Chembio Diagnostics Inc.
Form SB-2
March 28, 2005

Registration No. 333-_____

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM SB-2

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

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

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

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

Lawrence A. Siebert
3661 Horseblock Road
Medford, New York 11763
(631) 924-1135
(Name, address and telephone number of agent for service)

Copy of all communications to:
Alan Talesnick, Esq.
Jon S. Ploetz, Esq.
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1660 Lincoln Street, Suite 1900
Denver, Colorado 80264
(303) 830-1776

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

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

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

offering. [ ]

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

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

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

CALCULATION OF REGISTRATION FEE

Title Of Each Class of Securities To Be Registered	Number of Units/Shares To Be Registered	Proposed Maximum Offering Price Per Unit (1)	Proposed Maximum Aggregate Offering Price (1)	Amount Of Registration Fee
Common Stock, $0.01 par value per share (2)	19,439,756	$0.78	$15,163,010	$1,784.69

(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 March 21, 2005.

(2) Includes (i) up to 8,716,382 shares issuable upon the conversion of 106.33 shares of the Registrant's 9% Series B Convertible Preferred Stock, (ii) up to 252,597 shares issuable upon the conversion of 5.05199 shares of the Registrant's 8% Series A Convertible Preferred Stock, (iii) up to 9,741,382 shares issuable upon the exercise of outstanding warrants, and (iv) up to 729,395 shares currently held by the selling stockholders.

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.

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 statement on Form SB-2 first filed with the Securities and Exchange Commission on June 7, 2004 (Commission File Number 333-116219) and also constitutes the prospectus for this registration statement.

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 MARCH 25, 2005

PROSPECTUS

CHEMBIO DIAGNOSTICS, INC.

40,691,304 SHARES OF COMMON STOCK

This prospectus relates to the sale by certain stockholders of Chembio Diagnostics, Inc. of up to 40,691,304 shares of our common stock which they own, or which they may at a later date acquire upon the conversion of shares of our 8% series A convertible preferred stock, upon the conversion of shares of our 9% series B convertible preferred stock, or upon the exercise of warrants and options to purchase shares of our common stock.

Our common stock is quoted on the OTC Bulletin Board under the symbol "CEMI." On March 23, 2005 the closing bid and ask prices for one share of our common stock were $0.73 and $0.80, respectively, as reported by the OTC Bulletin Board website. These over-the-counter quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

These securities are speculative and involve a high degree of risk. You should consider carefully the "Risk Factors" beginning on Page 5 of this prospectus before making a decision to purchase our stock.

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

The date of this prospectus is _____, 2005

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PROSPECTUS SUMMARY

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

Overview

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

Our Business

We are a developer and manufacturer of rapid diagnostic tests that aid in the detection of infectious diseases; until recently, we also manufactured pregnancy tests. Our revenues until 2004 were primarily from private label over-the-counter pregnancy tests. In 2004 we sold substantially all of the business related to our private label pregnancy test. We are currently focused on obtaining FDA regulatory approval for, and increasing revenues from, our HIV rapid test products. During 2004 we experienced a significant increase in sales of our HIV rapid test products as a result of a contract we entered into with an organization affiliated with the Brazilian government. We are engaged in marketing efforts for distribution of our HIV rapid test products in markets outside the United States. We also are focused on efforts to complete development of, and proceed to seek regulatory approval for, other rapid tests in the areas of tuberculosis (human and veterinary), dental bacteria and Mad Cow Disease.

Our main products and products under development are summarized in the following tables:

Existing or Proposed Product	Regulatory Status	Development Status	Partners Involved in the Development or Marketing of the Products
HIV Rapid Tests (Sure Check™ HIV; HIV 1/2 Stat Pak; HIV 1/2 Stat Pak Dipstick). Rapid Tests for detection of antibodies to HIV 1 and 2 in finger-stick whole blood, venous whole blood, serum and plasma	In December 2004 we completed clinical trials for Sure Check™ and HIV 1/2 Stat-Pak in the U.S. for FDA approval for sales in the U.S. with results that we believe will exceed the performance requirements for U.S. FDA approval. We are pursuing U.S. FDA approval for these products and on February 17, 2005 we submitted our Pre-Marketing Approval application to the FDA. We currently qualify under U.S. FDA export regulations to sell, subject to any required approval by the importing country, to customers outside the U.S. To date we have received approval from a number of potential importing countries, although Brazil is the only country in which we have significant sales. We have also just recently qualified for procurements by the United States Agency for International Development under the President's Emergency Plan for AIDS Relief and the World Health Organization's Bulk Procurement Scheme.	Completed	Thirteen-year supply and technology transfer agreement with FIOCRUZ-Bio-Manguinhos, a division of the Ministry of Health of Brazil. FIOCRUZ-Bio-Manguinhos will supply product to Brazilian public health market and potentially other markets in the region. We also have been actively seeking to have our tests procured by governmental and non-governmental organizations engaged in HIV prevention programs in numerous locations outside the United States.
Rapid test for detection of Bovine	Product has been evaluated for approval in	We are waiting for Prionics AG to	Subject to obtaining European Union approval

