

CHEMBIO DIAGNOSTICS, INC.  
Form POS AM  
April 26, 2006

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Registration No. 333-125942

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**  
**POST EFFECTIVE AMENDMENT NO. 1 TO**  
**FORM SB-2**  
**REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933**

**Chembio Diagnostics, Inc.**

(Name of small business issuer in its charter)

<b>Nevada</b>	<b>6282</b>	<b>88-0425691</b>
(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**  
**3661 Horseblock Road**  
**Medford, New York 11763**  
**(631) 924-1135**

(Name, address and telephone number of agent for service)

Copy of all communications to:

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**Jon S. Ploetz, Esq.**  
**Patton Boggs LLP**

**1660 Lincoln Street, Suite 1900  
Denver, Colorado 80264  
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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. [ ]

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## CALCULATION OF REGISTRATION FEE

<b>Title Of Each Class of Securities To Be Registered</b>	<b>Number of Units/Shares To Be Registered</b>	<b>Proposed Maximum Offering Price Per Unit (1)</b>	<b>Proposed Maximum Aggregate Offering Price (1)</b>	<b>Amount Of Registration Fee</b>
Common Stock, \$0.01 par value per share (2)	8,158,530	\$.60	\$4,895,118	Previously Paid

- (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 ask prices for the Registrant's common stock as reported on the OTC Bulletin Board on June 15, 2005.
- (2) Represents shares of common stock registered for resale by the holders (the "Selling Stockholders") of shares of 9% Series B Convertible Preferred Stock consisting of (i) 2,353,423 shares of common stock that may be issued to pay semi-annual dividends to the Selling Stockholders, and (ii) 5,805,107 shares of common stock that may be issued to the Selling Stockholders under the anti-dilution provisions of the 9% Series B Convertible Preferred Stock.

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

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**EXPLANATORY NOTE**

Pursuant to Rule 429 promulgated under the Securities Act of 1933, as amended, the prospectus included in this registration statement is a joint prospectus that updates and replaces the prospectus included in the registration statements on Form SB-2 first filed with the Securities and Exchange Commission on June 7, 2004 (Commission File Number 333-116219) and on March 28, 2005 (Commission File Number 333-123600), and also constitutes the prospectus for this registration statement (Commission File Number 333-125942).

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

**SUBJECT TO COMPLETION, DATED APRIL 26, 2006**

**PROSPECTUS**

**CHEMBIO DIAGNOSTICS, INC.**

**47,546,237 SHARES OF COMMON STOCK**

This prospectus relates to the sale by certain stockholders of Chembio Diagnostics, Inc. of up to 47,546,237 shares of our common stock which they own, or which they may at a later date acquire upon the conversion of shares of our 8% series A convertible preferred stock, upon the conversion of shares of our 9% series B convertible preferred stock, upon the exercise of warrants and options to purchase shares of our common stock, or as payments of semi-annual dividends on our 9% series B convertible preferred stock.

Our common stock is quoted on the OTC Bulletin Board under the symbol "CEMI." On April 24, 2006 the closing bid and ask prices for one share of our common stock were \$.86 and \$.91, respectively, as reported by the OTC Bulletin Board website. These over-the-counter quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

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**These securities are speculative and involve a high degree of risk. You should consider carefully the "Risk Factors" beginning on Page 5 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 \_\_\_\_\_, 2006

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## PROSPECTUS SUMMARY

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

### Overview

Chembio Diagnostic Systems Inc. was formed in 1985. Since inception we have been involved in developing, manufacturing, selling and distributing medical diagnostic tests, including rapid tests, for a number of diseases and for pregnancy. On May 5, 2004, Chembio Diagnostic Systems Inc. completed a merger through which it became a wholly-owned subsidiary of Chembio Diagnostics, Inc., formerly known as Trading Solutions.com, Inc. (“Chembio” or the “Company”). As a result of this transaction, the management and business of Chembio Diagnostic Systems Inc. became the management and business of the Company.

### Our Business

We are a developer and manufacturer of rapid diagnostic tests that aid in the detection of infectious diseases. We are currently focused on obtaining Food and Drug Administration (FDA) regulatory approval for, and increasing revenues from, our HIV rapid test products, and we received an approvable letter from the FDA for our HIV rapid test products on April 18, 2006. During 2005 we experienced a significant increase in sales of our HIV rapid test products as a result of a contract we entered into with an organization affiliated with the Brazilian government and as a result of our focused efforts on the African continent. We are engaged in marketing efforts for distribution of our HIV rapid test products in markets outside the United States and are in discussions with a U.S. marketing partner for distribution in the U.S. once we receive final approval from the FDA. We also are focused on marketing efforts for distribution of our Chagas disease rapid test and efforts to complete development of, and proceed to seek regulatory approval for rapid tests for human and veterinary tuberculosis.

Our main products and products under development are summarized as follows:

HIV Rapid Tests: HIV ½ STAT-PAK®, HIV SURE CHECK® and HIV ½ STAT

Chagas Rapid Test: Chagas STAT-PAK

Tuberculosis (TB): Prima TB STAT-PAK and Veterinary products

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

We have a history of losses and we continue to incur operating and net losses. We own no patents though we have non-exclusive licenses to lateral flow patents from Abbott Laboratories, Inc. and to reagents including those that are used in our HIV rapid tests. However, these licenses do not necessarily insulate us from patent challenges by other patent holders. We have recently filed for two lateral flow patents that we believe may insulate us if we can successfully develop products incorporating the patent claims.

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

### The Offering

By means of this prospectus, a number of our stockholders are offering to sell up to 6,288,238 shares of common stock which they own, up to 14,783,600 shares of common stock which they may at a later date acquire upon the conversion of our series A and/or series B preferred stock, up to 19,394,466 shares of common stock which they may at a later date acquire upon the exercise of warrants and/or options, up to 2,353,423 shares of common stock which they may at a later date acquire as dividends payable semi-annually on the series B preferred stock, and up to 5,805,107 shares of common stock which they may at a later date acquire pursuant to the anti-dilution provisions of the series B preferred stock. In this prospectus, we refer to these persons as the selling security holders.

As of March 22, 2006 we had 9,178,764 shares of common stock issued and outstanding, which includes shares offered by this prospectus. The number of outstanding shares of common stock does not give effect to common stock which may be issued pursuant to the conversion of our series A and B preferred stocks and the exercise of options and/or warrants previously issued by Chembio Diagnostics, Inc.



We will not receive any proceeds from the sale of common stock by the selling security holders pursuant to this prospectus. If any of the shares registered are not issued as dividends, or under the anti-dilution provisions, to the holders of the series B preferred stock, we will not sell these shares to third parties and will de-register those shares.

### Summary Financial Data

The following table presents summary historical financial information for the fiscal years ended December 31, 2005 and 2004. The financial statements are set forth beginning on page F-1 of this prospectus, and you should read this information for a more complete understanding of the presentation of this information.

	<u>Year Ended</u> <u>December</u> <u>31, 2005</u>	<u>Year Ended</u> <u>December</u> <u>31, 2004</u>
Revenue	\$ 3,940,730	\$ 3,305,932
Operating Expenses	4,630,133	3,807,447
Net Loss	(3,252,000)	(3,098,891)
Current Assets	2,468,193	1,211,060
<b>Total Assets</b>	<b>3,016,406</b>	<b>1,426,449</b>
Current Liabilities	1,818,474	1,663,196
<b>Total Liabilities</b>	<b>1,963,703</b>	<b>1,950,413</b>
<b>Convertible Redeemable Preferred Stockholders' Equity (Deficit)</b>	<b>n/a</b>	<b>2,427,030</b>
	1,052,703	(2,950,994)

### RISK FACTORS

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

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

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

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

impose its own requirements and can delay or refuse to grant approval or clearance, even though a product has been approved in another country.

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

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

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

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

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

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

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

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

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

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

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

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

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

We received \$331,198 or 8.4% of our revenues in 2005 and \$556,789 or 16.84% of our revenues in 2004 from grant and contract development work in connection with grants from the United States National Institute of Health, as well as from universities and commercial companies related to product development efforts for our tuberculosis, mad cow, and dental bacteria rapid test development work. These revenues have funded some of our personnel and other research and developmental costs and expenses for us. However, if these awards are not funded in their entirety or if new grants and contracts are not awarded in the future, our ability to fund future research and development and implement technological improvements would be diminished which could negatively impact our ability to compete in our industry.

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

Although the Company's revenues and gross margins increased significantly in 2005 as compared to 2004, it has sustained significant operating losses in 2005 and 2004. At December 31, 2005, the Company had a positive stockholders' equity of \$1,052,703 and working capital of \$650,000. The Company believes its resources are sufficient to fund its needs through early 2006 and it is considering alternatives to provide for its capital requirements for the balance of 2006 and beyond in order to continue as a going concern. Its liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenue growth; (2) the extent to which, if any, that revenue growth improves operating cash flows; (3) its investments in research and development, facilities, marketing, regulatory approvals, and other investments it may determine to make, and (4) the investment in capital equipment and the extent to which it improves cash flow through operating efficiencies. There are no assurances that it will be successful in raising sufficient capital.

On March 30, 2006, the Company sold \$1 million of additional Series B preferred stock to a Series B Preferred shareholder pursuant to provisions of the January 2005 Series B 9% Preferred Stock financing agreements. Such provisions were exclusive to said shareholder. The Company is continuing to pursue additional financing opportunities in order to provide for its longer term financing needs.

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

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

regulatory requirements and customs regulations;

cultural and political differences;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Since the inception of Chembio Diagnostic Systems, Inc. in 1985 and through the period ended December 31, 2005, we have incurred net losses. As of December 31, 2005, we have an accumulated deficit of \$(18,868,428). We incurred net losses of \$(3,252,000) and \$(3,098,891) in 2005 and 2004, respectively.

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

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

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

#### **Risks related to our common stock**

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

Our common stock is classified as penny stock. Penny stocks generally are equity securities with a price of less than \$5.00 and trade on the over-the-counter market. As a result, an investor may find it more difficult to dispose of or obtain accurate quotations as to the price of the shares of the common stock being registered in this registration statement. In addition, the "penny stock" rules adopted by the Commission under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), subject the sale of the shares of the common stock to regulations which impose sales

practice requirements on broker-dealers, causing many broker-dealers to not trade penny stocks or to only offer the stocks to sophisticated investors that meet specified net worth or net income criteria identified by the Commission. These regulations contribute to the lack of liquidity of penny stocks.

The average daily trading volume of our common stock on the over-the-counter market was less than 59,000 shares per day over the three months ended March 31, 2006. If limited trading in our stock continues, it may be difficult for investors to sell their shares in the public market at any given time at prevailing prices. Since the certificates of designation creating our series A and series B preferred stock contain restrictions on our ability to declare and pay dividends on our common stock, the lack of liquidity of our common stock could negatively impact the rate of return on your investment.

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

At the time of effectiveness of the registration statement, the number of shares of our common stock eligible to be immediately sold in the market will increase approximately from 180,000 to 40,798,309. If the selling stockholders sell significant amounts of our stock, our stock price could drop. Even a perception by the market that selling stockholders will sell in large amounts after the registration statement is effective could place significant downward pressure on our stock price.

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

On May 5, 2004, we completed three separate private placements in which we issued 151,579.84 shares of our series A preferred stock and warrants to acquire 9,094,801 shares of our common stock at an exercise price of \$.90 per share. The shares of series A preferred stock are convertible into 7,578,985 shares of our common stock. We also issued warrants to purchase 425,000 shares of our common stock at an exercise price of \$.72 per share and warrants to purchase 510,000 shares of common stock at an exercise price of \$1.08 per share to designees of our placement agents. We also issued warrants pursuant to an employment agreement with Mark L. Baum, our former president and former member of our board of directors, to purchase 425,000 shares and 425,000 shares of our common stock, respectively, at exercise prices of \$.60 and \$.90 per share respectively. In connection with the acquisition of Chembio Diagnostic Systems, Inc., we assumed the obligation to issue 690,000 shares of our common stock upon the exercise of warrants, which warrants are exercisable at prices ranging from \$.45 to \$4.00 per share. We also adopted the stock option plan of Chembio Diagnostic Systems Inc. and assumed all of the obligation to issue 704,000 common shares upon the exercise of the options outstanding as of the merger date. On January 28, 2005, we completed a private placement in which we issued 100 shares of our 9% Series B Convertible Preferred Stock, which we refer to as the "Series B Stock," together with warrants to purchase 7,786,960 shares of our common stock. For each \$.61 invested in this private placement, an investor received (a) \$.61 of face amount of Series B Stock, which is convertible into one share of our common stock, and (b) a five-year warrant to acquire .95 of a share of our common stock. Each full share of the Series B Stock was purchased for \$50,000, with fractional shares of Series B Stock being purchased by investments of less than \$50,000. In connection with the January 28, 2005 offering, we also issued to the placement agent Series B Stock in an aggregate amount equal to 5% of the amount of cash proceeds from the private placement, together with accompanying warrants to purchase our common stock. We also issued to the placement agent warrants to purchase 737,712 shares of our common stock. As of March 31, 2006, there were 1,529,750 options issued and outstanding under the stock option plan and 1,470,250 options available for issuance under the stock option plan. As a result, the conversion of the outstanding preferred stock and the exercise of the outstanding warrants and options will result in substantial dilution to the holders of our common stock.

