

CHEMBIO DIAGNOSTICS, INC.

Form 424B3

February 06, 2007

**Table of Contents**

Filed Pursuant to Rule 424(b)(3)  
Registration Statement on Form SB-2  
File No. 333-138266

**PROSPECTUS  
CHEMBIO DIAGNOSTICS, INC.  
20,008,319 SHARES OF COMMON STOCK**

This prospectus relates to the sale by certain stockholders of Chembio Diagnostics, Inc. of up to 20,008,319 shares of our common stock which they own, or which they may at a later date acquire upon the conversion of shares of our 9% series B convertible preferred stock, upon the conversion of shares of our 7% series C convertible preferred stock, upon the exercise of warrants to purchase shares of our common stock, as payments of semi-annual dividends on our 9% series B convertible preferred stock and our 7% series C senior convertible preferred stock, upon the trigger of the anti-dilution provisions of the 9% series B convertible preferred stock, the warrants related to the debentures issued June 29, 2006 and the 7% series C senior convertible preferred stock. In this prospectus, we refer to these persons as the selling security holders.

Our common stock is quoted on the OTC Bulletin Board under the symbol CEMI. On January 12, 2007 the closing bid and ask prices for one share of our common stock were \$0.69 and \$0.73, 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 2 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 February 6, 2007

---

**TABLE OF CONTENTS**

<u>Prospectus Summary</u>	1
<u>Risk Factors</u>	2
<u>Use of Proceeds</u>	8
<u>Dilution</u>	8
<u>Selling Security Holders</u>	9
<u>Plan of Distribution</u>	11
<u>Legal Proceedings</u>	12
<u>Directors, Executive Officers and Control Persons</u>	12
<u>Security Ownership of Certain Beneficial Owners and Management</u>	14
<u>Description of Securities</u>	16
<u>Description of Business and Organization</u>	20
<u>Cautionary Statement Regarding Forward-Looking Statements</u>	31
<u>Management's Discussion and Analysis and Plan of Operation</u>	31
<u>Description of Property</u>	40
<u>Certain Relationships and Related Transactions</u>	40
<u>Market for Common Equity and Related Stockholder Matters</u>	42
<u>Executive Compensation</u>	43
<u>Financial Statements</u>	47
<u>Experts</u>	48
<u>Legal Matters</u>	48
<u>Disclosure of Commission Position of Indemnification for Securities Act Liabilities</u>	48
<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	48
<u>Additional Information</u>	48

---

**Table of Contents**

**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. On May 25, 2006 we received regulatory approval from the Food and Drug Administration (the FDA ) of two pre-market applications for rapid HIV tests. One pre-market application approval was for our SURE CHECK® HIV 1/2, which incorporates the proprietary barrel technology; the other pre-market application approval was for our HIV 1/2 STAT PAK® rapid HIV test in a cassette format. We also have a third rapid HIV test, HIV 1/2 STAT PAK Dipstick that is only sold outside of the U.S. Applications for Clinical Laboratory Improvement Act waivers for these two FDA-approved tests have since been submitted to the FDA, and a CLIA waiver was granted by the FDA for HIV 1/2 STAT PAK on November 20, 2006. The CLIA waiver application for the SURE CHECK® HIV 1/2 is currently pending.

During 2005 and 2006 year to date, we have had significant increases in sales of our rapid HIV tests to international customers. The majority of these sales have been to an agency of the Brazilian government, and for programs in Africa funded by major bi-lateral and multi-lateral programs, particularly the President's Emergency Plan for AIDS Relief. On September 29, 2006, we executed marketing and license agreements with Inverness Medical Innovations, Inc., pursuant to which Inverness will exclusively market both FDA approved products in the U.S., and SURE CHECK HIV 1/2, globally. Through these agreements, we have also received from Inverness a non-exclusive license to all of their lateral flow intellectual property for certain product lines we have and/or are developing. We also are focused on (1) marketing efforts to expand distribution of our Chagas disease rapid test; (2) efforts to complete development of, and to complete regulatory approval for our rapid tests for the detection of tuberculosis in a number of animal species; and (3) development of a number of other rapid test applications using our patent-pending Dual Path Platform (DPP ) technology, including an oral fluid rapid HIV test and a human tuberculosis test.

Our main products are as follows:

HIV Rapid Tests: HIV 1/2 STAT-PAK® Cassette, HIV 1/2 SURE CHECK® and HIV 1/2 STAT-PAK® Dipstick

Chagas Rapid Test: Chagas STAT-PAK

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

We also are in the process of developing rapid tests employing our patent-pending Dual Path Platform (DPP ) technology including, but not limited to an oral fluid rapid HIV test and a human tuberculosis test.

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, whether single or dual path, 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 a strip downstream from either the point of application of the sample or of another reagent. 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 held by Inverness and Abbott Laboratories, Inc. and to reagents including those that are used in our HIV rapid tests. These licenses do not necessarily insulate us from patent

challenges by other patent holders. We have filed applications for two lateral flow patents that incorporate features that we believe may further protect us from patent challenges. On January 16, 2007, the Company received notice that it is to receive a Notice of Allowance from the United States Patent & Trademark Office which substantially increases the likelihood that a patent for DPP will be issued.