Spongeiform Encephalopathy in cattle	the European Union and approval is pending.	complete the transfer of production specifications in order to begin production scale-up, validation, and regulatory submission.	and completing the technology transfer, Prionics AG, Zurich, Switzerland has contracted with Chembio to provide manufacturing services. Additionally, Prionics AG will exclusively market product directly and through its designated distributors.
Dental Bacteria Test	Regulatory submissions in the European Union will be made in 2005 if product development is satisfactorily completed in accordance with development timetable.	Discussing revised development plan with marketing partner Ivoclar Vivadent, AG due to technical issues.	If a new development plan is agreed upon, Ivoclar Vivadent AG, Schaan, Liechtenstein will exclusively market the product and is the exclusive licensee of patented antibodies being incorporated by Chembio in product development.
Cerebral Spinal Fluid (CSF) Leak Rapid Test	Not yet submitted for approval.	Initial development work being supported with matching funds from the State of New York.	The State University of New York at Stony Brook (SUNY) is developing antibodies against this marker. SUNY has applied for a patent for the antibodies and the test. Chembio has an exclusive option to license the technology once the patent is issued.
Rapid diagnostic test for the detection of antibodies to active pulmonary tuberculosis in non-human primate whole blood samples	Submitted to United States Department of Agriculture for regulatory approval in the U.S. in March 2005.	Product validation completed.	Sequella Corporation, Rockville, MD and Chembio have entered into an agreement whereby Chembio will have exclusive worldwide marketing and manufacturing rights for the product.
Rapid diagnostic test for the detection of antibodies to active pulmonary tuberculosis in human whole blood samples	Evaluation by World Health Organization to be completed in 2005 to support use in international programs is pending. We do not plan to market this product in the U.S. or Europe and	Product validation completed.	Public Health Research Institute, Newark, NJ provided initial research collaboration on product development.

	have no plans for seeking regulatory approval in these markets.		
Rapid diagnostic test for the detection of antibodies to Chagas Disease	Evaluation by World Health Organization to be completed in 2005 to support use in international programs is pending. We do not plan to market this product in the US or Europe and have no plans for seeking regulatory approval in these markets.	Product validation completed. Studies have been completed that have increased awareness of product. United Nations Development Program began to procure product in 2004.	A consortium of researchers from Latin America collaborated to develop the recombinant antigen incorporated in this product.
Private label pregnancy tests	Cleared for marketing by FDA.	Completed	During 2004 we sold substantially all of the business related with this product line for the right to receive participation in future profits, if any, derived from this product line. We have also continued to supply the buyer with certain components for these products.

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

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

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

We have a history of losses and we continue to incur operating and net losses. We own no patents though we have non-exclusive licenses to lateral flow patents from Abbott Laboratories, Inc. and to reagents including those that are used in our HIV rapid tests. However, these licenses do not necessarily insulate us from patent challenges by other patent holders.

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

The Offering

By means of this prospectus, a number of our stockholders are offering to sell up to 6,288,238 shares of common stock which they own, up to 14,783,600 shares of common stock which they may at a later date acquire upon the conversion of our series A and/or series B preferred stock, and up to 19,619,466 shares of common stock which they may at a later date acquire upon the exercise of warrants and/or options. In this prospectus, we refer to these persons as the selling security holders.

As of March 18, 2005, we had 7,048,086 shares of common stock issued and outstanding, which includes shares offered by this prospectus. The number of outstanding shares of common stock does not give effect to common stock which may be issued pursuant to the conversion of our series A and B preferred stocks and the exercise of options and/or warrants previously issued by Chembio Diagnostics, Inc.

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

Summary Financial Data

The following table presents summary historical financial information for the fiscal years ended December 31, 2004 and 2003. The audited financial statements are set forth on page F-1 of this prospectus, and you should read this information for a more complete understanding of the presentation of this information. As described in the audited financial statements, on January 28, 2005 the Company substantially improved its balance sheets with the completion of the $5,047,500 Series B Private Placement financing. However, Pro Forma financial data to reflect the completion of this transaction are not presented in this summary table or in the audited financial statements.

	Year Ended December 31, 2004	**Year Ended December 31, 2003**
Revenue	3,305,932	2,818,351
Operating Expenses	3,923,701	1,516,076
Net Loss	(3,098,891)	(1,059,074)
Current Assets	1,211,060	772,680
Total Assets	1,426,449	1,086,745
Current Liabilities	1,663,196	1,503,418
Total Liabilities	1,950,413	3,544,186
Convertible Redeemable Preferred	2,427,030	-
Stockholders' Deficit	(2,950,994)	(2,457,441)

RISK FACTORS

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

Risks related to our industry, business and strategy

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We received $556,789 or 16.84% of our revenues in 2004 and $275,730 or 9.7% of our revenues in 2003 from grant and contract development work in connection with grants from the United States National Institute of Health, as well as from universities and commercial companies related to product development efforts for our tuberculosis, mad cow, and dental bacteria rapid test development work. During the first quarter of 2005, we entered into a license and technology transfer agreement for certain rapid test technology. These revenues have funded some of our personnel and other research and developmental costs and expenses for us. However, if these awards are not funded in their entirety or if new grants and contracts are not awarded in the future, our ability to fund future research and development and implement technological improvements would be diminished which could negatively impact our ability to compete in our industry.