On March 30, 2006, we issued to an investor 20 shares (face amount \$1,000,000) of the Company's series B preferred stock with warrants to purchase a total of 1,557,377 shares of Company's common stock at an exercise price of \$.61 per share for a period of five years. The Company agreed to issue, and the investor agreed to purchase for \$1,000,000, the securities described above pursuant to the terms of a Securities Purchase Agreement dated January 26, 2005 by

and among the Company and various purchasers. This transaction represents the second closing under the Agreement, and was triggered upon the Company's achieving, as of the fourth fiscal quarter of 2005, certain financial milestones. As compensation for services rendered to the Company by Midtown for the second closing, the Company agreed to issued to Midtown two shares (face amount \$100,000) of its Series B Preferred and warrants to purchase a total of 155,738 shares of its Common Stock at an exercise price of \$.061 per share for a period of five years.

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

As of April 15, 2006, our named executive officers, directors and 5% stockholders beneficially owned approximately 32.49% of our voting power. For the foreseeable future, to the extent that our current stockholders vote similarly, they will be able to exercise control over many matters requiring approval by the board of directors or our stockholders. As a result, they will be able to:

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

**USE OF PROCEEDS**

We will not receive proceeds from the sale of shares under this prospectus by the selling security holders. If any of the shares registered are not issued as dividends, or under the anti-dilution provisions, to the holders of the series B preferred stock, we will not sell these shares to third parties and will de-register those shares.

**DILUTION**

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

**SELLING SECURITY HOLDERS**

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

although they are not obligated to do so.

In addition, the holders of the series B preferred stock may sell pursuant to this prospectus up to an aggregate of (i) 2,353,423 shares of common stock which they may at a later date acquire as dividends payable semi-annually on the series B preferred stock, and (ii) 5,805,107 shares of common stock which they may at a later date acquire pursuant to the anti-dilution provisions of the series B preferred stock, as description in section “Description of Securities - Series B Preferred Stock.” These shares are not included in the table below.

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Certain of the individuals listed below received the shares offered hereby in connection with the merger described under the caption "Description of Business - Merger." In connection with the merger, we agreed to prepare and file at our expense, as promptly as practical, and in any event, by June 4, 2004, a registration statement with the Securities and Exchange Commission covering the resale of the shares received in the merger by the individuals listed below. The list of selling security holders also includes Mark L. Baum, who acquired, or has the right to acquire, the shares and warrants indicated next to his name pursuant to an employment agreement dated May 5, 2004 with Chembio Diagnostics, Inc. Also named as selling security holders are designees of H.C. Wainwright & Co., Inc. and WellFleet Partners, Inc., each of which received common stock and warrants to purchase the indicated number of shares of common stock in connection with serving as placement agents in connection with our May 5, 2004 private placement of series A preferred stock, and Patton Boggs LLP, which received 37,319 shares as payment for a past obligation of \$27,989, that we owed. Also included are a total of 25,000 shares and options to acquire 166,250 shares that we issued to non-employee third parties for services performed, together with 375,000 options to purchase shares issued to employees and directors.

Certain of the entities or individuals listed below acquired the shares offered hereby in connection with our May 5, 2004 private placement of series A preferred stock. Pursuant to this private placement, we received \$2.2 million in cash as payment for 73.3333 shares of preferred stock that are convertible into 3,666,664 shares of common stock. We also issued to the investors in the series A preferred stock warrants to acquire 4.4 million shares of common stock at an exercise price of \$.90 per share. Based on the \$2.2 million paid, the purchase price per common share is \$.60, without allocating any portion of the purchase price to the warrants. At the same time as this transaction, a conversion of \$1,009,803 face amount and accrued interest of convertible notes that had been issued in March 2004 occurred. Of this conversion, \$330,696 face amount and interest was converted into 826,741 shares of common for a conversion price, based on the face amount of the notes, of \$.40 per share; and \$679,107 face amount and interest was converted into 33.83682 shares of our series A preferred, together with warrants to purchase 2,030,217 shares of common stock at \$.90 per share. The 33.83682 shares of series A preferred are convertible into 1,691,835 shares of our common stock, which based on the face amount of the notes, represents a purchase price of \$.40 per share of common stock, without allocating any portion of the purchase price to the warrants. Also simultaneously with the other two private placement transactions, we issued 44.40972 shares of our series A preferred stock, convertible into 2,220,486 shares of our common stock, together with warrants to purchase 2,664,584 shares of our common stock at an exercise price of \$.90 per share, in exchange for \$1,332,292 face amount of our debt obligations. Based on the face amount of these obligations, the price per common share is \$.60 per share, without allocating any portion of the purchase price to the warrants. On December 29, 2004 the Company converted \$361,560 of additional debt into 12.05199 shares of series A preferred stock and associated warrants to purchase 723,120 shares of common stock. Also in connection with these three private placements, we agreed to prepare and file at our expense, as promptly as practical, and in any event, by June 4, 2004, a registration statement with the Securities and Exchange Commission covering the resale of the shares of common stock issuable upon conversion of the series A preferred stock and the shares of common stock issuable upon exercise of the warrants. The Company issued 312,773 shares of common stock on May 14, 2005 as payment of dividends on the series A preferred stock. These shares of common stock are not registered with the Securities and Exchange Commission and are not a part of this prospectus.

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

warrants to acquire 388,588 shares of common stock at an exercise price of \$.61 per share. The Company also issued to Midtown Partners & Co., LLC, or its designees, warrants to purchase 737,712 shares of the Company's common stock at an exercise price of \$.80 per share.

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

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

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

- the number of shares of common stock beneficially owned as of April 15, 2006 and prior to the offering contemplated hereby,
- the number of shares of common stock eligible for resale and to be offered by each selling security holder pursuant to this prospectus,
- the number of shares owned by each selling security holder after the offering contemplated hereby assuming that all shares eligible for resale pursuant to this prospectus actually are sold,
- the percentage of shares of common stock beneficially owned by each selling security holder after the offering contemplated hereby, and
- in notes to the table, additional information concerning the selling security holders including any NASD affiliations and any relationships, excluding non-executive employee and other non-material relationships, that a selling security holder had during the past three years with the registrant or any of its predecessors or affiliates.



<b>Selling security holders (C)</b>	<b>Number of Shares of Common Stock Owned Before Offering (A)</b>	<b>Number of Shares To Be Offered (B)</b>	<b>Number of Shares Owned After Offering</b>	<b>Percentage of Shares of Common Stock Owned After Offering</b>
Alchemy, LLC <sup>1</sup>	40,471	40,471	-	0.00%
Alpha Capital AG <sup>2,3</sup>	1,275,819	1,232,000	43,819	0.41%
Bassett, Truman <sup>1</sup>	42,526	42,526	-	0.00%
Baum, Mark L. <sup>2</sup>	1,638,333	1,629,703	8,630	0.08%
Bell, Lon E. <sup>2</sup>	292,234	282,198	10,036	0.10%
Beller, Claudio <sup>2</sup>	150,599	145,582	5,017	0.05%
BioEquity Partners, Inc. <sup>1,4</sup>	109,375	109,375	-	0.00%
Breitbart, Ted <sup>1,5</sup>	18,208	18,208	-	0.00%
Bruce, Richard <sup>1</sup>	125,500	75,500	50,000	0.52%
Calamaro, Jean-Paul <sup>2</sup>	319,617	309,581	10,036	0.10%
CEOcast, Inc.	76,250	76,250	-	0.00%
Chrust, Steve <sup>1</sup>	127,656	127,656	-	0.00%
Clarke, John R. <sup>1,6</sup>	158,400	158,400	-	0.00%
Colby, Russ <sup>1</sup>	12,500	12,500	-	0.00%
Crestview Capital Master, LLC <sup>7</sup>	12,977,272	9,590,162	3,387,110	15.07%
Dabush, Ami <sup>2</sup>	587,718	569,718	18,000	0.18%
Daedalus Consulting, Inc. <sup>8</sup>	35,963	35,963	-	0.00%
Dashefsky, Jeff <sup>1</sup>	12,500	12,500	-	0.00%
Diamond Deecembra <sup>8</sup>	143,853	143,853	-	0.00%
DKR Soundshore Oasis Holding Fund, Ltd. <sup>9</sup>	584,016	537,081	46,935	0.47%
Eckert, Christopher & Lynn <sup>2,10</sup>	193,304	186,666	6,638	0.07%
Engel, Sam <sup>1</sup>	4,118	4,118	-	0.00%
Esfandiari, Javan <sup>1</sup>	254,580	167,080	87,500	0.90%
Falvo, Pete <sup>2</sup>	40,000	40,000	-	0.00%
FAMALOM, LLC <sup>8</sup>	179,817	179,817	-	0.00%
Feldman, Stephen <sup>1</sup>	2,055	2,055	-	0.00%
Fuchs, Ari <sup>2,6</sup>	49,058	49,058	-	0.00%
Ginsberg, Mike <sup>1</sup>	2,375	2,375	-	0.00%
Glass, Marc <sup>1</sup>	20,708	20,708	-	0.00%
	52,875	52,875	-	0.00%

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Goldberg, Jeffrey 1,11				
Greenblatt, Phil <sup>1</sup>	10,347	10,347	-	0.00%
Gregoretti, Gordan	81,146	79,916	1,230	0.01%
Gressel, Daniel <sup>1,12</sup>	462,501	462,501	-	0.00%
Guzikowski, Frank J. <sup>1</sup>	178,114	178,114	-	0.00%
H.C. Wainwright & Co. <sup>1,13</sup>	390,867	390,867	-	0.00%
Haendler, Kurt <sup>1</sup>	439,940	434,288	5,652	0.06%
Haendler, Renata <sup>1</sup>	141,089	138,211	2,878	0.03%
Haendler, Tomas <sup>2,14</sup>	543,610	540,710	2,900	0.03%
Haim, Eduardo <sup>1</sup>	7,115	7,115	-	0.00%
Hamblett, Michael <sup>15</sup>	514,034	498,714	15,320	0.15%
Hanson, Andrew Merz <sup>2,16</sup>	123,559	119,545	4,014	0.04%
Hunt, David <sup>1</sup>	-	-	-	0.00%
Ide, Bruce J. <sup>2,17</sup>	500,071	491,062	9,009	0.09%
Jacob, Sam <sup>1</sup>	10,000	10,000	-	0.00%
Jacoby, Richard A. <sup>2</sup>	483,228	469,545	13,683	0.14%
Joffe, Wendy <sup>2</sup>	37,968	37,222	746	0.01%
Jordan, Bruce <sup>18</sup>	101,187	67,931	33,256	0.35%
JP Turner <sup>1,5</sup>	41,250	41,250	-	0.00%
Keskinen, Karen <sup>1</sup>	1,579	1,579	-	0.00%
Klaus, Elaine <sup>1</sup>	2,242	2,242	-	0.00%
Knasin, Paul and Ellen <sup>2</sup>	157,324	152,307	5,017	0.05%
Koch, Scott F. <sup>1,6</sup>	158,400	158,400	-	0.00%
Kolstad Jr., Kaare <sup>1</sup>	50,589	50,589	-	0.00%
Kreger, Richard <sup>18</sup>	593,693	453,435	140,258	1.39%
Krumholz, Jacob & Arlene	66,869	66,869	-	0.00%
Kurzman Partners, LP <sup>19</sup>	68,654	65,265	3,389	0.04%
Lankenau, Robert <sup>1</sup>	230,400	226,585	3,815	0.04%
Lanouette, Kevin P.	33,366	31,966	1,400	0.01%
Larkin, Richard <sup>2</sup>	198,695	109,189	89,506	0.92%
Lawrence, Colin <sup>1</sup>	7,115	7,115	-	0.00%
Ledowitz, Bill <sup>1</sup>	7,118	7,118	-	0.00%
Lew, Felicia <sup>1</sup>	31,250	31,250	-	0.00%
Lew, Hanka <sup>1</sup>	31,250	31,250	-	0.00%
Lifshitz, Joshua <sup>20</sup>	101,302	98,959	2,343	0.02%
Little Gem Life Sciences Fund LLC <sup>21</sup>	180,037	173,248	6,789	0.07%
Lyashchenko, Konstantin <sup>1</sup>	35,500	10,500	25,000	0.26%
Maloney & Company, LLC	83,419	79,916	3,503	0.04%

