
- 1.8. "Net Sales" shall mean the gross amount invoiced by Chembio and its Affiliates for the sale or disposition of a Licensed Product to a Third Party less the following deductions for amounts actually paid, allowed or accrued by Chembio and its Affiliates related to such sale or other disposition:

- (a) normal, customary trade discounts, including volume discounts, credits and rebates and documented allowances and adjustments for rejections, recalls, reasonable or contractually permitted, documented cancellations or returns;
- (b) freight, insurance, sales, use, exercise, value-added and similar taxes or duties imposed on the sale and included in the gross amount charged.

Net Sales shall include any and all pre-approval sales allowed by regulatory authorities, including but not limited to named-patient sales. Sales between or among Chembio and its Affiliates shall be excluded from the computation of Net Sales except where the purchaser is an end user, that is, where there is no further sale or distribution of Licensed Product other than to a patient, but Net Sales shall include any subsequent final sales to a Third Party, other than a patient, by Chembio or its Affiliates.

- 1.9. "Party" or "Parties" shall mean, in the singular Chembio or SSI and in the plural Chembio and SSI.
- 1.10. "Price Index" shall mean the Danish price index titled "Nettoprisindekset" issued by Statistics Denmark or in case issuance ceases a similar Danish index covering price increases of goods and labour.
  - 1.11. "Third Party(ies)" shall mean any party other than a Party to this Agreement or an Affiliate of any of the foregoing.

#### 2.LICENSE GRANT

- 2.1.Subject to the terms and conditions of this Agreement, SSI hereby grants to Chembio a worldwide, non-exclusive license, with no right to sublicense or transfer (except as specifically permitted in Sections 10.1 and 18.3 (c) herein), to the Licensed Patents and SSI Know-How, to use, undertake research in, and develop Licensed Material solely for use thereof in Licensed Product(s) in the Field, and under identical terms, to undertake research into, develop, use, market, sell, supply and otherwise commercialise such Licensed Products; provided that in no event shall the foregoing license grant to Chembio include any right to make or have made Licensed Material except as provided in section 5.1 or as otherwise expressly stated herein, or any right to undertake any form of composition of matter research or development related to any vaccine use of the Diagnostic Antigen known as CFP-10, or any right to undertake any composition of matter modification to CFP-10's nucleic acid sequence or amino acid sequence.
- 2.2.For the sake of clarity and without prejudice to Chembio's undertakings herein regarding payments due to SSI and to the sub-licensing prohibitions above, the grant of the license in Section 2.1 impose no restrictions on Chembio's sale of Licensed Products in the Field.

### 3.Payments and Reports

3.1.Chembio shall, as partial consideration for the license granted above, pay to SSI the following fees in anticipation of, and for the use of the license granted above, all of which payments shall be nonrefundable and non-creditable, except as otherwise expressly stated herein:

a. Fifteen Thousand Euros (EUR 15,000.00), payable upon execution of this Agreement;

b.Annual payments of Ten Thousand Euros (EUR 10,000.00), due and payable on each anniversary of the Effective Date for the duration of the Agreement. Each such annual payment shall be creditable by Chembio against the sum of payments due pursuant to Sections 3.2 and 3.5 only for the applicable year;

- 3.2.As partial consideration for the continued use of the license granted by SSI to Chembio pursuant to this Agreement, Chembio shall pay to SSI six and one-half per cent (6.5%) royalty on all Net Sales of Licensed Products invoiced during each twelve (12) month period.
- 3.3.Chembio shall have the option to have the hybrid and patents listed in Annex B included in the definitions of Licensed Material and Licensed Patents, respectively. Said option expires four (4) months after the Effective Date or from receipt of said hybrid, whichever is longer.
- 3.4.In the event Chembio exercises the option in Section 3.3, the royalty rate set forth in Section 3.2 shall be increased by one and one-fourth per cent point (1.25%).
- 3.5.As partial consideration for the rights and licenses granted herein, Chembio shall also pay SSI royalty payments of 10% of any fees or other revenue ("Distributor Revenue"), in cash or otherwise, received by Chembio from any distributor of Licensed Products, other than revenue from Net Sales, including but not limited to upfront, milestone and annual or other periodic payments. Notwithstanding the preceding sentence, said royalty shall apply only to Distributor Revenue in excess of a one-time, single aggregate threshold of fifty thousand Euros (EUR 50,000.00), which, for the sake of clarity, is not an annual threshold. However said threshold shall not apply to Distributor Revenue from distributors with exclusive distribution rights for Licensed Products in USA, Canada, Europe, Japan, Australia and/or New Zealand, all of which Distributor Revenue shall in its entirety be subject to said 10% royalty.
- 3.6.Royalties payable herein shall be calculated on a calendar quarterly basis and shall be due and payable within forty-five (45) days after the end of such calendar quarter, commencing upon the completion of the first calendar quarter during which the first commercial sale occurs. Royalty of fees received by Chembio from any distributor of Licensed Products shall be payable within fifteen (15) days following receipt by Chembio.
- 3.7.Within twenty (20) days following the end of each calendar quarter during the term of this Agreement, Chembio shall furnish to SSI a written report that includes (a) the identity of the countries in which sales of Licensed Product have been made, (b) the Net Sales of each Licensed Product and the number thereof sold in each such country, and (c) the identity of each distributor of Licensed Products, as well as the amount of Distributor Fees and the total transfer price for supply of Licensed Product paid by each distributor to Chembio during such quarter. Such reports shall be due together with the royalty payments under Section 3.2 for each calendar quarter subsequent to launch of the Licensed Products. Such reports shall be made whether or not Chembio has engaged in any sales of Licensed Product during said quarter. All information provided by Chembio pursuant to this Section 3.5 shall be Conf idential Information and subject to the terms of Section 14 hereto.