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

As a result of the completion of the $5,047,500 Series B Private Placement on January 28, 2005, we believe that our current cash balances, together with cash generated from operations, will be sufficient to fund operations through December 2006. This estimate is based upon several assumptions including that we will continue to grow our revenues from the sales of our HIV rapid tests and become profitable by the end of 2006. However, we also may face additional unanticipated expenses. Although we don't anticipate that we will be required to obtain additional capital through the sale of additional equity or debt securities, or through additional credit facilities before the end of 2006, if at all, any additional equity financing will result in dilution to existing shareholders. If we are unable to obtain any such additional equity financing on satisfactory terms, we will not be able to effectively carry out our business plan.

The amount of additional capital we need and our ability to obtain it will depend on a number of factors. These factors primarily include (1) whether we can generally achieve revenue growth for our HIV rapid tests and the extent, if any, to which that revenue growth improves operating cash flows; (2) our investments in research and development, facilities, marketing, regulatory approvals, and other investments we may determine to make; (3) the availability and cost of raising additional capital and potential dilution to shareholders; and (4) the extent, if any, to which any of the Company's outstanding options or warrants are exercised for cash.

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

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

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

· economic conditions and the absence of available funding sources.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks related to our common stock

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

Our common stock is classified as penny stock. Penny stocks generally are equity securities with a price of less than $5.00 and trade on the over-the-counter market. As a result, an investor may find it more difficult to dispose of or obtain accurate quotations as to the price of the shares of the common stock being registered in this registration statement. In addition, the “penny stock” rules adopted by the Commission under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), subject the sale of the shares of the common stock to regulations which impose sales practice requirements on broker-dealers, causing many broker-dealers to not trade penny stocks or to only offer the stocks to sophisticated investors that meet specified net worth or net income criteria identified by the Commission. These regulations contribute to the lack of liquidity of penny stocks.

The average daily trading volume of our common stock on the over-the-counter market was less than 13,000 shares per day over the three months ended February 28, 2005. If limited trading in our stock continues, it may be difficult for investors to sell their shares in the public market at any given time at prevailing prices. Since the certificates of designation creating our series A and series B preferred stock contain restrictions on our ability to declare and pay dividends on our common stock, the lack of liquidity of our common stock could negatively impact the rate of return on your investment.

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

At the time of effectiveness of the registration statement, the number of shares of our common stock eligible to be immediately sold in the market will increase approximately from 180,000 to 41,023,309. If the selling stockholders sell significant amounts of our stock, our stock price could drop. Even a perception by the market that selling stockholders will sell in large amounts after the registration statement is effective could place significant downward pressure on our stock price.

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

On May 5, 2004, we completed three separate private placements in which we issued 151.57984 shares of our series A preferred stock and warrants to acquire 9,094,801 shares of our common stock at an exercise price of $.90 per share. The shares of series A preferred stock are convertible into 7,578,985 shares of our common stock. We also issued warrants to purchase 425,000 shares of our common stock at an exercise price of $0.72 per share and warrants to purchase 510,000 shares of common stock at an exercise price of $1.08 per share to designees of our placement agents. We also issued warrants pursuant to an employment agreement with Mark L. Baum, our former president and a current member of our board of directors, to purchase 425,000 shares and 425,000 shares of our common stock, respectively, at exercise prices of $0.60 and $0.90 per share respectively. In connection with the acquisition of Chembio Diagnostic Systems, Inc., we assumed the obligation to issue 690,000 shares of our common stock upon the exercise of warrants, which warrants are exercisable at prices ranging from $0.45 to $4.00 per share. We also adopted the stock option plan of Chembio Diagnostic Systems, Inc. and assumed all of the obligation to issue 704,000 common shares upon the exercise of the options outstanding as of the merger date. On January 28, 2005, we completed a private placement in which we issued 100 shares of our 9% Series B Convertible Preferred Stock, which we refer to as the "Series B Stock," together with warrants to purchase 7,786,960 shares of our common stock. For each $.61 invested in this private placement, an investor received (a) $.61 of face amount of Series B Stock, which is convertible into one share of our common stock, and (b) a five-year warrant to acquire .95 of a share of our common stock. Each full share of the Series B Stock was purchased for $50,000, with fractional shares of Series B Stock being purchased by investments of less than $50,000. In connection with the January 28, 2005 offering, we also issued to the placement agent Series B Stock in an aggregate amount equal to 5% of the amount of cash proceeds from the private placement, together with accompanying warrants to purchase our common stock. We also issued to the placement agent warrants to purchase 737,712 shares of our common stock. As of March 7, 2005, there were 1,105,000 options issued and outstanding under the stock option plan and 395,000 options available for issuance under the stock option plan. As a result, the conversion of the outstanding preferred stock and the exercise of the outstanding warrants and options will result in substantial dilution to the holders of our common stock.