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Mayer-Wolf, Mike 1	18,379	18,379	-	0.00%
McCarthy, Michael 1	4,145	4,145	-	0.00%
McGusty, Edwin 1	125,000	125,000	-	0.00%
Metasequoia, LLC 2	38,659	37,332	1,327	0.01%
Midtown Partners & Co., LLC 22	185,708	116,639	69,069	0.71%
Millennium 3 Opportunity Fund, LLC 23	3,320,364	3,196,720	123,644	0.99%
Moran, Sean	24,126	23,360	766	0.01%
MSAS Trust 2	761,255	742,666	18,589	0.19%
Nite Capital, LP	750,781	719,261	31,520	0.31%
Patton Boggs LLP 1	37,319	37,319	-	0.00%
Pelossof, Avi 2	671,487	570,685	100,802	1.02%
Pelossof, Elijior 2	87,669	84,659	3,010	0.03%
Perlmutter, Alan 1	50,000	50,000	-	0.00%
Phillips, Chris 8	88,694	86,264	2,430	0.03%
Phillips, Scott W. 1	14,589	14,589	-	0.00%
Poole, Colin 2	140,014	135,981	4,033	0.04%
Poole, John G. 1	68,365	68,365	-	0.00%
Raker, Gilbert 2	86,381	84,659	1,722	0.02%
Reibman, Spencer 1	18,780	18,780	-	0.00%
Rohan, J. Rory 18	561,726	453,435	108,291	1.09%
Rojas, Zilma 1	15,500	5,500	10,000	0.11%
Ross, Anne 1	63,236	63,236	-	0.00%
Sandler, J & S 1	8,287	8,287	-	0.00%
Sandler, Mark and Lori 2	193,304	186,666	6,638	0.07%
Schnipper, Steve 24	164,448	160,426	4,022	0.04%
Schwartz, Eric 1	5,496	5,496	-	0.00%
Seren, Stanley 1	8,287	8,287	-	0.00%
Shapiro, Alex 1	112,412	112,412	-	0.00%
Siderowf, Richard 2,25	87,840	86,624	1,216	0.01%
Siebert Best, Ellen 2	44,057	43,311	746	0.01%
Siebert, Lawrence 26	6,474,864	1,163,078	5,311,786	38.05%
Sive Paget & Reisel 1	2,055	2,055	-	0.00%
Smith, Robin 1,27	119,883	119,883	-	0.00%
Spatacco, Jr., Anthony J. 28	52,432	51,010	1,422	0.02%
Speer, Sandy 1	95,468	65,468	30,000	0.32%
Spilka, R. Edward 2,29	319,776	313,138	6,638	0.07%
Starboard Capital Markets, LLC 30	9,711	9,604	107	0.00%
Starobin Partners 1,5	110,000	110,000	-	0.00%
	776,244	750,195	26,049	0.26%

Straightline Capital  
Opportunities Fund  
I, LLC <sup>2</sup>

Talesnick, Alan L. <sup>2,31</sup>	246,852	241,088	5,764	0.06%
TCMP3 Partners	333,679	319,671	14,008	0.14%
Thunderbird Global Corporation <sup>2,32</sup>	1,041,823	1,021,750	20,073	0.20%
Total M.I.S., Inc. <sup>2</sup>	579,917	560,000	19,917	0.20%
Tyson, John <sup>2,33</sup>	16,250	16,250	-	0.00%
Vicis Capital Master Fund <sup>2,34</sup>	5,799,178	5,600,000	199,178	1.34%
Wachs, Mark <sup>2</sup>	15,118	14,116	1,002	0.01%
Weiss, Gunther <sup>1</sup>	28,334	28,334	-	0.00%
Westbury Diagnostics, Inc. <sup>2</sup>	149,623	144,485	5,138	0.05%
<b>TOTALS</b>	<b>49,560,043</b>	<b>39,387,707</b>	<b>10,172,336</b>	

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

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

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

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

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

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

[4] Provides marketing consulting services to the Company.

[5] Affiliated with Wellfleet Partners.

[6] Affiliated with HC Wainwright, investment banking services.

- [7] Affiliated with Dillion Capital, a NASD member. Robert Hoyt has ultimate control over Crestview Capital Master, LLC and the shares held by Crestview Capital Master, LLC.
- [8] Affiliated with Midtown Partners & Co., LLC, investment banking services.
- [9] DKR SoundShore Oasis Holding Fund Ltd. (the "Fund") is a master fund in a master-feeder structure. The Fund's investment manager is DKR Oasis Management Company LP (the "Investment Manager"). Pursuant to an investment management agreement among the Fund, the feeder funds and the Investment Manager, the Investment Manager has the authority to do any and all acts on behalf of the Fund, including voting any shares held by the Fund. Mr. Seth Fischer is the managing partner of Oasis Management Holdings LLC, one of the general partners of the Investment Manager. Mr. Fischer has ultimate responsibility for trading with respect to the Fund. Mr. Fischer disclaims beneficial ownership of the shares.
- [10] Christopher Eckert is an employee of Smith Barney.
- [11] Affiliated with Wellfleet Partners and Starobin Partners, investment banking services.
- [12] Former Director of CDS.
- [13] NASD member.
- [14] Former President of CDS and Director.
- [15] Employee of Starboard Capital Markets, LLC, investment banking services.
- [16] Assisted the Company in fundraising.
- [17] Form Director of CDS.
- [18] Employee of Midtown Partners & Co., LLC, investment banking services.
- [19] Affiliated with Needham & Company, investment banking services, until February 4, 2005.
- [20] Except for 26,393 shares, the sale of these shares is registered under Chembio's Registration Statement on Form SB-2 that became effective with the SEC on November 4, 2004. The sale of these shares also is included in this Prospectus so that Chembio can make any future amendments for the Registration Statement of which this Prospectus is a part, together with amendments of the 2004 Registration Statement, in a single joint prospectus.
- [21] Except for 81,582 shares, the sale of these shares is registered under Chembio's Registration Statement on Form SB-2 that became effective

with the SEC on November 4, 2004. The sale of these shares also is included in this Prospectus so that Chembio can make any future amendments for the Registration Statement of which this Prospectus is a part, together with amendments of the 2004 Registration Statement, in a single joint prospectus.

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

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

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

[25] Registered sales representative with RBC Dain Rauscher.

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

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

[28] Assisted the Company in fundraising; employee of Starboard Capital Markets LLC.

[29] Stockholder of Lehman Brothers.

[30] NASD member.

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

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

[33] Provides marketing consulting services.

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



## PLAN OF DISTRIBUTION

Each selling stockholder (the “Selling Stockholders”) of the common stock (the “Common Stock”) of the Company and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their shares of Common Stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. A Selling Stockholder may use any one or more of the following methods when selling shares:

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

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

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

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



The Selling Stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Stockholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the Common Stock. In no event shall any broker-dealer receive fees, commissions and markups which, in the aggregate, would exceed eight percent (8%).

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

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

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

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

## LEGAL PROCEEDINGS

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. Other than as set forth below, we know of no material, existing or pending legal proceedings against us, nor are we involved as a plaintiff in any material proceeding or pending litigation. There are no proceedings in which any of our directors, officers or affiliates, or any registered or beneficial shareholder, is an adverse party or has a material interest to our interest. The outcome of the open unresolved legal proceeding set forth below is presently indeterminable. We do not believe the potential outcome from this legal proceeding will significantly impact our financial position, operations or cash flows.

*Saliva Diagnostic Systems Dispute.* The Company is involved in a patent litigation with Saliva Diagnostic Systems, Inc. (“SDS”), the assignee of a patent related to a method for collecting samples. The Company has requested relief from the court that its Sure Check HIV test does not infringe SDS’s patent, that such patent is invalid, and that it is unenforceable due to inequitable procurement. SDS has answered and counterclaimed, alleging that the Company has

infringed the patent, which the Company has denied. In the years 2001 through 2003, the Company paid royalties to SDS and took several other actions based upon SDS's representations regarding its alleged patent.

In response to the Company's aforementioned request for relief, the Court has decided that it is not yet prepared to rule on the significant issues in the case. The Company does not believe that the Court's decision adversely affects the strength of its position. Accordingly, we are not presently appealing this decision, although we believe we have a meritorious basis for future appeal. The discovery phase of the litigation is proceeding pursuant to a scheduling order and trial is presently expected to convene in late 2006.

**DIRECTORS, EXECUTIVE OFFICERS AND CONTROL PERSONS**

**Lawrence A. Siebert (49)**, President, Chief Executive Officer and Director. Mr. Siebert was appointed President of Chembio Diagnostics, Inc. and a member of our board of directors upon consummation of the merger. Mr. Siebert has been Chairman of Chembio Diagnostic Systems Inc. for approximately 12 years and its President since May 2002. Mr. Siebert's background is in private equity and venture capital investing. From 1982 to 1991, Mr. Siebert was associated with Stanwich Partners, Inc, which during that period invested in middle market manufacturing and distribution companies. From 1992 to 1999, Mr. Siebert was an investment consultant and business broker with Siebert Capital Corp. and Siebert Associates LLC, and was a principal investor in a privately held test and measurement company which was sold in 2002. Mr. Siebert received a JD from Case Western Reserve University School of Law in 1981 and a BA with Distinction in Economics from the University of Connecticut in 1978.

**Richard J. Larkin (49)**, Chief Financial Officer. Mr. Larkin was appointed as Chief Financial Officer of Chembio Diagnostics, Inc. upon consummation of the merger. Mr. Larkin oversees our financial activities and information systems. Mr. Larkin has been the Chief Financial Officer of Chembio Diagnostic Systems Inc. since September 2003. Prior to joining Chembio Diagnostic Systems Inc., Mr. Larkin served as CFO at Visual Technology Group from May 2000 to September 2003, and also led their consultancy program that provided hands-on expertise in all aspects of financial service, including the initial assessment of client financial reporting requirements within an Enterprise Resource Planning (Manufacturing) environment through training and implementation. Prior to joining VTG, he served as CFO at Protex International Corporation from May 1987 to January 2000. Mr. Larkin holds a BBA in Accounting from Dowling College and is a member of the American Institute of Certified Public Accountants.

**Avi Pelossof (43)**, Vice President Sales, Marketing and Business Development. Mr. Pelossof joined Chembio Diagnostic Systems Inc. in 1996 and has been responsible for developing Chembio Diagnostic System's marketing strategy and collaborations. From 1991 to 1996, he was Managing Director and co-founder of The IMS Group, Inc., which provided strategic marketing advisory services to companies involved in Latin American markets including Chembio Diagnostics, Inc. Prior to IMS he was a Citibank Vice President in the International Corporate Finance Group focused on Latin America. Mr. Pelossof received his MBA in finance and international business from New York University in 1986 and a BA with Distinction in economics from the University of Michigan in 1984.

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

**Rick Bruce (51)**, Vice President, Operations. Mr. Bruce was hired in April 2000 as Director of Operations. He is responsible for production, maintenance, inventory, shipping, receiving, and warehouse operations. Prior to joining Chembio Diagnostic Systems Inc., he held director level positions at Wyeth Laboratories from 1984 to 1993. From 1993 to 1998, he held various management positions in the Operations department at Biomerieux. From 1998 to 2000, he held a management position at V.I. Technologies. Mr. Bruce has over 25 years of operations management experience with Fortune 500 companies in the field of in-vitro diagnostics and blood fractionation. Mr. Bruce received his BS in Management from National Louis University in 1997.

**Les Stutzman (54)**, VP of Marketing. In 2005, Mr. Stutzman joined Chembio as Vice President of Marketing to lead the development and launch of rapid tests for veterinary and human TB and other veterinary products. Mr. Stutzman has spent over twenty years in marketing leadership positions within various diagnostics companies. He has held Global Director and Business Development Director positions in Marketing for diagnostic companies including

bioMérieux Inc., (formerly Organon Teknika Corp.), Durham, North Carolina from 1997 to 2002 and TREK Diagnostic Systems, Cleveland, Ohio from 2002 to 2005. Mr. Stutzman received his MBA in Marketing from Duke University Fuqua School of Business in 1988 and his Masters in Microbiology from Wagner College in 1982. Mr. Stutzman is MT (ASCP) SM certified.

**Tom Ippolito (43)**, VP of Regulatory Affairs, QA and QC. Mr. Ippolito joined Chembio in June 2005. He has over twenty years experience with in vitro diagnostics for infectious diseases, protein therapeutics, vaccine development, Process Development, Regulatory Affairs and Quality Management. Over the years, Mr. Ippolito has held Vice President level positions at Biospecific Technologies, Corp. from 2000 - 2005, Director level positions in Quality Assurance, Quality Control, Process Development and Regulatory Affairs at United Biomedical, Inc. from 1987 - 2000. Since 2003, he has been a guest instructor for "drug development process" and "FDA regulations", a BioScience Certificate program at New York State University of Stony Brook.

**Alan Carus, CPA (67)**, Director, Audit Committee chair. Mr. Carus was elected to Chembio's Board of Directors on April 15, 2005. He is a co-founder of LARC Strategic Concepts LLC, a consulting firm dedicated to guiding emerging companies to next stage development. Prior to co-founding LARC Strategic Concepts LLC, Mr. Carus was Senior Vice President of Maritime Overseas Corporation ("MOC") and a senior executive of Overseas Ship holding Group, Inc. ("OSG") from 1981 to 1998 when he retired. MOC was managing agent for OSG, one of the world's largest ship-owners. He was a member of OSG's senior management committee and had senior responsibility in areas relating to administration, accounting, tax, finance, budgets, long-range projections, and human resources. Mr. Carus was involved in numerous acquisitions, debt and equity offerings, complex transaction structuring, and was active in the management of OSG's major investments in the cruise industry and other development stage companies. From 1964 to 1981, he was with Ernst & Young (including predecessors), the last seven years as a partner. Mr. Carus has a B.B.A. from the Baruch School of Business of the City College of New York.