3.8.Chembio shall keep full, complete and accurate records and accounts of Net Sales of each Licensed Product and amounts of Licensed Products supplied to distributors hereunder in sufficient detail to enable the royalties payable to SSI to be determined. Upon reasonable notice to Chembio, SSI shall have the right to have an independent certified public accountant audit Chembio's records pertaining to Licensed Products and manufacture and supply of Licensed Product during normal business hours to verify the royalties payable pursuant to this Agreement; provided, however that (a) such audit shall not take place more frequently than once a year, and (b) shall not cover such records for more than the preceding three (3) years. Such audits shall be at SSI's expense unless such audit determines that Chembio has paid SSI less than ninety five percent (95%) of the amount determined to be due for a given time period, in which case such audit shall be at Chembio's expense and Chembio shall pay to SSI the cost of such audit and any shortfall in payments due to SSI within thirty (30) days following SSI's invoice to Chembio thereof. Chembio shall preserve and maintain all such records and accounts required for audit for a period of three (3) years after the calendar year to which such records and accounts apply.

3.9.All payments due hereunder shall be made in Euros by wire transfer of immediately available funds to the following account:

Danske Bank
Holmens Kanal 2-12
DK-1092 Copenhagen K
Swift code: DABADKKK
Account no.: 3001-3119-115507.

or to such other account as SSI may designate from time to time.

- 3.10.Any past due payments under this Agreement shall accrue interest until paid at twelve percent (12%) per annum, or the maximum rate permitted by law, whichever is less. Any payments received from Chembio by SSI shall be applied first to any unpaid, accrued interest and then to the satisfaction of any unpaid principal.
- 3.11.Currency conversions to Euros shall be calculated using an average rate of exchange. This average shall be computed using the rate of exchange quoted by the European Central Bank as of the end of the current month plus the rate of the end of the prior month and dividing by two.
- 3.12.SSI shall pay all Danish taxes levied on account of all payments it received under this Agreement. Except for any withholding tax for which SSI receives a tax credit in the same amount, any withholding taxes imposed upon any payment due by Chembio to SSI shall not reduce the amount of any payment due SSI herein, and all such payments set forth herein are net of any such withholding tax. Provided, however, that if SSI's tax status in the future is changed, such that it by law may deduct any such withholding tax from payment of its own taxes, it shall reimburse Chembio the amount the deduction allowed SSI, subject to documentation of Chembio's payment of said withholding tax.

#### 4. Withdrawal of ESAT6

- 4.1.SSI may withdraw ESAT6 from the Licensed Material for use in the portion of the Field relating to in vitro diagnosis of Tuberculosis in humans (but not deer, badgers and non-human primates) by giving Chembio six (6) month written notice of such withdrawal, provided, however, that ESAT6 being withdrawn from any licenses with any third party in the Field, and SSI not developing its own serological assay containing ESAT6 in the Field.
- 4.2.Notwithstanding any other provision in this Agreement, Chembio shall NOT have the right, and hereby expressly waives any such right, to any compensation, including but not limited to reduced royalty payments, for SSI's withdrawal of ESAT6 from the Licensed Material under Clause 4.1, subject to Chembio's option rights under Section 3.3.
- 4.3.If Chembio at the time of SSI's withdrawal of ESAT6 under Section 4.1 has already exercised the option under Section 3.3 to have the hybrid listed in Annex B included in Licensed Material, the Parties shall in good faith negotiate the terms on which an alternative replacement of ESAT6 can be provided.

### 5. Supply of Licensed Material

- 5.1.For reasons of quality assurance of all Licensed Products, SSI and Chembio agree as follows: for a period of five years from the execution hereof, Chembio shall purchase exclusively from SSI all Licensed Material that Chembio may reasonably require for Chembio's development, production and commercialization of Licensed Products for use in the Field.
- 5.2.Beginning as soon as reasonably possible but in no event later than six (6) months after the Effective Date and within the first five (5) calendar days of each calendar quarter during the Term, Chembio shall provide SSI with a forecast of Chembio's requirements for Licensed Material for each quarter during the twelve (12) month period commencing three (3) months after the date of such forecast (the "Firm Forecast"). Chembio shall simultaneously with each Firm Forecast provide SSI with a forecast of Chembio's requirements for Licensed Material for each of the four (4) consecutive quarters (the "Extended Forecast"), the first of which commences on the first day after the end of period forecasted by the Firm Forecast. By way of example, during the last five days of Q1, Chembio would provide SSI with Firm Forecasts for Q3-Q6 and Extended Forecasts for Q7-Q10.
- 5.3.The amount of Licensed Material forecast for the first three (3) months of each Firm Forecast (the "Ordered Amount"), shall be Chembio's firm and binding order therefore. Chembio may however within one (1) month after each Firm Forecast, by providing SSI with a written notice and by prepaying fifty percent (50%) of the price of the Ordered Amount, defer delivery of said order for up to 3 months. SSI shall, subject to the above mentioned right of deferred delivery, deliver the Licensed Material covered by such purchase order not more than ninety (90) days from receipt of such purchase order from Chembio, except in regard to the first purchase order, whereby delivery must take place not more than (180) days from receipt of said first purchase order; provided, however, if any purchase order exceeds the quantity previously forecasted for the applicable three (3) month period (even if such quantity f alls within production capacities), SSI may at its sole

discretion (but without any obligation to do so) deliver such excess quantity, and in such event SSI shall, subject to the above mentioned right to deferral of delivery, have up to one hundred thirty-five (135) days from the date of receipt of such purchase order to deliver said excess quantity. Furthermore the Ordered Amount shall always be divisible by ten (10) milligram.