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

**The Offering**

By means of this prospectus, a number of our stockholders are offering to sell up to 172,082 shares of common stock which they own, up to 9,976,433 shares of common stock which they may at a later date acquire upon the conversion of our series B and/or

**Table of Contents**

series C preferred stock, up to 3,027,617 shares of common stock which they may at a later date acquire upon the exercise of warrants, up to 2,808,145 shares of common stock which they may at a later date acquire as dividends payable semi-annually on the series B and series C preferred stock, up to 3,868,042 shares of common stock which they may at a later date acquire pursuant to the anti-dilution provisions of the series B and series C preferred stock and up to 156,000 shares of common stock which they may at a later date acquire pursuant to the anti-dilution provisions of the debenture warrants. In this prospectus, we refer to these persons as the selling security holders.

As of January 31, 2007 we had 11,692,540 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, B and C 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 or series C 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 nine months ended September 30, 2006 and the fiscal years ended December 31, 2005 and 2004. The financial statements are set forth beginning on page F-1 of this prospectus, and you should read those financial statements for a more complete understanding of the following information.

	<b>For the Nine months Ended September 30, 2006</b>	<b>Year Ended December 31, 2005</b>	<b>Year Ended December 31, 2004</b>
Revenue	\$ 3,893,093	\$ 3,940,730	\$ 3,305,932
Operating Expenses	\$ 4,803,084	4,630,133	3,807,447
Net Loss	\$ (3,965,076)	(3,252,000)	(3,098,891)
Current Assets	\$ 5,612,940	2,468,193	1,211,060
<b>Total Assets</b>	<b>\$ 6,587,101</b>	<b>3,016,406</b>	<b>1,426,449</b>
Current Liabilities	\$ 3,776,304	1,818,474	1,663,196
<b>Total Liabilities</b>	<b>\$ 4,341,716</b>	<b>1,963,703</b>	<b>1,950,413</b>
<b>Convertible Redeemable Preferred</b>	<b>\$ 3,143,415</b>	n/a	<b>2,427,030</b>
<b>Stockholders Equity (Deficit)</b>	<b>\$ (898,030)</b>	<b>1,052,703</b>	<b>(2,950,994)</b>

**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 U.S. by the U.S. Food and Drug Administration, the U.S. 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.

## **Table of Contents**

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, and 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 , 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.

We are developing an oral fluid rapid HIV test as well as other applications utilizing our Dual Path Platform technology which we believe could enhance our competitive position in HIV rapid testing and other fields. However, we have not completed development of any DPP product, and we still have technical, manufacturing, regulatory and marketing challenges to meet before we will know whether we can successfully commercialize products incorporating this technology. There can be no assurance that we will overcome these challenges.

We have granted Inverness exclusive rights to market our SURE CHECK® HIV 1/2 globally and our HIV 1/2 STAT PAK® in the U.S. Inverness has no rapid HIV tests that are approved for marketing in the U.S., we are not aware of any rapid HIV products that Inverness is even contemplating for the U.S., and Inverness is obligated to inform us of any such products as soon as it is able to do so. Inverness does have rapid HIV tests manufactured by certain of its subsidiaries outside the U.S. that are being actively marketed outside the U.S., primarily in developing countries. Our HIV 1/2 STAT PAK cassette and dipstick products compete against these Inverness Products, and we specifically



acknowledge in our agreements with Inverness the existence of such other products. Moreover, except for a product in the HIV barrel field as defined in our agreement with Inverness, Inverness is permitted under our agreements to market certain types of permitted competing rapid HIV tests in the U.S. Under these conditions, we could choose to terminate the applicable agreement with Inverness or change the agreement to a non-exclusive agreement, and Inverness would expand the lateral flow license granted to the Company to allow the Company to market the product independently or through other marketing partners. While we believe that Inverness is committed to successfully marketing our products particularly in the U.S. and other developed countries where our products are or become approved for

## **Table of Contents**

marketing, Inverness may choose to develop or acquire competing products for marketing in the U.S. as well as other markets where they are marketing our SURE CHECK HIV 1/2 product, and such an action could have at least a temporary material adverse effect on the marketing of these products until such time as alternative marketing arrangements could be implemented. While we also believe that the expansion of our license to the Inverness lateral flow patents substantially facilitates our ability to make alternative marketing arrangements, there can be no assurance that the modification of marketing arrangements and the possible corresponding delays or suspension of sales would not have a material adverse effect on our business.

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.

**We own no issued patents covering lateral flow technology, and the field of lateral flow technology is complex and characterized by a substantial amount of litigation, so the risk of potential patent challenges is ongoing for us in spite of our pending patent applications.**

Although we have been granted non-exclusive licenses to lateral flow patents owned by Inverness Medical Innovations, Inc. and Abbott Laboratories, Inc., there is no assurance that their lateral flow patents will not be challenged or that licenses from other parties may not be required, if available at all. In the event that it is determined that a license is required and it is not possible to negotiate a license agreement under a necessary patent, we may be able to modify our HIV rapid test products and other products such that a license would not be necessary. However, this alternative could delay or limit our ability to sell these products in the U.S. and other markets, which would adversely affect our results of operations, cash flows and business.