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

**Gerald A. Eppner (66)**, Director. Mr. Eppner was elected to our Board of Directors on March 15, 2005. Mr. Eppner is Counsel in the Corporate and Finance Department of Kaye Scholer where his practice includes matters under the federal securities laws. He has engaged in private law practice in New York City for over 40 years and retired as a partner in Cadwalader, Wickersham & Taft at the end of 2004 and as Senior Counsel to that firm in 2005. Mr. Eppner is Vice Chairman and General Counsel of Emeritus Capital Partners, LLC, a New York City-based capital strategies firm that specializes in large asset-based securitizations and secondary market intermediation of senior life settlement insurance portfolios. He is also a Managing Director of Access Equity Partners, LLC, a New York-and Chicago-based venture capital firm. Prior to coming to New York, Mr. Eppner was an employee of agencies and departments of the United States government.

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

The following table sets forth certain information regarding the beneficial ownership of our common stock by each person or entity known by us to be the beneficial owner of more than 5% of the outstanding shares of common stock, each of our directors and each of our “named executive officers” and all of our directors and executive officers as a group as of April 15, 2006.

<b><u>Name and Address of Beneficial Owner</u></b>	<b><u>Number of Shares Beneficially Owned</u></b>	<b><u>Percent of Class</u></b>
Lawrence Siebert <sup>(1)</sup> 3661 Horseblock Road Medford, NY 11763	2,046,139	22.94%
Avi Pelosof <sup>(2)</sup> 3661 Horseblock Road Medford, NY 11763	599,314	6.76%
Javan Esfandiari <sup>(3)</sup> 3661 Horseblock Road Medford, NY 11763	185,830	2.15%
Richard Bruce <sup>(4)</sup> 3661 Horseblock Road Medford, NY 11763	100,500	1.17%
Richard J. Larkin <sup>(5)</sup> 3661 Horseblock Road Medford, NY 11763	99,513	1.16%
Alan Carus <sup>(6)</sup> 3661 Horseblock Road	51,000	.60%

Medford, NY 11763		
Gary Meller (7)	51,000	.60%
3661 Horseblock Road Medford, NY 11763		
Gerald Eppner (8)	51,000	.60%
3661 Horseblock Road Medford, NY 11763		
All officers and directors as a group <sup>(9)</sup>	3,184,296	32.49%
Mark Baum (10)	1,400,000	14.99%
580 Second Street, Suite 102 Encinitas, CA 92024		
Thunderbird Global Corporation (11)	487,504	5.74%
c/o The Baum Law Firm 580 Second Street, Suite 102 Encinitas, CA 92024		
Daniel Gressel (12)	462,501	5.42%
460 E. 79 <sup>th</sup> Street, Apt. 17B New York, NY 10021		
Tomas Haendler <sup>(13)</sup>	454,720	5.33%
31 Cogswell Lane Stamford, CT 06902		



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

The term “named executive officer” refers to our chief executive officer and each of our other executive officers who received at least \$100,000 of compensation in 2005.

This table does not include convertible securities which, due to contractual restrictions, are not exercisable within 60 days of the date of this prospectus. Specifically, at no time may a holder of shares of series A or series B preferred stock convert shares of the series A or series B preferred stock if the number of shares of common stock to be issued pursuant to such conversion would exceed, when aggregated with all other shares of common stock owned by such holder at such time, the number of shares of common stock which would result in such holder beneficially owning (as determined in accordance with Section 13(d) of the Securities Exchange Act) in excess of either 4.999% or 9.999% of the then issued and outstanding shares of common stock outstanding at such time, unless the holder has provided us with sixty-one (61) days notice that the holder has elected to waive this restriction.

- ( Includes 220,000 shares issuable upon exercise of options exercisable within 60 days and 207,566 warrants. Also 1) does not include 1,937,220 shares issuable upon conversion of series A preferred stock, 2,324,666 shares issuable upon exercise of warrants, 88,971 shares issuable upon conversion of series B preferred stock and 77,868 shares issuable upon exercise of warrants because conversion of any of those shares of series A or series B preferred stock or exercise of those warrants would result in the holder beneficially owning in excess of 4.99% of the then issued and outstanding shares of common stock outstanding at that time.
  - ( Includes 350,000 shares issuable upon exercise of options exercisable within 60 days and 22,555 shares issuable 2) upon exercise of warrants. Does not include 50,000 shares issuable upon exercise of options that are not exercisable within the next 60 days. Also does not include 10,078 shares issuable upon conversion of series A preferred stock and 12,095 shares issuable upon exercise of warrants because conversion of any of those shares of series A preferred stock or exercise of any of those warrants would result in the holder beneficially owning in excess of 4.99% of the then issued and outstanding shares of common stock outstanding at that time.
  - ( Includes 163,750 shares issuable upon exercise of options exercisable within 60 days and 2,007 shares issuable 3) upon exercise of warrants. Does not include 68,750 shares issuable upon exercise of options that are not exercisable within the next 60 days.
  - ( Includes 95,000 shares issuable upon exercise of options exercisable within 60 days and 500 shares issuable upon 4) exercise of warrants. Does not include 25,000 shares issuable upon exercise of options that are not exercisable within the next 60 days
  - ( Includes 137,500 shares issuable upon exercise of options exercisable within 60 days and 250 shares issuable upon 5) exercise of warrants. Does not include 43,750 shares issuable upon exercise of options that are not exercisable within the next 60 days. Also does not include 30,236 shares issuable upon conversion of series A preferred stock and 25,196 shares issuable upon exercise of warrants because conversion of any of those shares of series A preferred stock or exercise of any of those warrants would result in the holder beneficially owning in excess of 4.99% of the then issued and outstanding shares of common stock outstanding at that time.
  - ( Includes 51,000 shares issuable upon exercise of options exercisable within 60 days. Does not include 36,000 6) shares issuable upon exercise of options that are not exercisable within the next 60 days.
  - ( Includes 51,000 shares issuable upon exercise of options exercisable within 60 days. Does not include 36,000 7) shares issuable upon exercise of options that are not exercisable within the next 60 days.
  - ( Includes 51,000 shares issuable upon exercise of options exercisable within 60 days. Does not include 36,000 8) shares issuable upon exercise of options that are not exercisable within the next 60 days.
- ( 9) Includes footnotes (1)-(8).
- (10) Includes 850,000 shares issuable upon exercise of warrants. Does not include 108,333 shares issuable upon conversion of series A preferred stock and 130,000 shares issuable upon exercise of warrants because conversion of any of those shares of series A preferred stock or exercise of those warrants would result in the holder beneficially owning in excess of 4.99% of the then issued and outstanding shares of common stock outstanding at that time.
  - (11) Does not include 251,963 shares issuable upon conversion of series A preferred stock and 302,356 shares issuable upon exercise of warrants because conversion of any of those shares of series A preferred stock or exercise of any of those warrants would result in the holder beneficially owning in excess of 4.99% of the then issued and outstanding shares of common stock outstanding at that time. Gustavo Montilla may be deemed to have voting or investment control over the shares held by Thunderbird Global Corporation.
  - (12) Includes 42,065 shares issuable upon exercise of warrants exercisable within 60 days.

(13) Includes 38,197 shares issuable upon exercise of options exercisable within 60 days. Does not include 35,556 shares issuable upon conversion of series A preferred stock and 53,334 shares issuable upon the exercise of warrants because conversion of any of those shares of series A preferred stock or exercise of any of those warrants would result in the holder beneficially owning in excess of 4.99% of the then issued and outstanding shares of common stock outstanding at that time.

## DESCRIPTION OF SECURITIES

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

### Common stock

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

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

Action Stock Transfer acts as our transfer agent and registrar

### Series A Preferred Stock

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

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

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

change the nature of our business.

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

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

*Conversion.* The series A preferred stock is convertible, at the option of the holders, into shares of common stock at an initial conversion price of \$.60 per share. Based on its original purchase price of \$30,000.00 per share, each share of series A preferred stock is initially convertible into 50,000 shares of common stock. The series A preferred stock is issuable in fractional shares. The series A preferred stock contains adjustment provisions upon the occurrence of stock splits, stock dividends, combinations, reclassifications or similar events of our capital stock. The series A preferred stock also provides for adjustment of the conversion price if the Company sells common stock at a price, or issues a security convertible into common stock with a conversion price, less than the then-current conversion price for the series A preferred stock.

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

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

*Redemption.* In the event of:

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

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

Upon the occurrence of any of the following events:

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

each holder of series A preferred stock has the right to require us to redeem all or a portion of that holder's shares of series A preferred stock at a price per share of series A preferred stock equal to 120% of the then current liquidation preference amount for the series A preferred stock, plus any accrued and unpaid dividends; provided that with respect to some of the triggering events referenced above, we will have the sole option to pay the redemption price in cash or

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

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

## Series B Preferred Stock

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

This prospectus covers 2,353,423 shares of our common stock which represents the number of shares of our common stock that may be issued in payment of three years of dividends on the currently outstanding shares of our series B preferred stock assuming that each share of our series B preferred stock remains issued and outstanding for three years, and that we pay all of the dividends in those three years in shares of our common stock.

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

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

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

*Redemption.* In the event of:

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

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



dividends, plus (iii) all liquidated damages and other amounts due in respect of the series B preferred stock.

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

## DESCRIPTION OF BUSINESS AND ORGANIZATION WITHIN THE LAST FIVE YEARS

### General

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

### HIV Rapid Tests

We continue to believe our revenue growth in 2006 will come primarily from sales of our rapid HIV tests. A large percentage of individuals that are HIV positive worldwide are unaware of their status. Part of the reason for this is that even those that do get tested in public health settings will often not return or call back for their test results when samples have to be sent out to a laboratory which can take at least several days to process. The increased availability, greater efficacy, and reduced costs for anti-retroviral treatments (ARVs) for HIV is also having a tremendous impact on the demand for being tested, as the stigma associated with the disease is lessened and the ability to resume normal activities is substantially improved.

Our SURE CHECK HIV rapid test eliminates the need for a separate sample collection system when used to collect finger-stick whole blood samples. We believe this improves ease of use and safety. Our HIV 1/2 STAT-PAK and HIV 1/2 STAT-PAK Dipstick, like all competitive rapid HIV tests, require that the finger-stick whole blood sample first be transferred to the test device. HIV 1/2 STAT-PAK is value priced and more flexible than SURE CHECK for samples of venous whole blood, plasma and serum as well as finger-stick whole blood. HIV 1/2 STAT-PAK Dipstick is our most economical format and also flexible as to the aforementioned sample types. This product was designed in order to provide a low cost product with performance equal to our other products for resource-constrained markets in the developing world. All three of our HIV tests use a standardized test strip which we developed by using patented materials licensed non-exclusively to us from third parties as well as our own proprietary know-how and trade secrets. All three of our rapid HIV tests are qualitative yes/no tests for the detection of antibodies to HIV 1 & 2.

### Regulatory Status:

The Company has made substantial progress toward FDA approval of its SURE CHECK HIV and HIV 1/2 STAT-PAK products. A pre-approval inspection of its facility was conducted in the third quarter of 2005 and based upon communications with the agency the Company received an "approvable" Pre-Marketing Approval (PMA) application letter from the FDA on April 18, 2006; the Company further expects to complete the full process during the first half of 2006, which would include receipt from the FDA of a waiver under the Clinical Laboratory Improvement Act ("CLIA"). A CLIA waiver is essential in order to market the product into public health clinics and physicians offices where the level of training is less than clinical laboratories and hospitals. The Company is nearing completion of the CLIA waiver studies so it will be in a position to submit its waiver application immediately upon receipt of the PMA license from the FDA.

The Company's HIV products currently qualify under U.S. FDA export regulations to sell, subject to any required approval by the importing country, to customers outside the U.S. To date we have received approval from a number of potential importing countries, although Brazil and Uganda are the only countries in which we have significant sales. Our HIV 1/2 STAT-PAK and HIV 1/2 STAT-PAK Dipstick products were also evaluated by the World Health Organization in 2004 and as a result in 2005 they were qualified for inclusion in the WHO Bulk Procurement Scheme, which is a pre-requisite for these products being eligible for procurements from programs funded by the United Nations and their partners' programs. SURE CHECK HIV and HIV 1/2 STAT-PAK are also eligible for procurements

pursuant to the President's Emergency Plan for AIDS Relief ("PEPFAR") as a result of a "waiver" status granted these products by the United States Agency for International Development.

**Partners Involved in the Product:**

In 2004 we entered into a thirteen-year supply and technology transfer agreement with FIOCRUZ-Bio-Manguinhos, an affiliate of the Ministry of Health of Brazil relating to our HIV 1/2 STAT-PAK product. FIOCRUZ-Bio-Manguinhos will supply this product, which will eventually be produced completely in Brazil, to the Brazilian public health market and potentially other markets in the region.

In September 2005 we were designated as the confirmatory test in Uganda's national rapid testing protocol and through the offices we have established in East Africa and Nigeria, we hope to be selected in more such national testing protocols. In February 2006 our HIV ½ STAT-PAK was designated by the Nigerian Ministry of Health in four out of the eight screening protocols in the Nigerian Interim Rapid Testing Algorithm. At the same time, we are identifying and appointing distributors in these regions, and are engaged with the multitude of stakeholders that are responsible for the delivery of rapid testing and related services in the markets. Our focus is on those African countries that are receiving funding from PEPFAR and other large relief programs.