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

As of December 31, 2004, our named executive officers, directors and 5% stockholders beneficially owned approximately 47.81% of our voting power. For the foreseeable future, to the extent that our current stockholders vote similarly, they will be able to exercise control over many matters requiring approval by the board of directors or our stockholders. As a result, they will be able to:

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

USE OF PROCEEDS

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

DILUTION

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

SELLING SECURITY HOLDERS

The securities are being offered by the named selling security holders below. The selling security holders hold one or more of the following securities which are described in section “Description of Securities”: Common stock, Series A preferred stock which is convertible into common stock at $.60 per share, Series B preferred stock which is convertible into common stock at $.61 per share, options to purchase common stock at prices ranging from $0.45per share to $4.00per 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 1,025,250 shares issuable to them upon the exercise of options that they hold. The selling security holders may, from time to time, offer and sell any or all of the shares that are registered under this prospectus, although they are not obligated to do so.

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

Certain of the entities or individuals listed below acquired the shares offered hereby in connection with our May 5, 2004 private placement of series A preferred stock. Pursuant to this private placement, we received $2.2 million in cash as payment for 73.3333 shares of preferred stock that are convertible into 3,666,664 shares of common stock. We also issued to the investors in the series A preferred stock warrants to acquire 4.4 million shares of common stock at an exercise price of $.90 per share. Based on the $2.2 million paid, the purchase price per common share is $.60, without allocating any portion of the purchase price to the warrants. At the same time as this transaction, a conversion of $1,009,803 face amount and accrued interest of convertible notes that had been issued in March 2004 occurred. Of this conversion, $330,696 face amount and interest was converted into 826,741 shares of common for a conversion price, based on the face amount of the notes, of $.40 per share; and $679,107 face amount and interest was converted into 33.83682 shares of our series A preferred, together with warrants to purchase 2,030,217 shares of common stock at $.90 per share. The 33.83682 shares of series A preferred are convertible into 1,691,835 shares of our common stock, which based on the face amount of the notes, represents a purchase price of $.40 per share of common stock, without allocating any portion of the purchase price to the warrants. Also simultaneously with the other two private placement transactions, we issued 44.40972 shares of our series A preferred stock, convertible into 2,220,486 shares of our common stock, together with warrants to purchase 2,664,584 shares of our common stock at an exercise price of $.90 per share, in exchange for $1,332,292 face amount of our debt obligations. Based on the face amount of these obligations, the price per common share is $.60 per share, without allocating any portion of the purchase price to the warrants. On December 29, 2004 the Company converted $361,560 of additional debt into 12.05199 shares of series A preferred stock and associated warrants to purchase 723,120 shares of common stock. Also in connection with these three private placements, we agreed to prepare and file at our expense, as promptly as practical, and in any event, by June 4, 2004, a registration statement with the Securities and Exchange Commission covering the resale of the shares of common stock issuable upon conversion of the series A preferred stock and the shares of common stock issuable upon exercise of the warrants.

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

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

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

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

- the number of shares of common stock beneficially owned as of March 18, 2005 and prior to the offering contemplated hereby,

- the number of shares of common stock eligible for resale and to be offered by each selling security holder pursuant to this prospectus,

- the number of shares owned by each selling security holder after the offering contemplated hereby assuming that all shares eligible for resale pursuant to this prospectus actually are sold,

- the percentage of shares of common stock beneficially owned by each selling security holder after the offering contemplated hereby, and

- in notes to the table, additional information concerning the selling security holders including any NASD affiliations and any relationships, excluding non-executive employee and other non-material relationships, that a selling security holder had during the past three years with the registrant or any of its predecessors or affiliates.

Selling security holders	Number of Shares of Common Stock Owned Before Offering	Number of Shares To Be Offered	Number of Shares Owned After Offering	Percentage of Shares of Common Stock Owned After Offering
Alchemy, LLC[1]	40,471	40,471	-	0.00%
Alpha Capital AG[2]	1,232,000	1,232,000	-	0.00%
Bassett, Truman[1]	42,526	42,526	-	0.00%
Baum, Mark L.[2]	1,792,666	1,792,666	-	0.00%
Bell, Lon E.[2]	282,198	282,198	-	0.00%
Beller, Claudio [2]	145,582	145,582	-	0.00%
BioEquity Partners, Inc. [1,3]	175,000	175,000	-	0.00%
Breitbart, Ted[1,4]	18,208	18,208	-	0.00%
Bruce, Richard[1]	75,500	75,500	-	0.00%
Calamaro, Jean-Paul[2]	309,581	309,581	-	0.00%
CEOcast, Inc.	76,250	76,250	-	0.00%
Chrust, Steve[1]	127,656	127,656	-	0.00%
Clarke, John R.[1,5]	158,400	158,400	-	0.00%
Colby, Russ[1]	12,500	12,500	-	0.00%
Crestview Capital Master, LLC[6]	9,590,162	9,590,162	-	0.00%
Dabush, Ami[2]	569,718	569,718	-	0.00%
Daedalus Consulting, Inc.[7]	35,963	35,963	-	0.00%
Dashefsky, Jeff[1]	12,500	12,500	-	0.00%
Diamond Deecembra[8]	143,853	143,853	-	0.00%
DKR Soundshore Oasis Holding Fund, Ltd.	1,198,770	1,198,770	-	0.00%
Eckert, Christopher & Lynn [2,9]	186,666	186,666	-	0.00%