During 2005 and 2006, the Company has made substantial additions to its intellectual property portfolio as a result of the development of a new rapid test platform, Dual Path Platform (DPP ). This platform has shown improved sensitivity as compared with conventional platforms in a number of preliminary studies using well characterized HIV, Tuberculosis and other samples. This technology has formed the basis of two patent applications that were filed, and may result in additional applications covering additional uses of this technology platform. On January 16, 2007, the Company received notice that it is to receive a Notice of Allowance from the United States Patent & Trademark Office which substantially increases the likelihood that a patent for DPP will be issued. Also, the Company believes that this new lateral flow platform is outside of the scope of currently issued patents in the field of lateral flow technology, thereby offering the possibility of a greater freedom to operate. There is no assurance that the patent application will be granted, or that its claims will not be modified upon review, or that the Company's patents or its products incorporating the patent claims will not be challenged at some time in the future.

**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. In the U.S. and other developed world markets where we will begin to market our FDA-approved products through Inverness and through other partners, 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.

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

Although the Company's revenues and gross margins increased significantly in recent periods, it sustained significant operating losses in the first nine months of 2006 and the years 2005 and 2004. At September 30, 2006, the Company had a Stockholders' Deficiency of \$898,030, and a working capital surplus of \$1,836,636. Including the funds received from the Series C 7%

## Table of Contents

Convertible Preferred Stock offering, (the Series C Offering see below), the Company believes its resources are sufficient to fund its needs through the end of 2007. The Company's liquidity and cash requirements will depend on several factors. These factors include: (1) the level of revenue growth; (2) the extent to which, if any, that revenue growth improves operating cash flows; (3) its investments in research and development, facilities, marketing, regulatory approvals and other investments it may determine to make; and (4) the investment in capital equipment and the extent to which it improves cash flow through operating efficiencies. If the Company's resources are not sufficient to fund its needs through 2007, there are no assurances that the Company will be successful in raising sufficient capital.

On March 30, 2006, the Company sold \$1 million of additional Series B Preferred stock to a Series B Preferred shareholder pursuant to provisions of the January 2005 Series B 9% Preferred Stock financing agreements. Such provisions were exclusive to said shareholder.

On June 29, 2006, the Company borrowed \$1,300,000. The loan was repaid in part on September 27, 2006 and the balance converted on October 5, 2006 and is secured by a lien on the assets of the Company. See Note 1 of the financial statements for further details.

On September 29, 2006 and October 5, 2006 the Company completed the Series C Offering for \$8,150,000. Some of the proceeds were used to repay the loan borrowed on June 29, 2006. This Series C offering will be enough to supply the Company's cash needs through the end of 2007.

**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 or foreign patents, although we have several license agreements for reagents. Our Sure Check trademark has been registered in the U.S.

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 U.S. 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

**Table of Contents**

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 U.S., we may be restricted from manufacturing a rapid HIV-2 test in the U.S. 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 and our Vice President of Research and Development, Javan Esfandiari. Due to the specific knowledge and experience of these executives regarding the industry, technology and market, the loss of the services of either 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 2008, and the contract with Mr. Esfandiari has a term of three years ending May 2007. We have obtained a key man insurance policy for Mr. Esfandiari.

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

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

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

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

We expect to continue to make substantial expenditures for sales and marketing, regulatory submissions, product development and other purposes. Our ability to achieve profitability in the future will primarily depend on our ability

to increase sales of our products, reduce production and other costs and successfully introduce new products and enhanced versions of our existing products into the marketplace. If we are unable to increase our revenues at a rate that is sufficient to achieve profitability, our operating results would be materially harmed.

**Table of Contents**

**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 33,000 shares per day over the three months ended December 31, 2006. If limited trading in our stock continues, it may be difficult for investors to sell their shares in the public market at any given time at prevailing prices. Since the certificates of designation creating our series A and series B preferred stock contain restrictions on our ability to declare and pay dividends on our common stock, the lack of liquidity of our common stock could negatively impact the rate of return on your investment.

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

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

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

On May 5, 2004, we completed three separate private placements in which we issued 151,579.84 shares of our series A preferred stock and warrants to acquire 9,094,801 shares of our common stock at an exercise price of \$.90 per share. The shares of series A preferred stock are convertible into 7,578,985 shares of our common stock. We also issued warrants to purchase 425,000 shares of our common stock at an exercise price of \$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 March 31, 2006,

**Table of Contents**

there were 1,529,750 options issued and outstanding under the stock option plan and 1,470,250 options available for issuance under the stock option plan. As a result, the conversion of the outstanding preferred stock and the exercise of the outstanding warrants and options will result in substantial dilution to the holders of our common stock.

On March 30, 2006, we issued to an investor 20 shares (face amount \$1,000,000) of the Company's series B preferred stock with warrants to purchase a total of 1,557,377 shares of Company's common stock at an exercise price of \$0.61 per share for a period of five years. The Company agreed to issue, and the investor agreed to purchase for \$1,000,000, the securities described above pursuant to the terms of a Securities Purchase Agreement dated January 26, 2005 by and among the Company and various purchasers. This transaction represents the second closing under the Agreement, and was triggered upon the Company's achieving, as of the fourth fiscal quarter of 2005, certain financial milestones. As compensation for services rendered to the Company by Midtown for the second closing, the Company agreed to issued to Midtown two shares (face amount \$100,000) of its Series B Preferred and warrants to purchase a total of 155,738 shares of its Common Stock at an exercise price of \$.061 per share for a period of five years.