In January of 2006 we became one of four recommended global suppliers to Former President Clinton's HIV/AIDS Initiative ("CHAI"), and through that we expect to generate revenues in many of the fifty countries that have agreements with CHAI.

For the US market, we are in discussions with potential marketing partners and direct customers in the United States as we near US FDA approval.

### **CHAGAS RAPID TEST**

Chembio has completed development of a rapid test for the detection of antibodies to Chagas Disease. This product, Chagas STAT-PAK, was developed in collaboration with a consortium of leading researchers in Latin America that have granted us an exclusive license to their recombinant antigens. Chagas Disease is endemic only in regions of Latin America yet there are an estimated 16-18 million Chagas Disease cases resulting in approximately 20,000 deaths annually, with an estimated 300,000 new cases each year. It is transmitted by a parasitic bug which lives in cracks and crevices of poor-quality houses usually in rural areas, through blood transfusion or congenitally from infected mother to fetus. There is an effective therapy available to treat the early chronic phase, but it only eliminates the infection if administered to children that are diagnosed with it. Chagas STAT-PAK is the only rapid test for Chagas disease to have performed well in multi-center studies in endemic regions of Latin America.

The Company received, in January of 2006, an order for \$1.2 million to supply its Chagas Disease rapid test to be delivered in the first half of 2006. This procurement is being made by the Pan American Health Organization, headquartered in Washington D.C., which is affiliated with the World Health Organization. The procurement will be used to implement a nationwide Chagas screening program for all children under the age of 10 in endemic regions of Bolivia. The Company is actively looking at developing additional business opportunities for this product in Bolivia, and other markets in Latin America that are impacted by this disease.

Prior to 2005, a majority of our revenues were from the contract manufacture of private label pregnancy tests for regional pharmacies, drug stores and mass merchants in the United States, Europe, Canada, and Central America. However, as a result of pricing pressures, regulatory changes and potential patent litigation in this field, and in order to focus our efforts on rapid HIV tests we sold substantially all of the business related to our private label pregnancy test. We have retained a profit share derived from the sales of these products by the buyer. This has resulted in a substantial reduction of our revenues from these products during 2004 and 2005. The extent to which we will derive a benefit from sales of these products is difficult to estimate because of uncertainties in regulatory changes, product pricing, manufacturing cost changes, and patent litigation.

As described below, we also have other commercially available products, such as rapid tests for Lyme disease and other products, the aggregate of whose revenues are currently not material to us. We also are involved, as described below under "Research and Development," in the development of new products.

### **Lateral Flow Technology**

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

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

We can develop and produce lateral flow tests that are qualitative (reactive/non-reactive), as in the case of our HIV tests, and we can develop semi-quantitative tests, reflecting different concentrations of the target marker(s) using different colored latex test lines for each concentration. We can also develop tests for multiple conditions, using different colored lines. We have developed proprietary techniques that enable us to achieve high levels of sensitivity and specificity [see definition below] in our diagnostic tests using our proprietary latex conjugate and buffer systems. These techniques include the methods we employ in manufacturing and fusing the reagents with the colored latex, or colloidal gold, blocking procedures used to reduce false positives, and methods used in treating the materials used in our tests to obtain maximum stability and resulting longer shelf life. We also have extensive experience with a variety of lateral flow devices, including the sample collection device used in our SURE CHECK HIV rapid test which we believe is easier to use than other finger-stick whole blood rapid tests. SURE CHECK eliminates the need for transferring finger-stick whole blood samples from the fingertip onto a test device, because the collection of the sample is performed within a tubular test chamber that contains the lateral flow test strip. The whole blood sample is absorbed directly onto the test strip through a small opening in one end of the test chamber and an absorbent pad positioned just inside this same end of the test chamber. *Please refer to the section entitled “Legal Proceedings” for a discussion of the legal issues we face with regard to SURE CHECK.*

During 2005 we developed a patent-pending lateral flow platform, which we believe provides several advantages for next generation product development (See “*Intellectual Property*”).

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

## **Target Market**

### **HIV Rapid Tests**

We believe that the prevention and treatment goals that have been established by large programs financed to thwart the spread of HIV will drive the growth and demand for rapid HIV tests geometrically in the coming years. Chembio is one of only two US-based manufacturers of rapid HIV tests and the only one with products that it believes can meet the various demands of the global market.

Based upon an analysis done by the Global Business Coalition of HIV/AIDS, approximately 500 million people will need to be tested with at least one rapid test (also a confirmatory rapid test will be needed in the case of a positive result) over the next three years in order to insure that treatment targets are achieved<sup>35</sup>. This is not just because of the continuing growth in the epidemic, but more importantly, because anti-retroviral treatments are available, affordable and are being funded, so that people actually have a reason to be tested.

Because HIV medicines have become much less expensive and more widely available, unprecedented multi-billion dollar financial commitments are being allocated in each of the next few years. Some of these commitments are being made by the UNAIDS “3 by 5” initiative<sup>36</sup>, The Global Fund<sup>37</sup>, and the U.S. Presidential Emergency Plan for AIDS Relief<sup>38</sup>, which will provide treatment to five million people, and in order to identify these five million people, rapid testing is being implemented on a very large scale. The United States is the largest donor, by far, to these programs. Each of these programs recognizes that a massive scale-up in the use of rapid HIV tests is the only way their treatment goals can hope to be achieved.

<sup>35</sup> [www.businessfightsaids.org/site/pp.asp?c=gwKXJfNVJtF&b=1008825](http://www.businessfightsaids.org/site/pp.asp?c=gwKXJfNVJtF&b=1008825) - Policy Documents/Facilitating Access to Testing

<sup>36</sup> [www.unaids.org/en/treat3millionby2005initiative.asp](http://www.unaids.org/en/treat3millionby2005initiative.asp)

<sup>37</sup> [www.theglobalfund.org/en](http://www.theglobalfund.org/en)

<sup>38</sup> [www.usaid.gov/our\\_work/global\\_health/aids/pepfar.html](http://www.usaid.gov/our_work/global_health/aids/pepfar.html)

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We further believe that the global demand for rapid HIV testing will increase at very high rates well beyond the next few years and for the foreseeable future. As of the end of 2004 (which is the latest data the Company has available to it), there were an estimated 40 million people infected with HIV/AIDS worldwide, of which an estimated 6 million were in need of antiretroviral therapy. The number of people in need of treatment will continue to grow as infection rates increase significantly worldwide, and there is little expectation for an effective vaccine anytime soon. As such, even with relatively low prevalence rates in Asia, UNAIDS estimates that 12 million new infections could occur in that region alone between 2005 and 2010<sup>39</sup>.

FDA approval for two of our rapid HIV tests is anticipated in the first half of 2006, and this will enable us to participate in the U.S. market as well, which is estimated to become at least a \$50 million market during the next few years<sup>40</sup>. The U.S. market opportunity has been developing first in the public health and hospital emergency room segments, and as a result of increased advocacy for routine testing, will likely increase and expand use of this technology into the physician's office, prisons, and other venues. In his State of the Union Address this year, President Bush called on Congress to reform and reauthorize the Ryan White CARE Act, which among other things provides counseling and testing for those in greatest need of HIV/AIDS assistance. The President has also proposed to direct a total of more than \$90 million to the purchase and distribution of rapid HIV test kits, facilitating the testing of more than 3 million additional Americans. Test kits would be distributed in areas of the country with the highest rates of newly discovered HIV cases and the highest suspected rates of undetected cases. We are also in preliminary discussions with a US marketing partner to serve these markets.

Finally, based upon recent pronouncements, we believe that the over the counter market is also likely to open up in the U.S., which would expand the U.S. market very significantly. We are already developing OTC opportunities outside the US, and we will consider adding an oral fluid feature to our product lines as such a feature may offer greater convenience provided there is equal performance when using oral fluid samples.

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

#### **Other Products Under Development.**

Chembio is developing rapid tests for other infectious diseases, particularly rapid tests for human and veterinary tuberculosis.

Tuberculosis ("TB") is the leading killer of people who have AIDS. Chembio's TB products will leverage several years of basic NIH-funded research by Chembio's scientists in TB and, if successfully completed, will result in products applicable to both human and veterinary TB, while also leveraging a marketing and distribution capability which the Company has been developing for its HIV products.

Tuberculosis is also a problem in a number of animal species either because of potential transmission to humans, costs to agricultural production or because of the impact on the cost of the animals themselves. For example, nonhuman primates used in research or in zoos are quite costly, and whole colonies can be lost if transmission is not effectively controlled through routine and accurate diagnosis. Bovine (Cattle) TB can be transmitted from livestock or deer to humans and to other animals. Under rules established by the Animal and Plant Health Inspection Service, a state can lose the right to move cattle across state lines if TB is detected in two or more herds as has recently happened in Texas and Michigan. TB control of meat at slaughterhouses is dependent upon visual inspection. The Company believes that



a rapid test could complement or supplant these visual inspections.

Chembio has already completed development of a rapid lateral-flow test for the detection of TB in Non-Human Primates (PrimaTB STAT-PAK), and has a similar test near completion for multiple host species, including cattle, deer, elephant and other exotic wildlife. The tests can use serum, plasma, whole blood or “meat juice” samples and provide results within 20 minutes. The Company believes, subject to USDA approvals, that commercialization of these products can begin in early 2007.

<sup>39</sup> [www.unaids.org/html/pub/global-reports/bangkok/unaidsglobalreport2004\\_en\\_html.htm](http://www.unaids.org/html/pub/global-reports/bangkok/unaidsglobalreport2004_en_html.htm)

<sup>40</sup> Market research prepared for Chembio

## **Distribution Channels& Marketing Strategy**

Approval from the FDA of our HIV rapid tests will not only permit sales in the U.S. but will also enhance marketing capability in the international markets. HIV 1/2 STAT-PAK and HIV 1/2 STAT-PAK Dipstick were recently made part of the World Health Organization (WHO) 2005 Bulk Procurement Scheme and, together with SURE CHECK HIV, the USAID blanket waiver list. These are both critically important for international sales. The WHO's endorsement is required for virtually all international procurements by governmental and non-governmental organizations. The USAID waiver allows our products to be procured with USAID and CDC (i.e., PEPFAR) funding even without FDA approval which, as mentioned above, is pending.

Our marketing strategy is to:

- Expand our international sales effort and strategic partnerships in the developing world for our global health rapid test products, particularly our HIV and Chagas Disease tests. We are actively engaged in expanding HIV test sales and marketing through our recently established East and West African offices. These offices are headed by seasoned professionals that have extensive marketing and/or public health experience in Africa and are establishing distributor relationships throughout the continent. We also have new collaborations and sales opportunities that we are pursuing in Southeast Asia, China, and South America for our HIV and/or Chagas Disease tests, as well as other new tests that we have under development.
- Launch our rapid HIV tests in the US and Europe. We anticipate FDA approval during the first half of 2006. Our products will be marketed initially in the public health and hospital markets, through our own direct sales people and/or with marketing and distribution partners with whom we are currently in discussion. Once we obtain approval we will move aggressively on approval in Europe.
- Pursue potential OTC marketing in the U.S. and internationally. There is discussion now to allow over-the-counter sale of HIV rapid tests in the U.S. as well as in other markets.
- Launch in 2006 our initial veterinary TB product, Prima TB Stat Pak(TM), within our growing line of veterinary TB tests. We anticipate USDA approval of our initial product, a nonhuman primate TB test, in late 2006. During 2007 we expect to obtain revenues from certain other veterinary TB products, at very favorable margins.

## **Strategic Alliances**

Strategic alliances are a key element in Chembio's business strategy.

**Clinton Foundation HIV/AIDS Initiative** - In January we entered into an agreement with the William J. Clinton Foundation's HIV/AIDS Initiative (CHAI) to be recommended by CHAI to receive the procurements from CHAI partner countries (more than 50 countries in the developing world and also including China, Brazil and India) that choose to access CHAI's suppliers products and their preferred pricing in exchange for their sharing information with CHAI and permitting CHAI to fill gaps that will improve and scale up the country's health care delivery systems. We are one of four companies worldwide (and the only US-based manufacturer) to be recommended by CHAI for sales of HIV rapid tests. While CHAI is not a procurer of the tests per se, it is an increasingly major factor in influencing which tests are to be procured. CHAI also has major agreements with generic HIV ARV manufacturers and manufacturers of viral load and CD-4 monitoring diagnostic tests, and those agreements have been very successful models.

**Brazilian Ministry of Health** - In addition, the Company is committed to securing alliances and technology-transfer agreements with government agencies and commercial entities. For example, Chembio signed, in early 2004, a thirteen year technology transfer, supply and license agreement with Bio-Manguinhos, an affiliate of the Brazilian Ministry of Health (MOH) and the predominant supplier for meeting public health needs in Brazil. Over a three-year period, Chembio will transfer its proprietary technology related to HIV 1/2 STAT-PAK to Bio-Manguinhos in exchange for commitments to purchase at least one million rapid tests. This purchase commitment was met during

2005, though we expect substantial additional procurements prior to the completion of the technology transfer agreement, currently anticipated for early 2007. Thereafter Bio-Manguinhos will have the right to produce its own rapid tests and Chembio will receive royalties for ten years.

