TRADING SOLUTIONS COM INC
Form SB-2
June 07, 2004

Registration No. 333-

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

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

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

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

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

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

| Title Of Each Class of Securities To Be Registered | Amount To Be Registered | Proposed Maximum Offering Price Per Unit (1) | Proposed Maximum Aggregate Offering Price (1) | Amount Of Registration Fee |
|---|---|---|---|---|
| | | | | |
| 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.

(2) 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.

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.

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

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

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The date of this Prospectus is _____, 2004

**TABLE OF CONTENTS**

**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 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 |
| **Total Liabilities** | 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 Chembio 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 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, 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 payable 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 27th, 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 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 up-front fees and royalties. In addition, if we are unable to obtain these types of licenses, our product development and commercialization efforts may be delayed or precluded.

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, or to manufacture in countries where such patents are in force and then sell into non-patent markets. Since HIV-2 patents are in force in the United States, we may be restricted from manufacturing a rapid HIV-2 test in the United States and selling into other countries, even if there were no HIV-2 patents in those other countries. The license agreement that we have in effect for the use and sale of the Adaltis HIV 1 and 2 peptides that are used in our HIV rapid test does not necessarily insulate us from claims by other parties that we need to obtain a license to other HIV-1 and/or HIV-2 patents. Although we have discussed additional HIV-2 licenses that would be advantageous for 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, possible, should, continue, or similar terms, variations of those te 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% |
| J & S Sandler | 8,287 | 8,287 | 0.00% |
| J.G. Poole | 68,365 | 68,365 | 0.00% |
| Javan Esfandiari | 92,080 | 92,080 | 0.00% |
| Jean-Paul Calamaro | 304,583 | 304,583 | 0.00% |
| Joshua Lifshitz | 132,990 | 132,990 | 0.00% |
| Wellfleet Partners | 183,333 | 183,333 | 0.00% |
| Kaare Kolstad Jr. | 50,589 | 50,589 | 0.00% |
| Karen Keskinen | 31,578 | 31,578 | 0.00% |
| Konstantin Lyashchenko | 10,500 | 10,500 | 0.00% |
| Kurzman Partners, LP | 73,370 | 73,370 | 0.00% |
| Kurt Haendler | 250,955 | 250,955 | 0.00% |
| Lawrence Siebert | 5,205,021 | 500,000 | 4,705,02140.78% |
| 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 | 350,0004.31% |

| | | | |
|---|---|---|---|
| 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% |
| 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% |
| 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 aforementioned 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 College and is a member of the American Institute of Certified Public Accountants.

**Avi Pelossof (41),** Vice President Sales, Marketing and Business Development. Mr. Pelossof joined 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 mana