- 5.4.Chembio shall purchase not less than sixty-five percent (65%) of the largest quantity of Licensed Material forecast for each of the following nine (9) months of each Firm Forecast. Further Chembio shall purchase not less than forty percent (40%) of the largest quantity of Licensed Material forecast in each Extended Forecast.
  - 5.5.SSI shall use its reasonable commercial efforts to supply Chembio with all of its requirements of Licensed Material.
- 5.6.SSI shall promptly notify Chembio if any order cannot be filled or if SSI believes that delivery will not occur within fifteen (15) days of the specified delivery date. In such case, SSI shall also provide Chembio with the reason for such delay and discuss with Chembio the means for promptly eliminating the delay.
- 5.7.If SSI, subject to the right to deferral of delivery set forth in Section 5.3 of this Agreement, does not supply the Licensed Material to Chembio within two hundred and ten (210) days of receipt of the first purchase order and one hundred and twenty (120) days of receipt of any subsequent purchase order from Chembio, SSI shall pay Chembio liquidated damages equal to one tenth of one percent (0.1%) of the price of the delayed Licensed Material for each day that delivery of the Licensed Material does not occur after said periods, up to a maximum of ten percent (10.0%) of the total price of the delayed Licensed Material. All such liquidated damages are fully creditable against and to be deducted from any additional recovery that Chembio receives under this Agreement arising from or related to said delay.
- 5.8.SSI shall, beginning as soon as reasonably possible, but in no event later than three (3) months prior to Chembio's expected Governmental Approval for commercial sale of the first (1st) Licensed Product as indicated in the annual report according to Section 6.1, and within ninety (90) days of receipt of any Firm Forecast from Chembio, ensure that it maintains a stock of Licensed Material of not less than sixty-five percent (65%) of the amount specified in the Firm Forecast, provided however, that if the stability of the Licensed Material precludes storage (including storage at temperatures below minus seventy (-70) centigrade) for more than one (1) year, SSI and Chembio shall use all reasonable endeavors to ensure that the stock provisions of this clause are met by other mechanisms. Where Chembio orders Licensed Ma terial in volumes exceeding those detailed in the Firm Forecast (the "Excess Volume"), the amount of stock to be held by SSI shall, for a period of three (3) months following the supply of the Excess Volume by SSI, be reduced by the amount of the Excess Volume.
- 5.9.At the time of delivery, SSI shall provide a certificate of analysis in accordance with the specifications in Annex C for each batch comprising such delivery. Licensed Material delivered to Chembio shall be manufactured in accordance with the specifications in Annex C. SSI shall include with each delivery of Licensed Material, solely for Chembio's use in performing quality control analysis, a sample of the Licensed Material delivered.
- 5.10.Chembio may, upon its written documentation to SSI that the delivered Licensed Material do not meet the release specifications in Annex C, return or, if SSI so requests, shall destroy, all Licensed Material delivered by SSI that does not meet the release specifications in Annex C. SSI shall i) bear all shipping costs or costs of destroying Licensed Material pursuant to this Section 5.10, ii) within seven (7) calendar days inform Chembio how and when a substitute delivery will take place, and iii) upon the receipt of the batch for destruction or the certification of the destruction hereof, issue a credit note to Chembio in the amount of the invoiced price of the destroyed or returned batch. Upon the second delivery in one twelve (12) month period by SSI of Licensed Material which does not meet the release specifications in Annex C, the Parties will meet and discuss appropriate measures to secure the supply of Licensed Material to Chembio which comply with the release specifications (including the possibility of giving Chembio priority over any other of SSI's obligations to supply Third Parties with Licensed Material or identifying and securing an alternative supply source). Subject to Sections 5.18 and 5.19, the relief provided by this Section 5.10 shall be the sole and complete remedy available to Chembio with respect to such nonconforming Licensed Material, provided, however, that any direct costs incurred by Chembio as a result of the nonconforming supply shall result in a corresponding diminution of Chembio's payment obligations in this Agreement, but in no event more than 10% of the price of the non-conforming Licensed Material.
- 5.11.The transfer price for all quantities of Licensed Material sold by SSI to Chembio in a bulk format hereunder shall be seventy-five thousand Euros (75,000.00) per gram, or seventy-five Euros (€75) per milligram, which may only be purchased in quantities divisible by ten (10) milligrams.
- 5.12.On each 1 January beginning twelve (12) months after the Effective Date, SSI may increase the transfer price in Section 5.11 for the immediately following twelve (12) month period in an amount not to exceed the increase in the Price Index as of July in the previous year. The price in Section 5.11 is based on the Price Index of July 2002 being 104.8.
- 5.13.If Chembio later requests Licensed Material in an alternative physical form or vehicle or changes the specifications in Annex C, the parties recognize and agree it may be necessary to amend the price in Section 5.11 and the time limits in Sections 5.3 and 5.7 as necessary to reflect all said changes.
- 5.14.Chembio shall carry out all finished packaging of Licensed Material and Licensed Product(s) at its expense, including all packaging and labeling for commercial sales of Licensed Product(s).
- 5.15.Delivery of Licensed Material shall be Ex Works (INCOTERMS 2000), SSI's facility, 5 Artillerivej, 2300 København S, Denmark. Title to and risk for Licensed Material shall pass to Chembio upon delivery to the freight carrier. In the absence of express, written and timely carrier and/or delivery instructions from Chembio, SSI may make such arrangements it deems reasonably appropriate and Chembio agrees to such arrangements.
- 5.16.Chembio shall obtain all necessary import and/or export licenses or permits and for the payment of all import and/or export fees, taxes or duties, etc., in connection with the purchase and/or delivery of Licensed Material hereunder.
- 5.17.The transfer price for Licensed Material supplied by SSI to Chembio hereunder is due and payable net thirty (30) calendar days of date of invoice for the delivery of the Licensed Material by SSI.