**Other Partnerships in Development** - Chembio is applying its Brazilian success to other areas of the world. The Company will endeavor to partner with qualified entities that will assemble and package semi-finished tests produced by Chembio under Chembio's quality control in the U.S. These unique arrangements would create an effective public-private partnership with local governments and ensure the availability of rapid HIV tests. This will foster self-reliance in these countries, create local jobs and contribute to their economic and technological growth.

## Competition

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

Industry competition in general is based on the following:

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

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

Our ability to develop and market other products is in large measure dependent on our having additional resources and/or collaborative relationships. Some of our product development efforts have been funded on a project or milestone basis. We believe that our proprietary know-how in lateral flow technology is instrumental in our obtaining the collaborations we have and that we continue to pursue.

Prior to 2005, we had very limited experience with regard to obtaining FDA or other required regulatory approvals, and no experience with obtaining pre-marketing approval of a biologic product such as HIV. See "Governmental Regulation" for definition of pre-marketing approval. For this reason, during 2004 and 2005 we hired employees and consultants that collectively have that experience from other companies. We believe this has been critical in our progress toward obtaining these approvals during the last year and in ensuring that we manufacture our products in accordance with FDA, USDA and other regulatory requirements.

Our access to capital is much less than that of several of our competitors, and this is a competitive disadvantage. We believe however that our access to capital may increase as we get closer to FDA approval of our rapid HIV tests and/or as we complete the development of, and the requisite regulatory approvals related to, our other products, including those that we have under development. ( See Management's Discussion And Analysis Of Financial Condition And Results Of Operations - *Overview* and in particular the last paragraph)

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



Competitive factors specifically related to our HIV tests are product quality, price and ease of use. Product quality for an HIV rapid test primarily means accuracy (sensitivity and specificity), early detection of cases, time elapsed between testing and confirmation of results, and product shelf life. We believe that our product offerings and business model position us well to compete effectively and win a meaningful share of this expanding market.

The leading products in the international market are UniGold(R), produced by Trinity Biotech in Ireland, and Determine(R), produced by Abbott Diagnostics in Tokyo. The Abbott Determine business was sold to Inverness Medical Innovations last year, although Abbott retained the distribution rights to the Determine product for approximately three years. Determine and UniGold have well established presences in many of the developing world markets, often as the screening and confirmatory tests, respectively. Inverness' Organics subsidiary in Israel has a rapid test, Double Check Gold, and this is one of the other three products recommended by CHAI; the other two companies whose products were selected by CHAI are based in India and China, respectively, and they have not yet established apparent marketing efforts outside their countries, although they are qualified by the WHO. In the developed world, particularly the United States, our competitors are Orasure Technologies with OraQuick(R), and, to a much lesser degree Trinity with its UniGold(R) product, both of which are FDA-approved, CLIA-waived products. We do not believe Inverness plans to submit either the Determine or the Organics product to the FDA.

We are targeting the developing world markets that are being funded by PEPFAR and The Global Fund where Determine and UniGold are the established tests. However, neither one of those products contains a true IgG control. This means that the control line does not confirm that the test was run properly with the patient sample; it only confirms that the buffer solution was applied. Thus the appearance of the control line in these tests does not necessarily mean that the test was validly performed, so it may not be a true non-reactive or negative result, and this can lead to potential false negative results.

Orasure has been focusing on building its brand and market share in the US market, and successfully so; its developing world sales are not significant as we believe its product is not suitable and not cost competitive to participate in the international market. Orasure has been successful in bringing attention to the need and availability of rapid HIV testing in the United States. Its main advantage is the fact that its test can be used with oral fluid samples, though its FDA approved sensitivity is 99.3% with these samples. OraQuick is not approved for use with serum samples which may limit its marketability in certain settings.

Chembio's HIV products' shelf life is 24 months, which is double that of UniGold and four times that of Orasure's product. We expect that our products will be approved by the FDA for finger-stick whole blood, venous whole blood, serum, and plasma. Our Sure Check format is extremely convenient, easier to use than OraQuick on finger-stick whole blood sample, much more cost competitive, and provides a safe, closed system. We believe that having high level executives in the field in East and West Africa that are engaged with public health officials, NGOs, and other organizations provides us with a competitive advantage. None of the competitors to the best of our knowledge has actually done a technology transfer which we can now replicate in markets of our choosing.

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

## **Research and Development**

We are focusing our research and development efforts on new rapid tests that will leverage our expertise and sales channels. Our research and development activities have been in three disease areas: HIV, Human and Veterinary

Tuberculosis, and Neglected Diseases such as Chagas Disease (**See section entitled *General***).

**HIV (See section entitled *General*)**

Our HIV development efforts are on developing different specialty next generation rapid tests such as tests for accurately screening newborns and confirmatory tests. Prototypes have been developed using our patent-pending lateral flow technology (See *Intellectual Property*).

**Tuberculosis**

Our tuberculosis rapid tests for humans are being designed to significantly increase the accuracy of existing tuberculosis screening methods and technologies. Our initial tuberculosis test was developed pursuant to Phase I and II Small Business Innovative Research grants from the National Institute of Health from 1998 until 2002, and our current test, TB STAT-PAK II, was completed in 2003. This test was evaluated by the World Health Organization in 2005 alongside more than fifteen other tests from various manufacturers, and although it was among the best performers, its sensitivity and specificity were not high enough as compared to the benchmarks employed to result in a recommendation by the WHO to switch from the current methodologies to our test or to any of the other tests in this evaluation.

In addition to our research and development efforts for tuberculosis tests for humans, we have developed a test for detecting active pulmonary tuberculosis in non-human primates (monkeys). We submitted this product for approval to the United States Department of Agriculture during the first quarter of 2005, and we expect to obtain approval of this product during the latter part of 2006. We are also engaged in collaborations related to the detection of active pulmonary tuberculosis in other animals as we can leverage our current technology for additional species. We do not anticipate any material revenues from these efforts during 2006.

During 2005 and 2004, \$1,364,898 and \$1,508,849, respectively, was spent on research and development activities. A significant portion of these expenditures have been on our human and non-human primate tuberculosis product development efforts.

### **Employees**

At December 31, 2005, we employed 64 people, including 62 full-time employees. In May 2004, we entered into employment agreements with Lawrence Siebert, President and Chairman, Avi Pelossof, VP Sales, Marketing and Business Development, and Javan Esfandiari, Director of research and development.

### **Governmental Regulation**

The Company's existing and proposed diagnostic products are regulated by the U.S. Food and Drug Administration (FDA), U.S. Department of Agriculture (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. The Company's FDA and USDA regulated products require some form of action by each agency before they can be marketed in the United States and after approval or clearance, The Company must continue to comply with other FDA requirements applicable to marketed products, e.g. CLIA regulations (for medical devices). Both before and after approval or clearance, failure to comply with the FDA's requirements can lead to significant penalties.

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

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

Every company that manufactures medical devices distributed in the United States must comply with the FDA's Quality System Regulations. These regulations govern the manufacturing process, including design, manufacture,



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

The Clinical Laboratory Improvement Act of 1988 (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 (via the FDA) applicable to the category of examination or procedure performed. Although a certificate is not required for the Company, it considers the applicability of the requirements of CLIA in the design and development of its products. The statutory definition of “laboratory” is very broad, and many of our customers are considered labs. A CLIA waiver will remove certain quality control and other requirements that must be met for certain customers to use the Company’s products and this is in fact critical to the marketability of a product into the point of care diagnostics market.

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

The Company 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 diagnostic 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. On the other hand, the fact that our HIV diagnostic tests are of value in the AIDS epidemic may lead to some government process being expedited. The extent of potentially adverse governmental regulation affecting Chembio that might arise from future legislative or administrative action cannot be predicted.

The Company’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 completed clinical trials for the SURE CHECK HIV and HIV 1/2 STAT PAK rapid tests in 2004 and filed the pre-market approval application with the FDA for approval of these products in February 2005. A facility inspection took place in September 2005 and an amendment was made in October 2005 to add an HIV-2 claim to the application. CLIA waiver studies are substantially completed. The Company believes that it will receive an approval of its PMA and a CLIA waiver during the first half of 2006. The Company also had its first veterinary tuberculosis rapid test under review by the USDA and expects to have its facility inspected by this agency during 2006 in connection with that submission.

## **Environmental Laws**

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

## **Intellectual Property**

### *Intellectual Property Strategy*

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

*Trade Secrets and Know-How*

We believe that we have developed a substantial body of trade secrets and know-how relating to the development of lateral flow diagnostic tests, including but not limited to the sourcing and optimization of materials for such tests, and how to maximize sensitivity, speed-to-result, specificity, stability and reproducibility. The Company possesses know-how to develop tests for multiple conditions using colored latex which is proprietary. Our buffer formulations enable extremely long shelf lives of our HIV rapid tests and we believe that this provides us with an important competitive advantage.

*Lateral Flow Technology and Reagent Licenses*

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

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

During 2005 the Company has made substantial additions to its intellectual property portfolio as a result of the development of a new rapid test platform that has shown improved sensitivity as compared with conventional platforms in a number of preliminary studies using well characterized HIV, Tuberculosis and other samples. This technology has formed the basis of two patent applications that were filed earlier this year and will likely result in additional applications covering additional uses of this technology platform. The Company anticipates signing new development projects based upon these new technologies in the near future that will provide new product applications and marketing opportunities. The Company believes that this new lateral flow platform is outside of the scope of currently issued patents in the field of lateral flow technology, thereby offering the possibility of a greater freedom to operate. There is no assurance that the patent application will be granted, or that its claims won't be modified upon review, or that Chembio's patents or its products incorporating the patent claims will not be challenged at any time.

We have also filed two patents relating to our veterinary tuberculosis rapid tests and improvements to the sample collection method in our Sure Check HIV device.

The peptides used in our HIV rapid tests are patented by Adaltis Inc. and are licensed to us under a 10-year license agreement dated August 30, 2002 which was recently amended. We also have licensed the antigens used in our tuberculosis and Chagas disease tests. We have negotiated license agreements related to intellectual property rights associated with HIV- 1 and HIV-2 and expect to conclude these agreements during 2006.

**Our Business Prior to the Merger**

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

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

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

## The Merger

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

## Glossary

AIDS	Acquired Immunodeficiency Syndrome. AIDS is caused by the Human Immunodeficiency Virus, HIV.
ANTIBODY	A protein which is a natural part of the human immune system produced by specialized cells to neutralize antigens, including viruses and bacteria that invade the body. Each antibody producing cell manufactures a unique antibody that is directed against, binds to and eliminates one, and only one, specific type of antigen.
ANTIGEN	Any substance which, upon entering the body, stimulates the immune system leading to the formation of antibodies. Among the more common antigens are bacteria, pollens, toxins, and viruses.
ARVs	Anti-Retroviral Treatments for AIDS
CD-4	The CD4+ T-lymphocyte is the primary target for HIV infection because of the affinity of the virus for the CD4 surface marker. Measures of CD4+ T-lymphocytes are used to guide clinical and therapeutic management of HIV-infected persons.
CDC	Centers for Disease Control and Prevention
C H A G A DISEASE	SChagas Disease is an infection caused by the parasite <i>Trypanosoma cruzi</i> . Worldwide, it is estimated that 16 to 18 million people are infected with Chagas disease; of those infected, 50,000 will die each year.
CHAI	Clinton HIV/AIDS Initiative
CLIA	Clinical Laboratory Improvement Act
DIAGNOSTIC	Pertaining to the determination of the nature or cause of a disease or condition. Also refers to reagents or procedures used in diagnosis to measure proteins in a clinical sample.
EITF	Emerging Issues Task Force
FASB	Financial Accounting Standards Board
FDA	U.S. Food and Drug Administration
FDIC	Federal Deposit Insurance Corporation
HIV	Human Immunodeficiency Virus. HIV (also called HIV-1), a retrovirus, causes AIDS. A similar retrovirus, HIV-2, causes a variant disease, sometimes referred to as West African

	AIDS. HIV infection leads to the destruction of the immune system.
IgG	IgG or Immunoglobulin are proteins found in human blood. This protein is called an "antibody" and is an important part of the body's defense against disease. When the body is attacked by harmful bacteria or viruses, antibodies help fight these invaders.
MOH	Ministry of Health
MOU	Memoranda of Understanding
NGO	Non-Governmental Organization
OTC	Over the Counter
PEPFAR	The President's Emergency Plan for AIDS Relief
PMA	Pre-Marketing Approval
PROTOCOL	A procedure pursuant to which an immunodiagnostic test is performed on a particular specimen in order to obtain the desired reaction.
REAGENT	A chemical added to a sample under investigation in order to cause a chemical or biological reaction which will enable measurement or identification of a target substance.
RETROVIRUS	A type of virus which contains the enzyme Reverse Transcriptase and is capable of transforming infected cells to produce diseases in the host such as AIDS.
Ryan White CARE Act	The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act is Federal legislation that addresses the unmet health needs of persons living with HIV disease by funding primary health care and support services. The CARE Act was named after Ryan White, an Indiana teenager whose courageous struggle with HIV/AIDS and against AIDS-related discrimination helped educate the nation.
SAB	Staff Accounting Bulletin
SENSITIVITY	Refers to the ability of an assay to detect and measure small quantities of a substance of interest. The greater the sensitivity, the smaller the quantity of the substance of interest the assay can detect. Also refers to the likelihood of detecting the antigen when present.
SFAS	Statement of Financial Accounting Standards
SPECIFICITY	The ability of an assay to distinguish between similar materials. The greater the specificity, the better an assay is at identifying a substance in the presence of substances of similar makeup.
SPUTUM	Expectorated matter; saliva mixed with discharges from the respiratory passages
TB	Tuberculosis (TB) is a disease caused by bacteria called Mycobacterium tuberculosis. The bacteria

usually attack the lungs. But, TB bacteria can attack any part of the body such as the kidney, spine, and brain. If not treated properly, TB disease can be fatal. TB is spread through the air from one person to another. The bacteria are put into the air when a person with active TB disease of the lungs or throat coughs or sneezes. People nearby may breathe in these bacteria and become infected.