On June 29, 2006, we issued \$1,300,000 of secured debentures to four investors. Pursuant to the terms of these debentures, investors agreed to receive back from the Company the full amount of their principal investment, plus interest on the unpaid principal sum outstanding at the rate of 0.667% per month. Each investor was also granted a warrant to purchase up to 400 shares of common stock for each \$1,000 of such investor's subscription amount, with an exercise price of \$0.75 per share, exercisable for a five year term.

On September 29, 2006 and October 5, 2006, we completed a private placement for \$8,150,000, consisting of 165 shares of 7% series C convertible preferred stock, which we refer to as the Series C Stock, together with warrants to purchase 2,578,125 shares of our common stock. For each \$0.80 of consideration received, an investor received (a) \$0.80 of face amount of series C stock, which shall pay cumulative dividends in cash or shares at the rate of 7% per annum payable semiannually beginning in the year 2007, and which is convertible into one share of the common stock, and (b) a five-year warrant to acquire shares of our common stock, equal to 25% of the investor's subscription amount divided by \$0.85, with an exercise price of \$1.00 share. Each full share of the Series C Stock was purchased for \$50,000, with fractional shares of series C preferred stock being purchased by investments of less than \$50,000. In connection with this private placement, we employed Midtown Partners & Co., LLC to serve as the placement agent with respect to investors investing \$1,000,000 in this offering. As compensation for services rendered to the Company, we agreed to (i) pay Midtown a cash fee equal to 5% of the amount of cash proceeds the Company received from the investors Midtown solicited, and (ii) issue to Midtown warrants to purchase 62,500 shares of our common stock. The warrants issued to Midtown are exercisable for a period of five years from their issuance and have an exercise price of \$1.00 per share.

**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 January 31, 2007, our named executive officers, directors and 5% stockholders beneficially owned approximately 25.85% 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 or the Series C 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 the Company. As such, there is no dilution resulting from the common stock to be sold in this offering.

**Table of Contents****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 the Description of Securities section: Common stock, series B preferred stock which is convertible into common stock at \$.61 per share, series C preferred stock which is convertible into common stock at \$.80 per share, or warrants to purchase common stock exercisable at prices ranging from \$0.55 per share to \$1.00 per share. However, the table below assumes the immediate conversion by series B and series C preferred stock into common stock and the immediate exercise of all warrants to purchase common 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 172,082 shares of our common shares now owned by them, 163,933 shares issuable to them upon the conversion of series B preferred stock that they hold, 9,812,500 shares issuable to them upon the conversion of series C preferred stock that they hold, 3,027,617 shares issuable to them upon the exercise of warrants 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.

The holders of the series B preferred stock may sell pursuant to this prospectus up to an aggregate of (i) 73,770 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) 118,042 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 below in section Description of Securities Series B Preferred Stock. These shares are not included in the table below.

Further, the holders of the series C preferred stock may sell pursuant to this prospectus up to an aggregate of (i) 2,734,375 shares of common stock which they may at a later date acquire as dividends payable semi-annually on the series C preferred stock, and (ii) 3,750,000 shares of common stock which they may at a later date acquire pursuant to the anti-dilution provisions of the series C preferred stock, as described below in section Description of Securities Series C Preferred Stock. These shares are not included in the table below.

In addition, the holders of the Company's Secured Debentures dated June 29, 2006, may sell pursuant to this prospectus up to an aggregate of (i) 520,000 shares of common stock which they may at a later date acquire if they exercise warrants to purchase common stock at an exercise price of \$0.75 per share, and (ii) 156,000 shares of common stock which they may at a later date acquire pursuant to the anti-dilution provisions of these secured debentures.

On March 30, 2006, the Company issued an investor 20 shares of its series B preferred stock. In connection with this issuance, the Company also issued this investor warrants to purchase a total of 1,557,377 shares of the Company's common stock at an exercise price of \$0.61 per share for a period of five years. These series B preferred shares are convertible into 1,639,340 shares of common stock, which the investor may sell pursuant to this prospectus, and the holder may also sell up to 1,557,377 shares of Company's common stock issuable to them upon the exercise of the warrants that they hold. In addition, as compensation for services rendered to the Company for this private placement, the Company issued the placement agent two shares of the Company's series B preferred shares, as well as warrants to purchase the Company's common stock. These series B preferred shares are convertible into 163,933 shares of common stock, which the placement agent may sell pursuant to this prospectus, and the placement agent may sell up to 155,738 shares of the Company's common stock, which it may acquire pursuant to the warrants it was granted. These warrants are exercisable at an exercise price of \$.061 per share for a period of five years.

Certain of the entities or individuals listed below acquired the shares offered hereby in connection with our September 29, 2006 private placement of series C preferred stock. Pursuant to this private placement; we received \$8,150,000 in cash as payment for (a) 165 shares of preferred stock that are convertible into 10,312,500 shares of common stock, and (b) warrants to acquire 2,578,125 shares of common stock at an exercise price of \$1.00 per share. Based on the \$50,000 paid per series C preferred share, the purchase price per common share is \$0.80, 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 45 days after

September 29, 2006, a registration statement with the SEC covering the resale of the shares of common stock issuable upon conversion of the series C preferred stock and the shares of common stock issuable upon exercise of the warrants. In the event this registration statement is not declared effective by the SEC within 120 days of September 29, 2006 (within 150 days of such date in the event of a full review by the SEC), then we will be subject to the payment of liquidated damages equal to 1% of the aggregate purchase price we received from each respective subscriber. \$600,245 of the private placement resulted from conversion of previously outstanding convertible debt of the Company. Based on the terms of the previously outstanding convertible debt, the \$600,245 of debt was converted at a discount of 12.5% to the price paid by the other investors.