5.18. Chembio shall not be obliged to pay for Licensed Material that is returned or destroyed in accordance with Section 5.10. If Chembio has paid for such Licensed Material, SSI shall refund or extend a credit to Chembio for the full amount paid by Chembio for such Licensed Material.

5.19.In the event SSI on three (3) or more occasions during any rolling twelve (12) month period i) fails to supply Chembio with Licensed Material complying with the release specifications in Annex C, or ii) fails to supply complying Licensed Material within the time limits of Section 5.3 of this Agreement Chembio may, at its own cost and without the right of recovery, procure the manufacture and supply of Licensed Material, solely for the use in a Licensed Product, from a Third Party selected by Chembio, until such time as SSI reasonably demonstrates to Chembio that it is capable of supplying Licensed Material to Chembio in a timely manner and in compliance with the release specifications in Annex C.

5.20.Chembio shall in addition to the royalty obligations in Section 3, above, pay a royalty in the amount of ten percent (10.0%) on all amounts invoiced Chembio for the Licensed Material manufactured and supplied by a Third Party during the period in which SSI can not deliver the Licensed Material.

- 5.21.SSI will provide Chembio with all assistance, consents, licenses and documentation reasonably required by Chembio solely for the purpose of enabling Chembio to exercise its rights under section 5.19.
- 5.22.The Parties recognizes that as of the Effective Date the commercially relevant composition of, the technical specifications for and the preferred method of manufacture of the Licensed Material are not known to the Parties. Each Party shall, as soon as reasonably possible, provide the other Party with all such unknown or unavailable information when it becomes known and/or available, and the Parties agree to meet and, as may be necessary to accommodate such change, to renegotiate in good faith and acting reasonably the terms and conditions of this Paragraph 5 if the obligations undertaken by this Paragraph prove unduly burdensome to either Party, <u>provided however</u>, that such burden at the time of execution of this Agreement was not nor should have been foreseeable.
- 5.23.For the sake of clarity, SSI may without restriction and in any Field use alpha\_crystallin\_MPT83 in any format, including but not limited to MPT83 and/or alpha-crystalline as single antigens and/or in fusions with other antigens, for its own purposes and/or in any collaboration with Third Parties in any type of commercialization. Further, Chembio expressly waives all rights to challenge SSI's use and commercialization of the alpha\_crystallin\_MPT83, as described in this section 5.24, including but not limited to waiving its rights based on any purported or actual intellectual property rights and/or know-how.

### 6.Diligence; Performance Obligations.

- **6.1.Commercial Development**. Chembio shall use its commercially reasonable efforts to develop and market Licensed Products within the Field. Chembio shall in good faith use commercially reasonable efforts to keep SSI generally informed of development and marketing plans for Licensed Products. Chembio shall submit an annual written report to SSI that summarizes Chembio's efforts toward development and commercialization of Licensed Products, including but not limited to expected Governmental Approvals. Such report shall be due within ten (10) days of the end of each calendar year until first commercial sale.
- **6.2.Notice of Governmental Approvals.** Within fifteen (15) days following receipt, Chembio shall promptly provide SSI with notice of all Governmental Approvals for commercial sales received by Chembio regarding Licensed Product.
- **6.3.Patents.** SSI shall, at its own expense, use diligent efforts to prepare, file, prosecute and maintain the Licensed Patents in accordance with SSI's standard practice and the judgment of SSI's in-house and/or external patent counsel. SSI shall use all reasonable commercial efforts to pursue a rapid issuance of patents with claims covering the diagnostic use of the Licensed Material in the Field in at least the United States and at least two (2) of the major countries in the European Union.
- **6.4.Marking.** Upon SSI's request, Chembio will include on all labels and other packaging material of the Licensed Product(s) as well as in any of its sales promoting materials, including but not limited to materials displayed in an electronic format, a reference to SSI as the provider of the Licensed Material, the patent numbers of the Licensed Patents in accordance with SSI's reasonable guidelines, and if SSI desires, a potential SSI trademark. Notwithstanding the above Chembio shall in case of change of ownership negotiate with SSI in good faith terms on which a reference to SSI as the provider of the Licensed Material, the patent numbers of the Licensed Patents, and a potential SSI trademark are to be included on all labels and other packaging material of the Licensed Product(s) as well as in any of its sales promoting materials, including b ut not limited to materials displayed in an electronic format.

### 7. Governmental Approvals.

Chembio shall obtain all Government Approvals in any country where Licensed Materials and/or Licensed Product shall be manufactured or sold or otherwise distributed. SSI agrees to provide Chembio, at Chembio's expense, with any assistance reasonably requested by Chembio, in obtaining such Governmental Approvals.