ALGORITHM	For rapid HIV testing this refers both to method or protocol for using rapid tests from different manufacturers in combination to screen and confirm patients at the point of care, and may also refer to the specific tests that have been selected by an agency or ministry of health to be used in this way.
UNAIDS	Joint United Nations Program on HIV/AIDS
USAID	United States Agency for International Development
USDA	U.S Department of Agriculture
WHO	World Health Organization



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

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

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

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

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

## OVERVIEW

The following management discussion and analysis relates to the business of Chembio Diagnostics, Inc. (the Company) and its subsidiaries, which develop, manufacture, and market lateral flow rapid diagnostic tests that detect infectious diseases. These tests are sold in the U.S. and/or internationally to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments. The products are made under the label of Chembio Diagnostic Systems, Inc. (CDS) or the private labels of its distributors or their customers. The products are used in the diagnosis of infectious diseases and other conditions in humans and animals. The Company's main products presently commercially available are its three HIV Rapid Tests (SURE CHECK(R) HIV, HIV 1/2 STAT-PAK(TM) and HIV 1/2 STAT-PAK Dipstick) and our rapid test for Chagas Disease. In 2005, the Company sold substantially all of the business related to its private label pregnancy test and is focusing on the products mentioned above.

The Company has made substantial progress toward FDA approval of its SURE CHECK HIV and HIV 1/2 STAT-PAK products. A pre-approval inspection of its facility was conducted in the third quarter of 2005 and based upon communications with the agency the Company received an "approvable" Pre-Marketing Approval (PMA) application letter from the FDA on April 18, 2006. The Company further expects to complete the full process during the second quarter of 2006, which would include receipt from the FDA of a waiver under the Clinical Laboratory Improvement Act ("CLIA"). A CLIA waiver is essential in order to market the product into public health clinics and physicians offices where the level of training is less than clinical laboratories and hospitals. The Company is nearing completion of the CLIA waiver studies so it will be in a position to submit its waiver application immediately upon receipt of the PMA license from the FDA.

Chembio Diagnostics, Inc. (the Company) was formerly known as Trading Solutions.com, Inc. On May 5, 2004, the Company issued 4,000,000 shares of its Common Stock to acquire all the outstanding Common Stock of Chembio Diagnostic Systems, Inc. (CDS) and assumed all outstanding options and warrants of CDS. On May 5, 2004, New Trading Solutions, Inc., a wholly owned subsidiary of the Company merged with and into CDS with CDS remaining as the surviving corporation (the "Merger"). The historical information presented for periods prior to the Merger is based on the activities of CDS. For financial reporting purposes, the acquisition has been treated as a recapitalization of Chembio Diagnostics, Inc., with CDS as the acquiror. The earnings per share presented in the statement of operations for periods prior to 2005 reflect the shares outstanding as if the merger had taken place as of January 1, 2004.

The 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. Although the Company's revenues and gross margins increased significantly in 2005 as compared to 2004, it has sustained significant operating losses in 2005 and 2004. At December 31, 2005, the Company had a positive stockholders' equity of \$1,052,703 and working capital of \$650,000. The Company believes its resources are sufficient to fund its needs through early 2006 and it is considering alternatives to provide for its capital requirements for the balance of 2006 and beyond in order to continue as a going concern. Its liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenue growth; (2) the extent to which, if any, that revenue growth improves operating cash flows; (3) its investments in research and development, facilities, marketing, regulatory approvals, and other investments it may determine to make, and (4) the investment in capital equipment and the extent to which it improves cash flow through operating efficiencies. There are no assurances that it will be successful in raising sufficient capital.

On March 30, 2006, the Company sold \$1 million of additional Series B preferred stock to a Series B Preferred shareholder pursuant to provisions of the January 2005 Series B 9% Preferred Stock financing agreements. Such provisions were exclusive to said shareholder. The Company is continuing to pursue additional financing opportunities in order to provide for its longer term financing needs.



**RESULTS OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2005 AS COMPARED WITH THE YEAR ENDED DECEMBER 31, 2004**

**Revenues:**

Revenues are comprised of \$3,359,532 in net product sales, \$250,000 in license revenue and \$331,198 in grants and development income for the year ended December 31, 2005 as compared with \$2,749,143 in net product sales, no license revenue and \$556,789 in grant and development income for the year ended December 31, 2004. The increase in sales is attributable to increased sales of our HIV product of \$1,158,000 which was partially offset by decreased sales of our pregnancy test kit of \$443,000 and decreases in other product sales aggregating \$94,000. The increase in license revenue of \$250,000 is due to a technology transfer agreement. The Company does not expect that this particular license revenue will continue in the future. The decrease in grant and development income of \$225,591 was due to grants received in 2004 that weren't continued or awarded in 2005. A substantial portion of the grant-related income is not expected to continue in 2006.

Net product sales for 2005 increased 22% compared to 2004. HIV net product sales increased 93% in 2005 compared to 2004. The Company believes that sales of its HIV products will continue to increase in 2006 both as a result of the international marketing strategies that were implemented in 2005 and from the sales to the United States market after anticipated approval from the U.S. Food and Drug Administration (FDA). The Company also received its first significant order for its Chagas test (Chagas is a disease which is primarily found in Latin America), in the amount of \$1.2 million which it expects to ship in the first half of 2006.

Net product sales for the three months ended December 31, 2005 increased 27% to \$1,356,000 compared to the same period in 2004. HIV product sales increased 64% to \$1,223,000 for the three months ended December 31, 2005 compared to the same period in 2004.

**Gross Margin:**

Gross margin on net product sales for the year ended December 31, 2005 was 22.3%, as compared to 5.4% for the year ended December 31, 2004. The increase in gross margin percentage is primarily attributable to the increased sales of HIV products, which were at a higher margin than other product lines; in addition, because sales volume in 2004 was lower, fixed overhead expenses per dollar of sales were disproportionately high.

The gross margin on net product sales for the three months ended December 31, 2005 improved to 38.1% from 30.8% in the comparable 2004 period.

**Research and Development:**

Research and development expenses for the year ended December 31, 2005 were \$1,364,898 compared with \$1,508,849 for the year ended December 31, 2004. This category includes costs incurred for regulatory approvals, product evaluations and registrations. Expenses for Clinical & Regulatory Affairs, totaled \$411,000 for the year ended December 31, 2005, a decrease of \$472,000 compared to the year ended December 31, 2004. This category also includes costs for clinical studies which decreased by \$437,000 and a reduction in outside regulatory consultants of \$77,000. The costs related to the clinical trials and consulting in 2004 were related to the evaluation of the Company's HIV tests in preparation of its FDA Pre-Marketing Approval ("PMA") application submitted in February of 2005. Expenses other than Clinical & Regulatory increased \$329,000 and were related to increased salaries and wage-related costs of \$211,000 for new hires in the R&D group, increased travel and entertainment of \$46,000 and grant payments to a university of \$35,000.

The Company presently plans to increase its spending on research and development because it believes such spending will result in the development of new and innovative products. The Company will continue to focus its development efforts on its tuberculosis related products and new lateral flow technologies, some of which have patents pending.

The Company currently has several R&D projects underway. Some highlights include:

**Rapid Test for the detection of antibodies to active pulmonary tuberculosis in non-human primate whole blood samples**

The Company has filed an application with the United States Department of Agriculture (USDA) to license its rapid test, Prima TB STAT-PAK(TM). A final set of clinical trials is scheduled for the second quarter of 2006, that, if successful, would lead to a conditional license (the ability to sell the product commercially with USDA approval on an order by order basis) by late in the fourth quarter of 2006. The Company anticipates that additional commercialization will begin in the first quarter of 2007, although there are no assurances that it will be successful.

### **Rapid Test for the detection of antibodies to active pulmonary tuberculosis in multiple host species**

Chembio has completed development and is approaching the final validation stage on a series of rapid lateral-flow tests for the detection of veterinary TB in multiple host species including; cattle, cervids, badgers, camels, elephants, and exotic wildlife species. The name for the technology is VETTB STAT-PAK(TM). Application to the USDA is targeted for the third quarter of 2006 for all species. The Company anticipates commercialization of these products to start in the first quarter of 2007, although there are no assurances that it will be successful.

### **New Generation Rapid Tests Based Upon Patent Pending Platform**

The Company has done substantial laboratory work on prototypes of its new patent-pending lateral flow rapid test platform. This work has confirmed the advantages of this new platform in terms of sensitivity to weak and early sero-conversion samples. The Company believes that this platform may provide the level of sensitivity that will be needed in order to complete development of a human TB rapid test which could not be achieved with sufficient sensitivity based upon the existing platform.

### **Selling, General and Administrative Expense:**

Selling, general and administrative expense increased \$966,637 to \$3,265,235 in the year ended December 31, 2005 compared with 2004. This increase was attributable to increased staff in the accounting, administration and sales and marketing departments of \$375,000 and related recruiting expenses of \$89,000. Increased sales resulted in an increase in royalties and commissions of \$319,000. In addition there was an increase of \$174,000 in costs regarding investor relations, \$62,000 of which resulted from an increase in the number of members of the Company's Board of Directors, \$22,000 from increased insurance liability cost, \$34,000 related to Sarbanes-Oxley compliance and increased legal and accounting expenses of \$237,000 related to patent applications, patent litigation, the filing of a registration statement and other required year-end and quarterly filings. These increases were partially offset by a reduction in officers' salaries of \$240,000, mostly due to the inclusion in 2004 of the cost of common stock issued to a former officer.

As the Company's sales of its HIV rapid test products increase, it expects selling, general and administrative expense to also increase. This will be in large measure due to increased costs for commissions and royalties on intellectual property licenses. At the end of 2005, the Company renegotiated one of its license agreements to provide for a decrease of 50% in the royalty rate, from 10% to 5% of sales of HIV products, in exchange for \$350,000 in up front cash payments. Such payment is being amortized over the life of the royalty agreement.

### **Other Income and Expense:**

Interest expense decreased by \$174,875 for the year ended December 31, 2005 compared with the year ended December 31, 2004. This was primarily attributable to the conversion during 2004 of \$1,694,000 of existing debt of Chembio Diagnostic Systems, Inc, into Series A Preferred Stock. Interest income for the year December 31, 2005 increased \$32,000 due to the availability of additional funds. In addition, approximately \$22,000 and \$209,000 is attributable to settlements of old outstanding payables due that were settled during the years 2005 and 2004, respectively and are reflected in other income as settlement of accounts payable.

### **LIQUIDITY AND CAPITAL RESOURCES**

The Company had a working capital surplus of \$650,000 at December 31, 2005 and a working capital deficiency of \$452,000 at December 31, 2004. On January 28, 2005, the Company completed a private placement offering which raised \$5,047,500 before costs in the form of 9% Convertible Series B Preferred Stock and associated warrants ("Series B Offering"). The proceeds from the Series B Offering have been and are being used primarily for general corporate purposes including for sales and marketing, research and development, and intellectual property, and also for working capital, investor relations, and capital expenditures.



The following table lists the future payments required on the Company's debt and any other contractual obligations as of December 31, 2005:

<b>OBLIGATIONS</b>	<b>Total</b>	<b>Less than 1 Year</b>	<b>1-3 Years</b>	<b>4-5 Years</b>	<b>Greater than 5 Years</b>
Long Term Debt(1)	\$ 220,812	\$ 120,000	\$ 100,812	\$ -	\$ -
Capital Leases (2)	\$ 82,785	\$ 38,368	\$ 44,417	\$ -	\$ -
Operating Leases	\$ 124,950	\$ 99,837	\$ 25,113	\$ -	\$ -
Other Long Term Obligations(3)	\$ 899,092	\$ 644,367	\$ 126,600	\$ 25,000	\$ 103,125
<b>Total Obligations</b>	<b>\$ 1,327,639</b>	<b>\$ 902,572</b>	<b>\$ 296,942</b>	<b>\$ 25,000</b>	<b>\$ 103,125</b>

- (1) This represents accrued interest which is currently being paid out at the rate of \$10,000 per month.  
(2) This represents capital leases used to purchase capital equipment.  
(3) This represents contractual obligations for fixed cost licenses and employment contracts.

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

Please see section entitled *Overview* and in particular the last paragraph.

During 2006, the Company expects to start marketing its SURE CHECK HIV and HIV 1/2 STAT-PAK in the U.S. as it has made substantial progress toward its FDA approval of these products as set for the in the second paragraph of Overview above..

