CHEMBIO DIAGNOSTICS, INC.
Form SB-2
June 17, 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.
Patton Boggs LLP
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. o

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. o

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. o

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. o

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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)	8,158,530	$.60	$4,895,118	$577

(1) Estimated solely for purposes of calculating the registration fee in accordance with Rule 457(c) under the Securities Act of 1933, as amended (the "Act"), based on the average of the bid and ask prices for the Registrant's common stock as reported on the OTC Bulletin Board on June 15, 2005.

(2) Represents shares of common stock registered for resale by the holders (the "Selling Stockholders") of shares of 9% Series B Convertible Preferred Stock consisting of (i) 2,353,423 shares of common stock that may be issued to pay semi-annual dividends to the Selling Stockholders, and (ii) 5,805,107 shares of common stock that may be issued to the Selling Stockholders under the anti-dilution provisions of the 9% Series B Convertible Preferred Stock.

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

EXPLANATORY NOTE

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

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

SUBJECT TO COMPLETION, DATED JUNE 17, 2005

PROSPECTUS

CHEMBIO DIAGNOSTICS, INC.

48,624,834 SHARES OF COMMON STOCK

This prospectus relates to the sale by certain stockholders of Chembio Diagnostics, Inc. of up to 48,624,834 of our common stock which they own, or which they may at a later date acquire upon the conversion of shares of our 8% series A convertible preferred stock, upon the conversion of shares of our 9% series B convertible preferred stock, upon the exercise of warrants and options to purchase shares of our common stock, or as payments of semi-annual dividends on our 9% series B convertible preferred stock.

Our common stock is quoted on the OTC Bulletin Board under the symbol "CEMI." On June 15, 2005 the closing bid and ask prices for one share of our common stock were $.56 and $.60, 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 marketing efforts for distribution of our Chagas disease rapid test and efforts to complete development of, and proceed to seek regulatory approval for, rapid tests for human and veterinary tuberculosis.

Our main products and products under development are summarized 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 ("PMA") to the FDA. Based upon recent correspondence with the FDA we expect to have an "approvable" PMA in July and for our facility inspection to be completed during the third quarter. Facility inspection is the main remaining step we have in achieving FDA approval. 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	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. We have hired an individual to direct our sales and marketing efforts in East Africa who will be based in that region and whose efforts will be primarily aimed toward participating in what we believe will be a substantial increase in demand for our HIV rapid tests from the PEPFAR program. We are in discussions with a number of other groups and individuals to assist us in our marketing efforts in markets that we have focused on in Africa.

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.

Existing or Proposed Product	Regulatory Status	Development Status	Partners Involved in the Development or Marketing of the Products
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 have no plans for seeking regulatory approval in these markets.	Product validation completed.	Public Health Research Institute, Newark, NJ, and Staten Serum Institute have provided research collaboration on product development.

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.

Existing or Proposed Product	Regulatory Status	Development Status	Partners Involved in the Development or Marketing of the Products
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.

Until recently we also had an ongoing development project for a rapid test for Mad Cow Disease in collaboration with Prionics AG, including a Manufacturing and Supply Agreement entered into in 2004 and a License Agreement entered into in February of 2005 for certain technology that Prionics desired to incorporate into the product. However, Prionics was required to transfer product specifications to Chembio and to date has not been willing and/or able to do so, thereby putting the outcome of this project in substantial doubt at this time.

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. We have recently filed for two lateral flow patents that we believe may insulate us if we can successfully develop products incorporating the patent claims.

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

The Offering

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

As of June 1, 2005, we had 7,673,418 shares of common stock issued and outstanding, which includes shares offered by this prospectus. The number of outstanding shares of common stock does not give effect to common stock which may be issued pursuant to the conversion of our series A and B preferred stocks and the exercise of options and/or warrants previously issued by Chembio Diagnostics, Inc.

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

Summary Financial Data

The following table presents summary historical financial information for the fiscal quarter ended March 31, 2005, as well as the fiscal years ended December 31, 2004 and 2003. The financial statements are set forth beginning on page F-1 of this prospectus, and you should read this information for a more complete understanding of the presentation of this information. 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. The Series B Private Placement financing is reflected in the financial statements for the three months ended March 31, 2005.

	Three Months Ended March 31, 2005 (Unaudited)	Year Ended December 31, 2004	Year Ended December 31, 2003
Revenue	731,885	3,305,932	2,818,351
Operating Expenses	890,811	3,923,701	1,516,076
Net Loss	(619,986)	(3,098,891)	(1,059,074)
Current Assets	4,766,750	1,211,060	772,680
Total Assets	5,135,090	1,426,449	1,086,745
Current Liabilities	1,278,191	1,663,196	1,503,418
Total Liabilities	1,525,926	1,950,413	3,544,186
Convertible Redeemable Preferred	5,783,793	2,427,030	-
Stockholders' Deficit	(2,174,629)	(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 at least through the third quarter of 2005. We anticipate this based upon our recently completed operating budget which assumes significant new expenditures this year that are intended to help us increase revenues and cash flow, and to achieve a variety of other corporate objectives that are aimed to increase shareholder value. The Company is considering alternatives to provide for its capital requirements for late 2005 and beyond. There are no assurances that it will be successful in raising sufficient capital. 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 Vice President of R&D, Javan Esfandiari, and our Vice President of Sales, Marketing, and Business Development, Avi Pelossof. Due to the specific knowledge and experience of these executives regarding the industry, technology and market, the loss of the services of any one of them would likely have a material adverse effect on the Company. The contract with Mr. Siebert has a term of two years ending May 2006, and the contracts with Messrs. Esfandiari and Pelossof have terms of three years ending May 2007. We have obtained key man insurance policies for Messrs. Esfandiari and Pelossof.

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

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

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

Since the inception of Chembio Diagnostic Systems, Inc. in 1985 and through the period ended December 31, 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 31,000 shares per day over the three months ended June 1, 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 40,798,309. If the selling stockholders sell significant amounts of our stock, our stock price could drop. Even a perception by the market that selling stockholders will sell in large amounts after the registration statement is effective could place significant downward pressure on our stock price.

You will experience substantial dilution upon the conversion of the shares of preferred stock and the exercise of warrants that we issued in 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 former member of our board of directors, to purchase 425,000 shares and 425,000 shares of our common stock, respectively, at exercise prices of $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 May 19, 2005, there were 1,169,000 options issued and outstanding under the stock option plan and 331,000 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. If any of the shares registered are not issued as dividends, or under the anti-dilution provisions, to the holders of the series B preferred stock, we will not sell these shares to third parties and will de-register those shares.

DILUTION

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

SELLING SECURITY HOLDERS

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

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

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

to non-employee third parties for services performed, together with 375,000 options to purchase shares issued to employees and directors.

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

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

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

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

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

- the number of shares of common stock beneficially owned as of June 2, 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 (C)	Number of Shares of Common Stock Owned Before Offering (A)	Number of Shares To Be Offered (B)	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] [3]	1,253,819	1,232,000	21,819	0.25%
Bassett, Truman [1]	42,526	42,526	—	0.00%
Baum, Mark L. [2]	1,796,963	1,792,666	4,297 &	