Engel, Sam[1]	4,118	4,118	-	0.00%
Esfandiari, Javan[1]	167,080	167,080	-	0.00%
Falvo, Pete[2]	40,000	40,000	-	0.00%
FAMALOM, LLC[10]	179,817	179,817	-	0.00%
Feldman, Stephen[1]	2,055	2,055	-	0.00%
Fuchs, Ari [2,11]	49,058	49,058	-	0.00%
Ginsberg, Mike[1]	2,375	2,375	-	0.00%
Glass, Marc[1]	20,708	20,708	-	0.00%
Goldberg, Jeffrey[1,12]	52,875	52,875	-	0.00%
Greenblatt, Phil[1]	10,347	10,347	-	0.00%
Gregoretti, Gordan	79,916	79,916	-	0.00%
Gressel, Daniel[1,13]	472,501	472,501	-	0.00%
Guzikowski, Frank J.[1]	178,114	178,114	-	0.00%
H. C. Wainwright & Co. [1,14]	390,867	390,867	-	0.00%
Haendler, Kurt[1]	434,288	434,288	-	0.00%
Haendler, Renata[1]	138,211	138,211	-	0.00%
Haendler, Tomas[2,15]	700,710	700,710	-	0.00%
Haim, Eduardo[1]	7,115	7,115	-	0.00%
Hamblett, Michael[16]	498,714	498,714	-	0.00%
Hanson, Andrew Merz[2,17]	119,545	119,545	-	0.00%
Hunt, David[1]	60,000	60,000	-	0.00%
Ide, Bruce J.[2,18]	501,062	501,062	-	0.00%
Jacob, Sam[1]	10,000	10,000	-	0.00%
Jacoby, Richard A.[2]	469,545	469,545	-	0.00%
Joffe, Wendy[2]	37,222	37,222	-	0.00%
Jordan, Bruce[19]	67,931	67,931	-	0.00%
JP Turner[1,20]	41,250	41,250	-	0.00%
Keskinen, Karen[1]	31,579	31,579	-	0.00%

Klaus, Elaine[1]	17,242	17,242	-	0.00%
Knasin, Paul and Ellen[2]	152,307	152,307	-	0.00%
Koch, Scott F.[1,21]	158,400	158,400	-	0.00%
Kolstad Jr., Kaare[1]	50,589	50,589	-	0.00%
Kreger, Richard[22]	453,435	453,435	-	0.00%
Krumholz, Jacob & Arlene	66,869	66,869	-	0.00%
Kurzman Partners, LP[23]	65,265	65,265	-	0.00%
Lankenau, Robert[1]	226,585	226,585	-	0.00%
Lanouette, Kevin P.	31,966	31,966	-	0.00%
Larkin, Richard[2]	109,189	109,189	-	0.00%
Lawrence, Colin[1]	7,115	7,115	-	0.00%
Ledowitz, Bill[1]	7,118	7,118	-	0.00%
Lew, Felicia[1]	31,250	31,250	-	0.00%
Lew, Hanka[1]	31,250	31,250	-	0.00%
Lifshitz, Joshua[24]	98,959	98,959	-	0.00%
Little Gem Life Sciences Fund LLC[25]	173,248	173,248	-	0.00%
Lyashchenko, Konstantin[1]	10,500	10,500	-	0.00%
Maloney & Company, LLC	79,916	79,916	-	0.00%
Mayer-Wolf, Mike[1]	18,379	18,379	-	0.00%
McCarthy, Michael[1]	4,145	4,145	-	0.00%
McGusty, Edwin[1]	125,000	125,000	-	0.00%
Metasequoia, LLC[2]	37,332	37,332	-	0.00%
Midtown Partners & Co., LLC[26]	116,639	116,639	-	0.00%
Millennium 3 Opportunity Fund, LLC	3,196,720	3,196,720	-	0.00%

Moran, Sean	47,950	47,950	-	0.00%
MSAS Trust[2]	742,666	742,666	-	0.00%
Nite Capital, LP	719,261	719,261	-	0.00%
Patton Boggs LLP[1]	37,319	37,319	-	0.00%
Pelossof, Avi[2]	570,685	570,685	-	0.00%
Pelossof, Elior[2]	84,659	84,659	-	0.00%
Perlmutter, Alan [1]	60,000	60,000	-	0.00%
Phillips, Chris[27]	86,264	86,264	-	0.00%
Phillips, Scott W.[1]	50,589	50,589	-	0.00%
Poole, Colin [2]	141,098	141,098	-	0.00%
Poole, John G.[1]	68,365	68,365	-	0.00%
Raker, Gilbert[2]	84,659	84,659	-	0.00%
Reibman, Spencer[1]	18,780	18,780	-	0.00%
Rohan, J. Rory[28]	453,435	453,435	-	0.00%
Rojas, Zilma[1]	5,500	5,500	-	0.00%
Ross, Anne [1]	63,236	63,236	-	0.00%
Sandler, J & S[1]	8,287	8,287	-	0.00%
Sandler, Mark and Lori[2]	186,666	186,666	-	0.00%
Schnipper, Steve[29]	160,426	160,426	-	0.00%
Schwartz, Eric[1]	5,496	5,496	-	0.00%
Seren, Stanley[1]	8,287	8,287	-	0.00%
Shapiro, Alex[1]	112,412	112,412	-	0.00%
Siderowf, Richard[2,30]	86,624	86,624	-	0.00%
Siebert Best, Ellen[2]	43,311	43,311	-	0.00%
Siebert, Lawrence[31]	6,318,138	1,163,078	5,155,060	43.33%
Sive Paget & Reisel[1]	2,055	2,055	-	0.00%
Smith, Robin[1,32]	119,883	119,883	-	0.00%
Spatacco, Jr., Anthony J.[33]	89,520	89,520	-	0.00%
Speer, Sandy[1]	65,468	65,468	-	0.00%