## 8. Publications.

Neither Party shall publish or disclose the terms or existence of this Agreement without the prior written consent of the other Party. Chembio shall not publish or present any scientific information relating to any aspect of the Licensed Materials, including, but not limited to, the development or manufacture of the Licensed Materials, without providing SSI the opportunity for prior review. Chembio shall provide to SSI at least (i) forty-five (45) days prior to each submission for publication of any detailed proposed publication such as manuscripts or other articles and (ii) twenty (20) business days prior to each submission of publication of any proposed limited publication such as abstracts, posters or revised submissions (provided that all revisions must be clearly marked or any such revised submission shall be subject to subsection 8(i)), relating to any aspect of the Licensed Materials and Chembio shall not proceed with such publication or presentation (a) to the extent SSI demonstrates that SSI's Confidential Information would be disclosed and (b) until SSI has had the opportunity to secure any necessary patent protection for a period of no more than ninety (90) days from Chembio's notice. SSI will use its commercially diligent efforts to inform Chembio (x) within thirty (30) days after receipt of scientific information for publication in category (i) whether SSI will use its forty-five (45) days review period, (y) within ten (10) business days

after receipt of scientific information for publication in category (ii) whether SSI will use its twenty (20) business days review period and (z) whether SSI believes that a further period for patent protection will be needed.

#### 9.Ownership of Inventions

- 9.1.All rights, title to and interest in SSI patents or patent applications of or related to the Licensed Material, including but not limited to pat-ents or patent applications licensed by SSI, as well as all SSI Know-How existing at any time, are and shall remain exclusively SSI's.
- 9.2.Any Invention made arising from the Parties joint development of Licensed Products, other than the Inventions the ownership of which is described in Section 9.1 hereof, shall be owned jointly by the Parties, in proportion to the financial, commercial and scientific and technical contribution made to said joint development, provided, however, that scientific and technical contributions must be substantial and quantifiable and must involve a substantial degree of scientific or technical efforts. Neither Party shall have the right to commercially exploit such Inventions without the prior written agreement of the other Party, such agreement to be negotiated in good faith. This Section 9.2 shall survive the expiration or termination of this Agreement for the life of all patents claiming such Inventions, or for ten (10) years in the event a patent never issues, unless the Parties otherwise agree in wr iting.
- 9.3.All rights, title and interests to any improvement made by a Party to the other Party's intellectual property rights, Know-How or Materials, or to any joint Invention, made through the exercise of the licenses granted herein, shall vest exclusively in the improving Party, which shall, however, grant the other Party a non-exclusive license to any said improvement on terms and conditions identical to those in this Agreement. Provided, however, that an improvement must involve substantial and quantifiable scientific or technical effort; otherwise, any said improvement shall vest exclusively in the Party possessing the original intellectual property rights, Know-How, or Materials, or, in the case of a joint Invention, in the Parties jointly, based on the ownership rights set forth in section 9.2.

### 10. Representations and Warranties.

- **10.1.Nontransfer.** Chembio represents and warrants that it will not transfer the Licensed Material, other than as part of the Licensed Products, to any of its Affiliates, or to any Third Party, including but not limited to distributors, without the prior written consent of SSI which consent shall not be unreasonably withheld.
- **10.2.Compliance with Law.** Chembio represents and warrants that all Licensed Material and Licensed Products manufactured by or for Chembio shall be manufactured in accordance with all applicable laws, rules and regulations of the country of manufacture or sale of such Licensed Material or Licensed Products, as applicable. Chembio further represents and warrants that all aspects of the Licensed Products made, used or sold by Chembio, its Affiliates and distributors hereunder shall be in compliance with this Agreement and with all applicable federal, state and local laws and regulations.
- **10.3.No Conflict.** Each Party hereby warrants that it is authorized to enter into this Agreement and that this Agreement does not, to the best of each Party's knowledge, create a conflict with any other right or obligation provided under any other agreement or obligation that a Party has with any Third Party.
- **10.4.Patent and Trademark rights.** SSI hereby warrants that, to the best of its knowledge as of the Effective Date, it has full ownership, title and interests in the Licensed Patents and, as of the Effective Date, is not aware of any pending or threatened claim of infringement that would invalidate, limit, or otherwise impact the validity or enforceability of the Licensed Patents for the intended purposes of the Agreement or which would require additional Patent Rights in order to enter into this Agreement. SSI does not give any warranty regarding the validity or enforceability in any jurisdiction of any SSI trademark.

### 11.Indemnification

- 11.1. Chembio hereby undertakes to indemnify, defend and hold harmless SSI from and against all claims, actions, proceedings, liabilities or losses, and reasonable legal expenses and costs, including but not limited to attorney fees (collectively, "Losses"), arising from or related to (a) any material breach of this Agreement by Chembio, (b) any manufacturing of Licensed Material or Licensed Product by Chembio or its affiliates, or (c) any use, marketing or sales of Licensed Material or Licensed Product; provided, however, that Chembio shall have no obligation to indemnify SSI to the extent that such Losses are the result of SSI's material breach of this Agreement or negligence.
- 11.2.SSI hereby agrees to indemnify, defend and hold harmless Chembio from and against all Losses arising from or related to SSI's material breach of this Agreement or negligence.
- **11.3.Insurance**. Chembio undertakes to maintain, and shall, upon written request, provide evidence of same to SSI, the following insurance or self-insurance necessary to meet its liability obligations under this Agreement and satisfactory to SSI in amounts no less than that specified for each type:
  - (i) general liability insurance with combined limits of not less than Two Million Euros (€2,000,000) per occurrence and Five Million Euros (€5,000,000) aggregate for bodily injury including death and property damage; and
  - (ii) professional liability coverage, including death and bodily injury, for the employees, contractors and agents providing services under this Agreement with limits not less than Two Million Euros (€2,000,000) per occurrence and Five Million Euros (€5,000,000) aggregate; and
  - (iii) Worker's Compensation Insurance in the amount required by law.
- 11.4.Insurance required by subsection 11.3 shall be maintained during the performance of this Agreement and, if on a "claims made" basis, for five (5) years thereafter. There shall be a thirty (30) day notice of cancellation with respect to the insurance coverage required hereunder, and the provision that SSI shall be notified in the event of any cancellation, intention of insurer not to renew or any material change in the insurance contract or coverages afforded. Chembio shall be solely responsible for the payment of any deductible or self-insured retention under any such policy.