Based upon the expected FDA approval and CLIA waivers referred to above, the Company is developing plans for marketing its HIV products in the U.S. and is considering entering into marketing arrangements with major companies who distribute diagnostic products in the U.S.

A recent development of note is the White House 2007 budget request for \$90 million to test an additional three million Americans using rapid HIV tests. Also, the Company has been following with great interest the consideration by an FDA advisory committee of the conditions under which rapid HIV tests could be approved for direct over-the-counter sales to U.S. consumers. On March 10, 2006, proposed guidelines will be presented to this committee. While the Company believes that both President Bush's budget request and the possibility for over-the-counter approval bode well for the expansion of the U.S. rapid HIV test market, there are still many obstacles and uncertainties to be overcome before these items become a reality and can result in realizable opportunities for the Company, and there are no assurance that they will be realized.

During 2005, the Company established offices in Nigeria and Tanzania which it believes will be significant in its continuing efforts to become part of the national testing protocols in many countries in Africa. The Company's STAT-PAK is designated as the confirmatory test in all of the national rapid HIV testing protocols in the Republic of Uganda and was just recently designated in four of the eight parallel testing algorithms (two tests used on each patient) adopted by the Nigerian Ministry of Health in its Interim National Testing Algorithm. The Company is making good progress towards having its HIV products designated in other countries where it has focused its efforts. The Company has registered its products and has established distribution partners in certain of these countries and is in negotiations to do so in other countries. The Company believes that its strategy of establishing offices in these



challenging markets is a very effective way to obtain sustainable and supportable business. The Company is also actively looking at several new opportunities for establishing distribution and/or local assembly programs for its rapid HIV tests with strong local partners such as it has done in Brazil.

In early 2006, Chembio was named as one of four companies selected by the Clinton Foundation HIV/AIDS Initiative ("CHAI") to make available low-cost rapid HIV tests in order to more quickly and cost effectively achieve treatment objectives. Under the CHAI agreement, the Company has agreed to offer its HIV STAT-PAK Dipstick, Chembio's lowest cost HIV rapid test product, at a reduced price in the expectation that the Company will receive significant order volume not otherwise obtainable; this should result in efficiencies of scale that will more than justify the reduced sales price. If these order volumes are not realized, the Company has the right to terminate the agreement or renegotiate pricing. Chembio is the only U.S.-based manufacturer of the four companies in this agreement. The CHAI Procurement Consortium is currently comprised of more than 50 countries in Africa, Asia, Eastern Europe, Latin America and the Caribbean that have Memoranda of Understanding (MOUs) with CHAI. Consequently, the Company is now actively engaged with CHAI in developing sales opportunities in a many of these 50+ countries. Although in some of these countries the Company has already made substantive sales efforts, there are many more where this is not the case. There is no commitment or assurance that either the Company's direct efforts to establish additional distributors and/or local assembly, or its activities through CHAI will materialize into meaningful sales.

The Company's technology transfer and supply agreement in Brazil is moving forward. The Company shipped 704,000 HIV rapid tests in 2005, a 254,000 test increase over the quantity sold in 2004. The Company expects to deliver components for an additional 800,000 tests during all of 2006, although there is no assurance that this will occur.

The Company also received, in January of 2006, an order for \$1.2 million to supply its Chagas Disease rapid test to be delivered in the first half of 2006. This procurement is being made by the Pan American Health Organization, headquartered in Washington D.C., which is affiliated with the World Health Organization. The procurement will be used to implement a nationwide Chagas screening program for all children under the age of 10 in endemic regions of Bolivia. The Company is actively looking at developing additional business opportunities for this product in Bolivia, and other markets in Latin America that are impacted by this disease.

In September 2005, the Company hired a senior diagnostics marketing executive to focus on its Tuberculosis products, both for veterinary and human TB. The Company's Non-human primate Tuberculosis product is currently under review by the United States Department of Agriculture (USDA) and it expects USDA approval toward the end of 2006 provided its tests meet certain performance and other criteria; and it plans to submit additional veterinary TB products to the USDA this year, including a cattle TB test, subject to having the necessary performance data of which there is no assurance.

During the second quarter of 2005 the Company filed a patent application for a new lateral flow device and method which it believes will provide it with proprietary intellectual property to develop a pipeline of products that it believes will have improved performance over currently available lateral flow technologies. The Company is continuing to refine this device and it believes it will be the basis for new product developments that can address significant needs for screening of tuberculosis and other infectious diseases that occur in markets that the Company is already serving with its HIV rapid tests.

### **Critical Accounting Policies and Estimates**

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

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

#### *Revenue Recognition -*

The Company sells its products directly through its sales force and through distributors. Revenue from direct sales of its product is recognized upon shipment to the customer. Income from research grants when earned. Grants are invoiced after expenses are incurred. Sales are recorded net of discounts, rebates and returns.

The Company recognizes income from research grants when earned. Grants are invoiced after expenses are incurred. Any grants funded in advance are deferred until earned.

#### *Research & Development Costs -*

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

*Valuation of Inventories -*

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

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*Allowance for doubtful accounts -*

The Company's policy is to review its accounts receivable on a periodic basis, no less than monthly. On a quarterly basis an analysis is made of the adequacy of its allowance for doubtful accounts and adjustments are made accordingly. The current allowance is approximately 1.6% of accounts receivable.

*Income Taxes -*

Income taxes are accounted for under SFAS No. 109, "Accounting for Income Taxes." SFAS No. 109 requires the asset and liability method of accounting for deferred income taxes. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities. Deferred tax assets or liabilities at the end of each period are determined using the tax rate expected to be in effect when taxes are actually paid or recovered. For example, if the Company does not become profitable it may be unable to utilize its deferred tax asset, which approximates \$6,128,000 at December 31, 2005.

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

Forming a conclusion that a valuation allowance is not needed is difficult when there is negative objective evidence such as cumulative losses in recent years. Cumulative losses weigh heavily in the overall assessment. As a result, the Company determined that it was appropriate to establish a valuation allowance for the full amount of its deferred tax assets.

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

## **DESCRIPTION OF PROPERTY**

Our administrative offices and research facilities are located in Medford, New York. We lease approximately 14,000 square feet of industrial space for \$8,167 per month. The space is utilized for R&D (approximately 1,600 square feet), offices (approximately 4,700 square feet) and production (approximately 7,700 square feet). The lease term expires on April 30, 2007. 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 former director of Chembio Diagnostics, Inc., entered into a nine-month employment agreement with Chembio Diagnostics, Inc., effective upon the closing of the merger, pursuant to which Mr. Baum received 400,000 shares of our common stock as well as a warrant to acquire 425,000 shares of common stock at \$.60 per share and a warrant to acquire an additional 425,000 shares of common stock at \$.90 per share. The warrants expire five years after the date of grant. Pursuant to the employment agreement, Mr. Baum was to advise Chembio Diagnostics, Inc. concerning management, marketing, strategic planning, corporate structure, business operations, expansion of services, acquisitions and business opportunities, matters related to our

public reporting obligations, and our overall needs through February 5, 2005. Mr. Baum also invested \$65,000 in the private placement of series A preferred stock, pursuant to which he received 2.167 shares of series A preferred stock convertible into 108,350 shares of common stock, and a warrant to purchase 130,020 shares of common stock. Mr. Baum also owns 300,000 shares of our common stock in addition to the stock and warrants described above. In November of 2004 as payment of dividends on the series A preferred he received 4,333 shares of common stock. Prior to the merger, Mr. Baum was the sole director and officer of Chembio Diagnostics, Inc. On March 18, 2005, as compensation for Mr. Baum's service on the Board of Directors of Chembio Diagnostics, Inc., the exercise price of Mr. Baum's warrant to acquire 425,000 shares of common stock at \$.90 per share was reduced to \$.75 per share. Mr. Baum received no other compensation for his services on the Board of Directors.

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

Mr. Siebert also invested \$18,700 in Chembio Diagnostic Systems Inc. pursuant to a private placement of convertible notes on March 22, 2004. Mr. Siebert converted the entire principal amount of the note that he received, together with accrued interest thereon, into .942 shares of Chembio Diagnostics, Inc.'s series A preferred stock, together with warrants to acquire 56,520 shares of common stock at \$.90 per share, pursuant to Chembio Diagnostics, Inc.'s private placement of its series A preferred stock on May 5, 2004. In November of 2004 as payment of dividends on the series A preferred he received 61,884 shares of common stock. Mr. Siebert exercised a warrant to purchase 66,869 shares of common stock on December 30, 2004 at a price of \$0.45 per share. These shares were gifted by Mr. Siebert to a third party. In May of 2005 as payment of dividends on the series A preferred he received 72,234 shares of common stock. In July of 2005 as payment of dividends on the series B preferred he received .03871 shares of series B preferred stock. In November of 2005 as payment of dividends on the series A preferred he received 77,488 shares of common stock.

Mr. Siebert prior to March 22, 2004 had either advanced funds to Chembio Diagnostic Systems, Inc. or paid vendors directly on Chembio Diagnostic Systems, Inc.'s behalf. The total amount so paid or advanced and not repaid totaled \$182,181 as of December 31, 2005.

Richard J. Larkin, the Chief Financial Officer of Chembio Diagnostics, Inc., invested \$10,000 in Chembio Diagnostic Systems Inc. pursuant to the March 22, 2004 private placement of convertible notes. Mr. Larkin converted the entire principal amount of the note that he received, together with accrued interest thereon, into .504 shares of Chembio Diagnostics, Inc.'s series A preferred stock, together with warrants to acquire 30,240 shares of common stock at \$.90 per share, pursuant to Chembio Diagnostics, Inc.'s private placement of its series A preferred stock on May 5, 2004. In November of 2004 as payment of dividends on the series A preferred he received 1,007 shares of common stock. In May of 2005 as payment of dividends on the series A preferred he received 999 shares of common stock. In November of 2005 as payment of dividends on the series A preferred he received 1,007 shares of common stock.

Avi Pelosof, the vice president of sales and marketing of Chembio Diagnostics, Inc., invested \$4,000 in Chembio Diagnostics, Inc. pursuant to the March 22, 2004 private placement of convertible notes. Mr. Pelosof converted the entire principal amount of the note that he received, together with accrued interest thereon, into .202 shares of Chembio Diagnostics, Inc.'s series A preferred stock, together with warrants to acquire 22,555 shares of common stock at \$.90 per share, pursuant to Chembio Diagnostics, Inc.'s private placement of its series A preferred stock on May 5, 2004. In November of 2004 as payment of dividends on the series A preferred he received 403 shares of common stock. In May of 2005 as payment of dividends on the series A preferred he received 399 shares of common stock. In November of 2005 as payment of dividends on the series A preferred he received 403 shares of common stock.



**MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS****Market Information**

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

<b>Fiscal Year</b>	<b>High Bid</b>	<b>Low Bid</b>
<b>2006</b>		
First Quarter	\$0.75	\$0.33

<b>Fiscal Year</b>	<b>High Bid</b>	<b>Low Bid</b>
<b>2005</b>		
First Quarter	\$0.90	\$0.50
Second Quarter	\$0.87	\$0.54
Third Quarter	\$0.66	\$0.52
Fourth Quarter	\$0.62	\$0.30

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

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



system, provided that current price and volume information with respect to transactions in that security is provided by the exchange or system), except for securities of companies that have tangible net assets in excess of \$2,000,000 or average revenue of at least \$6,000,000 for the previous three years. The Penny Stock Rule requires a broker/ dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document prepared by the Commission that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker/dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker/dealer and its salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker/dealer and salesperson compensation information, must be given to the customer orally or in writing prior to effecting the transaction and must be given to the customer in writing before or with the customer's confirmation. These disclosure requirements have the effect of reducing the level of trading activity in the secondary market for our common stock. As a result of these rules, investors may find it difficult to sell their shares.

### **Holders**

As of December 31, 2005, there were approximately 322 record owners of our common stock.

## Dividends

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

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

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

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

## Equity Compensation Plan Information as of December 31, 2005

### Equity Compensation Plan Information

<u>Plan Category</u>	<u>Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</u> (a)	<u>Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights</u> (b)	<u>Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column (a))</u> (c)
Equity compensation plans approved by security holders	1,285,750	1.20	1,714,250
Equity compensation plans not approved by security holders	--	--	--
Total	1,285,750	1.20	1,714,250



**EXECUTIVE COMPENSATION**

The following table summarizes the annual compensation paid to Chembio Diagnostics, Inc.'s named executive officers for the three years ended December 31, 2005, 2004 and 2003:

<b>Name and Position</b>	<b>Year</b>	<b>Annual Comp Salary</b>		<b>Long-Term Compensation Awards—Securities Underlying Stock Options</b>	
Lawrence A. Siebert, President, CEO, Chairman of Board of Chembio Diagnostics, Inc. <sup>(1)</sup>	2005	\$	160,151		
	2004		145,994		160,000
	2003		140,641		
Avi Pelossof, Vice President of Chembio Diagnostics, Inc. <sup>(2)</sup>	2005	\$	154,165		50,000
	2004		154,635		250,000
	2003		83,077		
Javan Esfandiari, Vice President of Chembio Diagnostic Systems, Inc. <sup>(3)</sup>	2005				