Spilka, R. Edward[2,34]	313,138	313,138	-	0.00%
Starboard Capital Markets, LLC[35]	9,604	9,604	-	0.00%
Starobin Partners[1,36]	110,000	110,000	-	0.00%
Straightline Capital Opportunities Fund I, LLC[2]	750,195	750,195	-	0.00%
Talesnick, Alan L.[2,37]	241,088	241,088	-	0.00%
TCMP3 Partners	319,671	319,671	-	0.00%
Thunderbird Global Corporation[2]	1,021,750	1,021,750	-	0.00%
Total M.I.S., Inc.[2]	560,000	560,000	-	0.00%
Tyson, John[2,38]	16,250	16,250	-	0.00%
Vicis Capital Master Fund[2,39]	5,600,000	5,600,000	-	0.00%
Wachs, Mark[2]	28,219	28,219	-	0.00%
Weiss, Gunther[1]	28,334	28,334	-	0.00%
Westbury Diagnostics, Inc.[2]	144,485	144,485	-	0.00%
TOTALS	**45,846,364**	**40,691,304**	**5,155,060**	

(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.

[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] Provides marketing consulting services to the Company.

[4] Affiliated with Wellfleet Partners.
[5] Affiliated with HC Wainwright, investment banking services.
[6] NASD member.
[7] Affiliated with Midtown Partners & Co., LLC, investment banking services.
[8] Affiliated with Midtown Partners & Co., LLC, investment banking services.
[9] Christopher Eckert is an employee of Smith Barney.
[10] Affiliated with Midtown Partners & Co., LLC, investment banking services.
[11] Affiliated with HC Wainwright, investment banking services.
[12] Affiliated with Wellfleet Partners and Starobin Partners, investment banking services.
[13] Former Director of CDS.
[14] NASD member.
[15] Former President of CDS and Director.
[16] Employee of Midtown Partners & Co., LLC, investment banking services.
[17] Assisted the Company in fundraising.
[18] Form Director of CDS.
[19] Employee of Midtown Partners & Co., LLC, investment banking services.
[20] Affiliated with Wellfleet Partners.
[21] Affiliated with HC Wainwright, investment banking services.
[22] Employee of Midtown Partners & Co., LLC, investment banking services.
[23] Affiliated with Needham & Company, investment banking services.
[24] 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.
[25] 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.
[26] NASD member, assisted the Company in fundraising.
[27] Affiliated with Midtown Partners & Co., LLC, investment banking services.
[28] Employee of Midtown Partners & Co., LLC, investment banking services.
[29] 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.
[30] Registered sales representative with RBC Dain Rauscher.
[31] 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.
[32] Provided marketing consulting services; affiliated with Wellfleet Partners and Starobin Partners.
[33] Assisted the Company in fundraising; employee of Starboard Capital Markets LLC.
[34] Stockholder of Lehman Brothers.
[35] NASD member.
[36] Affiliated with Wellfleet Partners.
[37] Partner at Patton Boggs LLP, our legal counsel.
[38] Provides marketing consulting services.
[39] Affiliated with HC Wainwright, investment banking services.

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

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

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

DIRECTORS, EXECUTIVE OFFICERS AND CONTROL PERSONS

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

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

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

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

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

Mark L. Baum (32), Director. Mr. Baum was elected to our Board of Directors on December 11, 2003. Mr. Baum has more than 11 years experience in creating, financing and growing development stage enterprises in a variety of industries. Mr. Baum has participated in numerous public spin-offs, venture fundings, private-to-public mergers, corporate restructurings, asset acquisitions and asset divestitures. Mr. Baum is a licensed attorney in the State of California and the principal attorney for The Baum Law Firm, a firm which he founded in 1998. Mr. Baum's law practice focuses on securities laws and related issues for small-cap and micro-cap publicly reporting companies. In 2002, Mr. Baum founded Business Consulting Group Unlimited, Inc., a Southern California-based merchant banking firm.

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

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.