#### 12.Limitation of Liability

NOTWITHSTANDING ANY OTHER PROVISION IN THIS AGREEMENT OR AT LAW, INCLUDING BUT NOT LIMITED TO THE CONVENTION FOR THE INTERNATIONAL SALE OF GOODS, NEITHER PARTY SHALL BE LIABLE WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY FOR (i) ANY INCIDENTAL, SPECIAL, INDIRECT, CONSEQUENTIAL OR PUNITIVE DAMAGES, OR LOST PROFITS OR (ii) COST OF PROCUREMENT OF SUBSTITUTE GOODS, TECHNOLOGY OR SERVICES. NEITHER PARTY SHALL HAVE ANY LIABILITY FOR ANY FAILURE OR DELAY DUE TO FORCE MAJEURE EVENTS. THE FOREGOING RESTRICTION SHALL NOT APPLY TO LOSSES AND DAMAGES ARISING FROM AWARDS INVOLVING PAIN AND SUFFERING IN ANY CLAIM FOR DEATH OR BODILY INJURY.

#### 13.Disclaimer of Warranties

WITHOUT PREJUDICE TO SECTION 10.4 SSI HEREBY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES WITH REGARD TO THE LICENSED MATERIAL, THE LICENSED PRODUCTS AND THE LICENSED PATENTS, EXPRESS OR IMPLIED, AND SPECIFICALLY DISCLAIMS ALL OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR USE, AND ALL OTHER STATUTORY WARRANTIES, AS WELL AS ALL WARRANTIES OF PATENTABILITY OR NON-INFRINGEMENT.

### 14. Confidentiality

14.1.Confidential Information. "Confidential Information" shall mean all information, whether patentable or not, including but not limited to all know-how and trade secrets, disclosed by a Party to the other Party in connection with this Agreement, either in writing, orally, electronically or visually, unless the information is expressly designated as non-confidential or that by its nature clearly is not confidential, and provided that if information is disclosed visually or orally, the disclosing party shall, within thirty (30) days of said disclosure, confirm in writing to the other Party the material elements of the disclosure. For the term of this Agreement and five (5) years from the date of expiration or termination, each Party (a) shall treat as confidential all Confidential Information provided by the other Party, (b) shall not use suc h Confidential Information except as expressly permitted under the terms of this Agreement and for the express pur-poses set forth herein, (c) shall implement reasonable procedures to prohibit the disclosure, unauthorized duplication, misuse or removal of such Confidential Information, and (d) shall not disclose such Confidential Information to any Third Party. Without limiting the foregoing, each of the parties undertakes to use at least the same procedures and degree of care to prevent the disclosure of Confidential Information as it uses to prevent the disclosure of its own confidential information of like importance, and in any event to use no less than reasonable procedures and a reasonable degree of care, including but not limited to limiting access to said confidential information to its employees, officers, directors and legal and financial advisors on a strictly need-to-know basis, and to keeping all said information only in secured places.

**14.2.**Exceptions. Notwithstanding the above, neither Party shall have liability to the other with regard to any Confidential Information that:

- (a) was generally known and available to the public domain at the time it was disclosed, or becomes generally known and available to the public domain through no fault of the receiver;
- (b) was known to the receiving Party at the time of disclosure as shown by the written records in existence at the time of disclosure;
- (c) is disclosed with the prior written approval of the disclosing Party;
- (d) becomes known to the receiving Party from a source other than the disclosing Party without breach of this Agreement by the receiving Party and in a manner which is otherwise not in violation of the disclosing Party's rights;
- (e) is developed at any point in time by a Party without any use of any part of the other Party's confidential information; or,
- (f) is disclosed pursuant to the order or requirement of a court, administrative agency, or other governmental body; provided, that the receiving Party shall provide reasonable advance notice to enable the disclosing Party to seek a protective order or otherwise prevent such disclosure.

## 15.Infringement.

15.1.(a) If any patent infringement action is brought against Chembio, its Affiliates or any of their suppliers, distributors, or customers because of actual or anticipated manufacture, use or sale of Licensed Material or a Licensed Product and such action claims that such manufacture, use, or sale infringes the intellectual property rights of a Third Party, Chembio shall promptly notify SSI and send SSI copies of all papers that have been served. SSI shall have the first right to decide and control the defence of such action at its own expense and Chembio shall at all times cooperate with SSI and continue to pay amounts due under Section 3 and 5 hereof during the pendancy of such action and any appeals. All costs and expenses incurred by SSI, including settlement costs, damages assessed against SSI or Chembio, and reasonable attorney fees, shall be paid by SSI, except that Chembio shall reimburse S SI for said costs, damages and attorney fees attributable to Chembio's material breach of this Agreement or negligence.

(b) If SSI fails to agree to defend such infringement action within sixty (60) days of Chembio's notification, Chembio shall have the right, but not the obligation, to defend the action itself. If Chembio does undertake such defence, SSI shall cooperate with Chembio and Chembio shall be entitled to select legal counsel of its choice. All costs and expenses attributable to Chembio's material breach of this Agreement or negligence, including settlement costs, damages assessed against Chembio, and reasonable attorney fees, shall be paid by Chembio. All reasonable costs and expenses incurred by Chembio under this Section 15.1(b) other than costs and expenses attributable to Chembio's material breach of this Agreement or negligence may be offset against the royalties payable to SSI under this Agreement; provided, however, that such offset shall occur on a quarte rly basis; and provided, further that in no event shall SSI receive in any quarter, as a result of such offset, less than fifty percent (50%) of the royalties otherwise payable hereunder for such quarter.