Certain of the entities or individuals listed below acquired the shares offered hereby in connection with our June 29, 2006 Secured Debenture offering which raised \$1,300,000. Pursuant to the terms of these debentures, each investor was granted a warrant to

**Table of Contents**

purchase up to 400 shares of common stock for each \$1,000 of such investor's subscription amount, with an exercise price of \$0.75 per share, and exercisable for a five year term.

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 January 31, 2007 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 <sup>(C)</sup>	Number of Shares of Common Stock		Number of Shares Owned After Offering	Percentage of
	Owned Before Offering <sup>(A)</sup>	Number of Shares To Be Offered <sup>(B)</sup>		Shares of Common Stock Owned After Offering
Alpha Capital AG <sup>1</sup>	2,057,539	746,875	1,310,664	10.11%
Big Bend XXXI Investments, LP	2,343,750	2,343,750		0.00%
Bristol Investment Fund, Ltd.	160,000	160,000		0.00%
Bushido Capital Master Fund, LP	1,171,875	1,171,875		0.00%
C.E. Unterberg, Towbin Capital Partners I, L.P.	666,875	666,875		0.00%
Bio-Business Science & Development LTDA	294,340	252,923	41,417	0.35%
Cranshire Capital, LP	390,625	390,625		0.00%
Crestview Capital Master, LLC <sup>2</sup>	16,572,249	2,000,000	14,572,249	57.61%
Ferrari, Braden	1,875	1,875		0.00%
Frankenthal, Stuart J.	234,375	234,375		0.00%
Howard M. Rossman Revocable Trust	234,375	234,375		0.00%
Imas, Ariel	2,500	2,500		0.00%
Inverness Medical Innovations, Inc.	3,125,000	3,125,000		0.00%
Investor Relations Group	288,750	255,414	33,336	0.28%
Iroquois Master Fund, Ltd.	40,000	40,000		0.00%
Jordan, Bruce <sup>3</sup>	107,006	35,092	71,914	0.61%

- (A) Includes shares underlying series A, series B and series C preferred stock into which the series A, series B and series C preferred stock is convertible, and shares underlying warrants and/or options held by the selling security holder that are covered by this prospectus, including any convertible securities that, due to contractual restrictions, may not be exercisable within 60 days of the date of this prospectus.
- (B) The number of shares of common stock to be sold assumes that the selling security holder elects to sell all the shares of common stock held by the selling security holder that are covered by this prospectus.
- (C) It is our understanding that any selling security holder

that is an affiliate of a broker-dealer purchased the securities offered hereunder in the ordinary course of business, and at the time of the purchase, had no agreements or understanding to distribute the securities.

- <sup>1</sup> Konrad Ackerman has ultimate control over Alpha Capital AG and the shares held by Alpha Capital AG.
- <sup>2</sup> Affiliated with Dillion Capital, a NASD member. Robert Hoyt has ultimate control over Crestview Capital Master, LLC and the shares held by Crestview Capital Master, LLC.
- <sup>3</sup> Employee of Midtown Partners & Co., LLC, investment banking services.



**Table of Contents**

	Number of Shares of Common Stock		Number of Shares Owned After Offering	Percentage of Shares of Common Stock Owned After Offering
	Owned Before Offering (A)	Number of Shares To Be Offered (B)		
<b>Selling Security Holders (C)</b>				
Kreger, Richard H. <sup>3</sup>	650,821	165,160	485,661	3.94%
Longview Fund, LP	781,250	781,250		0.00%
Midtown Partners & Co., LLC <sup>4</sup>	203,402	73,309	130,093	1.09%
Pierce Diversified Strategy Master Fund, LLC Series BUS	390,625	390,625		0.00%
RHK Midtown Partners LLC	8,333	8,333		0.00%
Rohan, J. Rory <sup>3</sup>	580,643	95,901	484,742	3.96%
<b>TOTALS for SB-2</b>	<b>30,306,208</b>	<b>13,176,132</b>	<b>17,130,076</b>	

**PLAN OF DISTRIBUTION**

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

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

settlement of short sales entered into after the date of this prospectus;

broker-dealers may agree with the Selling Stockholders to sell a specified number of such shares at a stipulated price per share;

a combination of any such methods of sale;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise; or

any other method permitted pursuant to applicable law.

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

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

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

<sup>4</sup> NASD member, assisted the Company in fundraising.

## **Table of Contents**

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. 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.

### **DIRECTORS, EXECUTIVE OFFICERS AND CONTROL PERSONS**

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

**Richard J. Larkin (50)**, 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.

**Table of Contents**

Mr. Larkin holds a BBA in Accounting from Dowling College and is a member of the American Institute of Certified Public Accountants.

**Avi Pelossof (44)**, 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.

Mr. Pelossof voluntarily resigned from the Company on December 6, 2006, effective January 31, 2007.