Gerald A. Eppner (65), Director. Mr. Eppner was elected to our Board of Directors on March 15, 2005. Mr. Eppner is a partner at Cadwalader, Wickersham & Taft, a law firm based in New York City, New York. Mr. Eppner has experience in domestic and international corporate and securities law matters. Mr. Eppner has been in private practice in New York City since 1966. For more than five years prior to 1966, Mr. Eppner was an employee of certain agencies and departments of the United States government.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table 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 December 31, 2004.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percent of Class
Lawrence Siebert [1] 75 Shady Knoll Drive Stamford, CT 06903	1,846,417	25.35%
Mark Baum [2] 580 2nd Street, Suite 102 Encinitas, CA 92024	1,554,333	20.04%
Avi Pelossof [3] 51A Edgewood Road Port Washington, NY 11050	498,512	6.94%
Javan Esfandiari [4] 1 Bowen Place Stonybrook, NY 11790	117,080	1.67%
Richard Bruce [5] 17 Amalia Lane Comack, NY 11725	75,500	1.08%
Konstantin Lyashchenko [6] 240 Mt. Vernon Pl. Apt#10-0 Newark, NJ 07106	10,500	.15%
All officers and directors as a group[7]	4,102,342	47.81%
Tomas Haendler [8] 31 Cogswell Lane Stamford, CT 06902	602,931	8.49%
Thunderbird Global Corporation [9] c/o The Baum Law Firm 580 2nd Street, Suite 102 Encinitas, CA 92024	467,431	6.77%
Daniel Gressel [10] 460 E. 79th Street, Apt. 17B New York, NY 10021	472,501	6.79%
H.C. Wainwright & Co., Inc. [11]	390,867	5.36%

245 Park Avenue, 44th
Floor
New York, NY 10167

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 2004.

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.

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

(2) Includes 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.

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

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

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

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

(7) Includes footnotes (1)-(6).

(8) Includes 160,000 shares issuable upon exercise of options exercisable within 60 days and 38,197 shares issuable upon exercise of warrants. Does not include 44,450 shares issuable upon conversion of series A preferred stock and 53,334 shares issuable upon the exercise of warrants because conversion of any of those shares of series A preferred stock or exercise of any of those warrants would result in the holder beneficially owning in excess of 4.99% of the then issued and outstanding shares of common stock outstanding at that time.

(9) 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.

(10) Includes 10,000 shares issuable upon exercise of options exercisable within 60 days and 42,065 shares issuable upon exercise of warrants.

(11) Includes 390,867 shares issuable upon exercise of warrants. ZGNY Investments Limited Partnership may be deemed to have voting or investment control over the shares held by H.C. Wainwright & Co., Inc. Bryan Zwan may be deemed to have voting or investment control over ZGNY Investments Limited Partnership.

DESCRIPTION OF SECURITIES

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

Common stock

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

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

Action Stock Transfer acts as our transfer agent and registrar

Series A Preferred Stock

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

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

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

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

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

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

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

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

Redemption. In the event of:

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

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

Upon the occurrence of any of the following events:

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

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

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

Series B Preferred Stock

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

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

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

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

Redemption. In the event of:

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

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

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

General

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

HIV Rapid Tests Commercially Available	**Regulatory Status**	**Partners Involved in the Product**
HIV Rapid Tests (Sure Check™ HIV; HIV 1/2 Stat-Pak; HIV 1/2 Stat-Pak Dipstick). Rapid	We currently qualify under U.S. FDA export regulations to sell, subject to any required approval by the importing country, to customers outside the U.S. To date we have	Thirteen-year supply and technology transfer agreement with FIOCRUZ-Bio-Manguinhos, an affiliate of the Ministry of

Tests for detection of antibodies to HIV 1 and 2 in finger-stick whole blood, venous whole blood, serum and plasma	received approval from a number of potential importing countries, although Brazil is the only country in which we have significant sales. In December 2004 we completed clinical trials for Sure Check™ HIV and HIV 1/2 Stat-Pak in the U.S. for FDA approval for sales in the U.S. with results that we believe will exceed the performance requirements for U.S. FDA approval. We are pursuing FDA approval for these products and on February 17, 2005 we submitted our Pre-Marketing Approval application to the FDA. Our HIV 1/2 Stat-Pak and HIV 1/2 Stat-Pak Dipstick products were also evaluated by the World Health Organization in 2004. In January 2005 we received a final report that confirms that these products meet the performance criteria for inclusion in the WHO Bulk Procurement Scheme, which is a pre-requisite for these products being eligible for procurements from programs funded by the United Nations and their partners' programs. We have also received confirmation from the United States Agency for International Development that our Sure Check™ HIV and HIV 1/2 Stat-Pak have met the criteria for being eligible for procurements pursuant to the President's Emergency Plan for AIDS Relief	Health of Brazil. FIOCRUZ-Bio-Manguinhos will supply product to Brazilian public health market and potentially other markets in the region. Other marketing partners are being actively pursued with a principal focus on those countries that are receiving funding from the United States pursuant to the Presidential Emergency Plan for AIDS Relief and from the United Nations programs and partners.