(c) In the event of termination of this Agreement by Chembio pursuant to Section 17.2 for SSI's material breach or pursuant to Section 17.5 for SSI's bankruptcy, any outstanding amounts owed to Chembio under this Article 15 shall be immediately paid in full by SSI upon

the effective date of the termination of this Agreement thereunder. If both SSI and Chembio are joined as defendants in any such action, they shall share said costs and expenses based upon the share of liability attributable to each and any costs and expenses of Chembio determined to be attributable to SSI's liability may be recovered by Chembio in accordance with the offset mechanism set forth in Section 15.1(b).

15.2.Neither Party shall be permitted to settle a legal action within the scope of this Section 15 relating to the licensed Patents without the prior written consent of the other Party, which consent shall not be unreasonably withheld.

### 16.Enforcement.

- 16.1.If during the term of this Agreement, either Party becomes aware of a Third Party infringement or threatened infringement of any Licensed Patents, the following provisions shall apply:
  - (a) The Party having such knowledge shall promptly give notice to the other Party, with all available details.
  - (b) SSI shall have the right, but not the obligation, to bring suit in its name at its own expense to restrain such infringement and to recover profits and damages. Chembio agrees at SSI's request to be joined as a party plaintiff and to cooperate in the prosecution thereof, as is reasonably necessary, at SSI's expense. If SSI decides to undertake such suit, then SSI shall have the sole right to control prosecution and shall retain all proceeds therefrom.
  - (c) If SSI fails to commence a substantive legal action within hundred and twenty (120) days after becoming aware of such infringement (or a shorter period of time, if the legal rules of the jurisdiction in which the Third Party infringement require quicker action) and said legal action would have been within the scope of this Agreement, in the first instance or by notice from Chembio, then Chembio, at any time prior to SSI thereafter filing an action, shall have the right, but not the obligation to take such action in its own name. SSI shall cooperate with Chembio, at Chembio's expense, as is reasonably necessary in any such action brought by Chembio. If Chembio brings legal action, Chembio shall have the sole right to control prosecution and shall retain all proceeds therefrom. Notwithstanding the foregoing, Chembio may commence an action for injunctive relief at any ti me it reasonably believes such an action is necessary to protect its interests, but it shall suspend said action if requested by SSI when SSI has agreed to take action as set forth in section 16.1(b).
  - (d) In the event of a cooperative legal action involving both SSI and Chembio (including as set forth in art. 16.1(b) and a monetary recovery in connection with such action is obtained, such recovery shall be applied in the following priority: (i) to reimburse SSI and Chembio by proportion and up to the extent of their actual out-of-pocket expenses (including reasonable attorney fees) in prosecuting such infringement, (ii) to be shared by the proportion and up to the extent of any damages established, including but not limited to Chembio's lost profits and SSI's lost royalties, and (iii) the balance, if any, to be shared one-half by SSI and one-half by Chembio.

#### 17.Term and Termination.

- 17.1.Term. The term of this Agreement shall be one (1) year after the last to expire of the Licensed Patents.
- **17.2.Termination for Material Breach**. Upon any material breach of this Agreement by either Party, the non-breaching Party may terminate this Agreement upon thirty (30) days written notice to the breaching Party. The notice shall become effective at the end of the thirty (30) day period unless the breaching Party has undertaken substantial measures to cure such breach within such period. For purposes of this Agreement, material breach shall be deemed to include without limitation (a) distribution of Licensed Material other than as a part of Licensed Products (b) failure to pay any of the amounts payable under Section 3 and 5, and (c) failure to comply with the publication obligations under Section 8, including the obligation to provide SSI thirty (30) days prior notice of any such publication.
- **17.3.Termination by Mutual Agreement**. The parties may mutually agree in writing to terminate this Agreement effective ninety (90) days following the date of such written agreement.
  - 17.4.Termination by Chembio. Chembio may terminate this Agreement by giving SSI 48 months' written notice hereof.
- **17.5.Bankruptcy.** Either Party may terminate this Agreement by giving thirty (30) days written notice to the other Party if such other Party (a) files a petition of bankruptcy or has any such petition filed against such other Party; (b) goes into compulsory liquidation; (c) has its business placed, as a result of its financial situation, in the possession of a receiver, a government or a government agency; (d) makes an assignment for the benefit of creditors; (e) is subject to a dissolution or winding up, or (f) if the senior management or board of directors or other governing body of such other Party takes any decision initiating any of the foregoing events.
- **17.6.Effects of Termination**. Neither expiration nor termination shall relieve either Party of its obligations under Sections 3.8 through 3.12, 8 through 16 and 18. Further, Chembio shall make all reports and payments as are required for the final quarter. Upon expiration or termination hereof, at SSI's option, Chembio shall return or destroy, and certify destruction of, any Licensed Material in Chembio's possession or control. Moreover, without prejudice to SSI's other rights herein and at law and equity, immediately upon any event or decision set forth in Section 17.5, all licenses granted herein to Chembio shall terminate, and Chembio undertakes to take all actions necessary to facilitate said termination, to cease the use of any Licensed Patent, SSI Know-How and Licensed Materials, and to transfer possession of these back to SSI.
- **17.7.Change of Ownership**. Chembio shall give written notice to SSI of any likely change of ownership, control or management of Chembio, and in any such case, SSI may terminate this Agreement with immediate effect if a major competitor of SSI appears likely to assume control of or have a substantial influence over, Chembio or its successors.