**Javan Esfandiari (40)**, Director of Research and Development. Mr. Esfandiari joined Chembio Diagnostic Systems, Inc, in 2000. Mr. Esfandiari co-founded, and became a co-owner of Sinovus Biotech AB where he served as Director of Research and Development concerning lateral flow technology until Chembio Diagnostic Systems Inc. acquired Sinovus Biotech AB in 2000. From 1993 to 1997, Mr. Esfandiari was Director of Research and Development with On-Site Biotech/National Veterinary Institute, Uppsala, Sweden, which was working in collaboration with Sinovus Biotech AB on development of veterinary lateral flow technology. Mr. Esfandiari received his B.Sc. in Clinical Chemistry and his M. Sc. in Molecular Biology from Lund University, Sweden. He has published articles in various veterinary journals and has co-authored articles on tuberculosis serology with Dr. Lyashchenko.

**Richard Bruce (52)**, Vice President, Operations. Mr. Bruce was hired in April 2000 as Director of Operations. He is responsible for manufacturing, maintenance, inventory, shipping, receiving, and warehouse operations. Prior to joining Chembio Diagnostic Systems Inc., he held director level positions at Wyeth Laboratories from 1984 to 1993. From 1993 to 1998, he held various management positions in the Operations department at Biomerieux. From 1998 to 2000, he held a management position at V.I. Technologies. Mr. Bruce has over 25 years of operations management experience with Fortune 500 companies in the field of in-vitro diagnostics and blood fractionation. Mr. Bruce received his BS in Management from National Louis University in 1997.

**Les Stutzman (54)**, VP of Marketing. In 2005, Mr. Stutzman joined Chembio as Vice President of Marketing to lead the development and launch of rapid tests for veterinary and human TB and other veterinary products. Mr. Stutzman has spent over twenty years in marketing leadership positions within various diagnostics companies. He has held Global Director and Business Development Director positions in Marketing for diagnostic companies including bioMérieux Inc., (formerly Organon Teknika Corp.), Durham, North Carolina from 1997 to 2002 and TREK Diagnostic Systems, Cleveland, Ohio from 2002 to 2005. Mr. Stutzman received his MBA in Marketing from Duke University Fuqua School of Business in 1988 and his Masters in Microbiology from Wagner College in 1982. Mr. Stutzman is MT (ASCP) SM certified.

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

**Alan Carus, CPA (67)**, Director, Audit Committee chair. Mr. Carus was elected to Chembio s Board of Directors on April 15, 2005. He is a co-founder of LARC Strategic Concepts LLC, a consulting firm dedicated to guiding emerging companies to next stage development. Prior to co-founding LARC Strategic Concepts LLC, Mr. Carus was Senior Vice President of Maritime Overseas Corporation ( MOC ) and a senior executive of Overseas Ship holding Group, Inc. ( OSG ) from 1981 to 1998 when he retired. MOC was managing agent for OSG, one of the world s largest ship-owners. He was a member of OSG s senior management committee and had senior responsibility in areas relating to administration, accounting, tax, finance, budgets, long-range projections, and human resources. Mr. Carus was involved in numerous acquisitions, debt and equity offerings, complex transaction structuring, and was active in the

management of OSG's major investments in the cruise industry and other development stage companies. From 1964 to 1981, he was with Ernst & Young (including predecessors), the last seven years as a partner. Mr. Carus has a B.B.A. from the Baruch School of Business of the City College of New York.

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

**Table of Contents****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 January 31, 2007.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percent of Class
Lawrence Siebert <sup>(2)</sup> 3661 Horseblock Road Medford, NY 11763	2,141,919	17.77%
Avi Pelosof <sup>(3)</sup> 3661 Horseblock Road Medford, NY 11763	650,113	5.43%
Javan Esfandiari <sup>(4)</sup> 3661 Horseblock Road Medford, NY 11763	229,580	1.93%
Richard J. Larkin <sup>(5)</sup> 3661 Horseblock Road Medford, NY 11763	145,261	1.23%
Alan Carus <sup>(6)</sup> 3661 Horseblock Road Medford, NY 11763	66,000	0.56%
Les Stutzman <sup>(1)</sup> 3661 Horseblock Road Medford, NY 11763	25,000	0.21%
Gary Meller <sup>(7)</sup> 3661 Horseblock Road Medford, NY 11763	51,000	0.43%
All officers and directors as a group <sup>(9)</sup>	3,308,873	25.85%
Mark Baum <sup>(10)</sup> 580 Second Street, Suite 102 Encinitas, CA 92024	1,408,597	11.23%

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,

**Table of Contents**

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 beneficial ownership percent in the table is calculated with respect to the number of outstanding shares (11,692,540) of the Company's common stock outstanding as of January 31, 2007. Each stockholder's ownership is calculated as the number of shares of common stock owned plus the number of shares of common stock into which any preferred stock, warrants, options or other convertible securities owned by that stockholder can be converted within 60 days. In addition to the 11,692,540 shares of common stock outstanding, the Company's outstanding series A, B and C preferred stock is convertible into a total of approximately 17.9 million shares of preferred stock, and there are warrants to purchase approximately 16.7 million shares of common stock outstanding. 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, series B or series C preferred stock convert shares of the series A, series B or series C 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. As a result of this provision, holders of preferred stock that is convertible into common stock and holders of warrants to purchase common stock who, with 61 days advance notice, can convert those securities into more than 5% of the Company's outstanding stock are not required to be listed in this table.