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

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

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

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

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

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

Lateral Flow Technology

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

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

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

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

Target Market

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

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

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

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

Distribution Channels

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

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

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

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

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

Competition

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

Industry competition in general is based on the following:

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

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

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

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

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

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

Competitive factors specifically related to our HIV tests are product quality, price and ease of use. Product quality for an HIV rapid test primarily means accuracy (sensitivity and specificity), early detection of cases, time elapsed between testing and confirmation of results, and product shelf life. We believe that our HIV 1/2 Stat-Pak, HIV 1/2

Stat-Pak Dipstick, and Sure Check™ HIV rapid tests are very competitive with the best products in the market on the basis of these competitive factors.

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

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

Research and Development

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

We have collaborated with Prionics AG, Zurich, Switzerland since late 2002 to develop and produce certain components of a rapid test for mad cow disease to be marketed by Prionics and/or their distributors under their name. In March 2004 we signed a contract to be one of two contract manufacturers of this product following Prionics' transfer of the completed product know-how to us and approval of the product in Europe. These steps are in process but have not been completed. The contract is for three years, which begins when the product approval is granted in Europe. Although we expected that the technology transfer and European regulatory approval would be completed in 2004, and that initial sales would occur in 2005, we cannot estimate the timing and extent of these events as there are many factors that are beyond our control that could delay this timetable, including delays or changes in regulatory requirements, delays in the technology transfer or changes to the product specifications. In this connection, on February 14, 2005, we entered into a license agreement by which Prionics will license certain technology owned by Chembio. The agreement provides for certain additional milestones for technology transfer which will need to be successfully concluded in order for the Supply Agreement to be maintained in full force and effect, as Prionics has indicated that it needs Chembio's technology in order to complete the know-how transfer in a way such that the product can be manufactured reproducibly.

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

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

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

Our tuberculosis rapid tests for humans are being designed to significantly increase the accuracy of existing tuberculosis screening methods. Our initial tuberculosis test was developed pursuant to a Phase I and II Small Business Innovative Research grant from the National Institute of Health with Public Health Research Institute, Newark, New Jersey that was in place from 1998 until 2002, and our test was completed in 2003. In 1998 we entered into a license agreement with Public Health Research Institute which provides for us to pay a royalty on sales of our antibody detection tuberculosis tests that incorporate any of the antigens covered by the agreement. A study of our serological test for active pulmonary tuberculosis in humans by Sumitomo Seiyaku Biomedical of Japan has shown that sensitivity can increase from 45% to 82% when used in combination with the sputum smear method (the current

standard in high incidence settings), and from 45% to 91% when used with the two-step confirmatory combination of sputum smear and culture testing. However, several other studies have shown less favorable results. We know that serological testing for tuberculosis is very complex and challenging, and we therefore believe that much further testing in a variety of geographic settings will be needed in order to confirm the performance of this test across diverse populations. Our test is being included in an evaluation being conducted by the Institute of Tropical Medicine, Antwerp, Belgium on behalf of the World Health Organization during the first half of 2005. The timing and results of this evaluation cannot be predicted and therefore the timing and extent of any sales that would be derived from this product can also not be estimated at this time.

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

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

The foregoing research and development efforts are summarized below:

Existing or Proposed Product	Regulatory Status	Development Status	Partners involved in the development or marketing of the products
Rapid test for detection of Bovine Spongeiform Encephalopathy, also known as mad cow disease, in cattle	Not yet submitted for approval	Under development	Prionics AG, Zurich, Switzerland
Dental Bacteria Test	Not yet submitted for approval	Phase 2 (Optimization of Test)	Ivoclar-Vivadent, AG, Schaan Liechtenstein
Tuberculosis Stat Pak II- rapid diagnostic test for detection of antibodies to active pulmonary tuberculosis in human whole blood samples	Not yet submitted for approval	Product validation completed	Public Health Research Institute and Statens Serum Institute
TBD Non-Human Primate Rapid Tuberculosis Test for the detection of antibodies to active pulmonary tuberculosis in non-human primate whole blood samples	Not yet submitted for approval	Product validation completed	Sequella Corporation, Rockville, Maryland
Combination HIV/Tuberculosis Rapid Test for the detection of antibodies to active pulmonary tuberculosis and HIV in human whole blood samples using different color latex test lines	Not yet submitted for approval	Initial Prototype	None
New Generation HIV Test	Not yet submitted for approval	Initial Prototype	None
Cerebral Spinal Fluid Leak Test	Not yet submitted for approval	Initial R&D on Monoclonal Antibodies	State University of New York at Stony Brook

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

Research & Development Expenditures

Employees

At December 31, 2004, we employed 60 people, including 58 full-time employees. In May 2004, we entered into employment agreements with Lawrence Siebert, President and Chairman, Avi Pelossof, VP Sales, Marketing and Business Development, and Javan Esfandiari, Director of research and development. We also entered into an employment agreement with Mark L. Baum, a member of our board of directors, to provide advice and guidance with respect to management, marketing, strategic planning, corporate structure, business operations, expansion of services, acquisitions and business opportunities, matters related to our public reporting obligations, and our overall needs.

Governmental Regulation

All of Chembio's existing and proposed diagnostic products are regulated by the FDA, U.S. Department of Agriculture, certain state and local agencies, and/or comparable regulatory bodies in other countries. This regula