- **18.1.Independent Contractors.** SSI and Chembio shall be independent contractors and shall not be deemed to be partners, joint venturers or each other's agents, and neither Party shall have the right to act on behalf of the other except as is expressly set forth in this Agreement.
- **18.2.Entire Agreement**; **Amendment**. This Agreement sets forth the entire agreement and understanding between the parties and supersedes all previous agreements, promises, representations, understandings, and negotiations, whether written or oral between the parties with respect to the subject matter hereof. There shall be no amendments or modifications to this Agreement, except by a written document signed by both parties.
- **18.3.** Assignment. Neither this Agreement nor any interest hereunder shall be assignable by either Party without the written consent of the other, provided however that:
  - (a) SSI may assign this Agreement together with those intellectual property rights, including but not limited to Licensed Patents, and that know-how, necessary for the performance of SSI's duties herein, without obtaining Chembio's consent to any corporation or other entity with which SSI may merge or consolidate, and/or to any corporation or other entity to which SSI may transfer all or substantially all of SSI's assets;
  - (b) SSI may freely assign any Licensed Patents, provided, however, that such assignment does not prejudice the rights of Chembio herein;
  - (c) Chembio may assign this Agreement with SSI's prior written consent, which consent will not be unreasonably withheld or delayed. Chembio shall, as regard to this section 18, be deemed to be Chembio Diagnostics Systems, Inc., as set forth in the introductory Paragraph of this Agreement, and any assignment by Chembio to any of its Affiliates shall require SSI's consent, which will not unreasonably withheld or delayed.
  - (d) this Agreement shall annure to and be binding upon the successors to each Party.
- 18.4.SSI is permitted by law to change its legal status to become a limited company in accordance with the Danish Company's Act (APS or A/S) provided, however, that no such change shall alter, amend or affect its obligations and liabilities under the Agreement.
- **18.5.Governing Law**. This Agreement shall be construed and enforced in accordance with the laws of the Kingdom of Denmark, without giving effect to its or any other jurisdiction's principles of conflicts of law.
- **18.6.Dispute Resolution**. Prior to engaging in any formal dispute resolution with respect to any dispute, controversy or claim arising out of or in relation to this Agreement or the breach, termination or invalidity thereof (each, a "Dispute"), the Chief Executive Officers of the respective parties shall attempt for a period not less than sixty (60) days to resolve such Dispute. Any Dispute that cannot be settled amicably by agreement of the parties pursuant to the preceding sentence, the exclusive venue for resolving all said disputes shall be the courts of Copenhagen; provided however, that proceedings may not be instituted until the Party alleging breach of this Agreement by the other Party has given the other Party not less than sixty (60) days notice (or in the case of non-payment pursuant to section 3 and 5 then fourteen (14) days notice) to remedy any alleged breach and the other Party has failed to do so.
- **18.7.Injunctive Relief**. Nothing in this Agreement shall be deemed as preventing either Party form seeking injunctive relief (or any other provisional remedy) from any court having jurisdiction over the Parties and the subject matter of the dispute as necessary to protect either Party's name, proprietary information, trade secrets, know-how or any other proprietary rights. Judgement upon the award may be entered in any court having jurisdiction, or application may be made to such court for judicial acceptance of the award and/or an order of enforcement as the case may be.
- **18.8.Severability.** If any provision of this Agreement is finally held to be invalid, illegal or unenforceable by a court of competent jurisdiction, the validity, legality and enforceability of the remaining provisions shall not be affected or impaired in any way.
- **18.9.Waiver**. Any delay or failure in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of a Party's right to the future enforcement of its rights under this Agreement.
- **18.10.Notice.** Any notice required or permitted by this Agreement to be given to either Party shall be in writing and shall be deemed given when delivered personally, by confirmed telecopy to a fax number designated in writing by the Party to whom notice is given, or by registered, recorded or certified mail, return receipt requested, and addressed to the Party to whom such notice is directed, at:

If to Statens Serum Institut:

Statens Serum Institut Artillerivej 5 2300 København S Denmark Attention: Administrerende Direktør Copy: Virksomhedsjurist Facsimile: +45 3268 3868

If to Chembio:
Chembio Diagnostic Systems, Inc.
3661 Horseblock Road
Medford, NY 11763
Attention: President
Copy: Director of R&D

Facsimile:US:631-924-6033

or at such other address or telecopy number as such Party to whom notice is directed may designate to the other Party in writing.

- **18.11.Force Majeure.** If the performance of this Agreement or any obligations hereunder is prevented, restricted or interfered with by reason of fire or other casualty or accident, strikes or labour disputes, war or other violence, any law, order, proclamation, ordinance, demand or requirement of any government agency, or any other act or condition beyond the control of the Parties hereto, the Party so affected, upon giving prompt notice to the other Party shall be excused from such performance (other than the obligation to pay money) during such prevention, restriction or interference.
- **18.12.Headings**. The section headings appearing in this Agreement are inserted only as a matter of convenience and in no way define, limit, construe or describe the scope or extent of such section or in any way affect such section.
- **18.13.Counterparts.** This Agreement may be signed in counterparts, each of which shall be deemed an original and all of which together shall constitute one instrument.

IN WITNESS WHEREOF, each of the Parties hereto has caused this License and Supply Agreement to be executed by its duly authorized officer as the date first written above.

STATENS SERUM INSTITUT	CHEMBIO DIAGNOSTICS SYSTEMS, INC. by:	
by:		
Nils Strandberg Pedersen, President and CEO	Lawrence A. Siebert President	
by:	by:	
Pia Lading, Executive Vice President Division of Vaccine		

### **CONSENT OF INDEPENDENT ACCOUNTANTS**

We hereby consent to the incorporation by reference in this Registration Statement on Form SB-2 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

June 3, 2004