The term "named executive officer" refers to our principal executive officer, our two most highly compensated executive officers other than the principal executive officer who were serving as executive officers at the end of 2006, and two additional individuals for whom disclosure would have been provided but for the fact that the individuals were not serving as executive officers of the Company at the end of 2006.

None of the preferred shares can be converted into common stock and none of the warrants can be exercised if the conversion or exercise would result in the holder owning more than 4.99% of the Company's outstanding common stock unless the holder provides the Company with 61 days advance written notice.

- (1) Includes 25,000 shares issuable upon exercise of options exercisable within 60 days.
- (2) Includes 220,000 shares issuable upon exercise of options exercisable within 60 days and 140,697 warrants. 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, 88,971  
shares issuable  
upon conversion  
of series B  
preferred stock  
and 77,868  
shares issuable  
upon exercise of  
warrants  
because  
conversion of  
any of those  
shares of series  
A or series B  
preferred stock  
or exercise of  
those warrants  
would result in  
the holder  
beneficially  
owning in  
excess of 4.99%  
of the then  
issued and  
outstanding  
shares of  
common stock  
outstanding at  
that time.

- (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  
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.

Mr. Pelosof  
voluntarily  
resigned from  
the Company on  
December 6,  
2006, effective  
January 31,  
2007.

- (4) Includes  
207,500 shares  
issuable upon  
exercise of  
options  
exercisable  
within 60 days  
and 2,007 shares  
issuable upon  
exercise of  
warrants. Does  
not include  
25,000 shares  
issuable upon  
exercise of  
options that are  
not exercisable

within the next  
60 days

- (5) Includes 137,500 shares issuable upon exercise of options exercisable within 60 days and 260 shares issuable upon exercise of warrants. Does not include 30,236 shares issuable upon conversion of series A preferred stock and 25,196 shares issuable upon exercise of warrants because conversion of any of those shares of series A preferred stock or exercise of any of those warrants would result in the holder beneficially owning in excess of 4.99% of the then issued and outstanding shares of common stock outstanding at that time.
- (6) Includes 51,000 shares issuable upon exercise of options exercisable

within 60 days.  
Does not  
include 36,000  
shares issuable  
upon exercise of  
options that are  
not exercisable  
within the next  
60 days.

(7) Includes 51,000  
shares issuable  
upon exercise of  
options  
exercisable  
within 60 days.  
Does not  
include 36,000  
shares issuable  
upon exercise of  
options that are  
not exercisable  
within the next  
60 days.

(8) Includes  
footnotes (1)-(7)

(9) 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.

**Table of Contents**

**DESCRIPTION OF SECURITIES**

Pursuant to our articles of incorporation, as amended, we are authorized to issue 100,000,000 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 the Company.

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 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.

In the event the Company elects to pay any dividend in shares of common stock or in shares of series A preferred stock, so long as Vicis Capital Master Fund owns any shares of series A preferred stock, Vicis Capital Master Fund will receive such dividend in cash unless it otherwise notifies the Company no later than five (5) trading days prior to the date of the applicable dividend payment. Such payment to Vicis Capital Master Fund will not affect the Company's election to make the applicable dividend payment in stock so long as the only holder receiving the dividend payment in cash is Vicis Capital Master Fund.

*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.

**Table of Contents**

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 a conversion price of \$.60 per share. Based on its original purchase price of \$30,000 per share, each share of series A preferred stock is 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.

**Table of Contents**

**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, in shares of series B preferred stock, or in shares of common stock, at our option. 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.

In the event any dividend is issued, any holder of the majority of the outstanding series B preferred stock at the dividend payment date, may elect whether to receive dividends on series B preferred stock in cash, in common stock or in shares of series B preferred stock in its sole discretion. As of the date of this prospectus, Crestview Capital Master LLC holds a majority of the outstanding shares of the series B preferred stock.

This prospectus covers 73,770 shares of our common stock which represents the number of shares of our common stock that may be issued in payment of three years of dividends on the currently outstanding shares of our series B preferred stock assuming that each share of our series B preferred stock remains issued and outstanding for three years, and that we pay all of the dividends in those three years in shares of our common stock.

*Voting Rights.* As long as any shares of series B preferred stock are outstanding, we cannot take any of the following actions without the separate class vote or written consent of 51% of the holders 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.

Notwithstanding the foregoing, so long as any shares of series B preferred stock are outstanding, the Company shall not, without the affirmative vote of the holders of 75% of the shares of series B preferred stock then outstanding, (a) decrease the dividend rate of 9% per annum; (b) amend the anti-dilution adjustment for subsequent equity sales; or (c) amend the terms for a forced conversion.

*Conversion.* The series B preferred stock is convertible, at the option of the holders, into shares of our common stock at a 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 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.

**Table of Contents**

*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.

**Series C Preferred Stock**

*Dividends.* Holders of series C preferred stock are entitled to a 7% per annum dividend per share. The dividend accrues and is payable semi-annually in cash, in shares of common stock or a combination thereof, at our option. Accrued but unpaid dividends are also payable upon the conversion or redemption of the shares of series C preferred stock and upon a liquidation event.

This prospectus covers 2,734,375 shares of our common stock which represents the number of shares of our common stock that may be issued in payment of three years of dividends on the currently outstanding shares of our series C preferred stock assuming that each share of our series C preferred stock remains issued and outstanding for three years, and that we pay all of the dividends in those three years in shares of our common stock.

*Voting Rights.* As long as any shares of series C preferred stock are outstanding, we cannot take any of the following actions without the separate class vote or written consent of 81% of the then outstanding shares of series C preferred stock:

amend, alter or repeal the provisions of the series C preferred stock so as to adversely affect any right, preference, privilege or voting power of the series C 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 C 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 C preferred stock; or

enter into any agreement with respect to the foregoing.

*Conversion.* The series C preferred stock is convertible, at the option of the holders, into shares of our common stock at a conversion price of \$.80 per share. Based on the original purchase price of \$50,000 per share, each share of series C preferred stock is convertible into 62,500 shares of our common stock. The series C preferred stock is issuable in fractional shares. The series C preferred stock contains adjustment provisions upon the occurrence of stock splits, stock dividends, combinations, reclassifications or similar events of our capital stock. The series C 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 C 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 C preferred stock, (D) our breach of any of our representations or warranties contained in the series C 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 C preferred stock has the right to require us to redeem all of that holder's shares of series C preferred stock at a price per share of series C 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 C preferred stock, plus (ii) any accrued but unpaid dividends, plus (iii) all liquidated damages and other amounts due in respect of the series C preferred stock.

*Rank; Liquidation Preference.* The holders of series C preferred stock rank pari passu to the holders of our series A preferred stock, series B preferred stock and, prior to the holders of our common stock, unless otherwise consented to by the holders of series C 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

## **Table of Contents**

for the series C preferred stock is an amount equal to \$50,000 per share plus any accrued and unpaid dividends and liquidated damages owing thereon.

### **DESCRIPTION OF BUSINESS AND ORGANIZATION**

#### **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 1/2, HIV 1/2 STAT-PAK and HIV 1/2 STAT-PAK Dipstick), and our rapid test for Chagas disease, Chagas STAT-PAK. We also have products under development in the areas of veterinary and human tuberculosis, emerging and neglected diseases, including products that are under development employing our patent pending Dual Path Platform.

#### **HIV Rapid Tests**

A major component of our revenue growth in 2006 through September 30, 2006 has come primarily from increased sales of our rapid HIV tests. A large percentage of individuals that are HIV positive worldwide are unaware of their status. Part of the reason for this is that even those that do get tested in public health settings will often not return or call back for their test results when samples have to be sent out to a laboratory which can take at least several days to process. The increased availability, greater efficacy and reduced costs for anti-retroviral treatments (ARVs) for HIV is also having a tremendous impact on the demand for being tested, as the stigma associated with the disease is lessened and the ability to resume normal activities is substantially improved.

Our SURE CHECK HIV 1/2 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 cassette format and HIV 1/2 STAT-PAK Dipstick format tests require that the sample (whether finger-stick whole blood, venous whole blood, serum or plasma) first be transferred to the test device, which is similar to competitive products. Both the cassette and dipstick formats of our HIV 1/2 STAT-PAK line is more competitively priced and more flexible than SURE CHECK for samples other than finger-stick whole blood. The HIV 1/2 STAT-PAK Dipstick, our most economical format, was designed in order to provide a low cost product with performance equal to our other products for resource-constrained markets in the developing world. All three of our HIV tests use a standardized test strip which we developed by using patented materials licensed non-exclusively to us from third parties as well as our own proprietary know-how and trade secrets. All three of our rapid HIV tests are qualitative yes/no tests for the detection of antibodies to HIV 1 & 2.

#### **Regulatory Status:**

##### **HIV Tests**

The Company obtained FDA approval of the Pre-Market Application of its SURE CHECK HIV 1/2 and HIV 1/2 STAT-PAK products on May 25, 2006. Subsequently, the Company completed additional studies and submitted to the FDA a waiver application under the Clinical Laboratory Improvement Act ( CLIA ) for these FDA-approved products on July 18, 2006 and July 27, 2006, respectively. A CLIA waiver was granted by the FDA for HIV 1/2 STAT-PAK on November 20, 2006. A CLIA waiver is essential in order to market the products into public health clinics and physicians' offices where the level of training is traditionally less than the training at clinical laboratories and hospitals, which constitute the largest portion of the available market for these products today. The Company believes that it has met all material aspects of the CLIA waiver requirements, and, subject to completing any issues identified by the FDA in its waiver applications, hopes to receive a CLIA waiver in the near future.

The Company has certificates of free sale for the FDA approved HIV tests. All three rapid HIV tests 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, Nigeria and Uganda are the only countries in which we have significant sales. Our HIV 1/2 STAT-PAK and HIV 1/2 STAT-PAK Dipstick products were also evaluated by the World Health Organization (the WHO ) in 2004, and in 2005 the WHO qualified these products for inclusion in the WHO Bulk Procurement Scheme, which is a pre-requisite for these products' eligibility for procurements from programs funded by the United Nations and their partners' programs. All three of our HIV tests have qualified for procurements under the President's Emergency Plan for AIDS Relief.

**Partners Involved in the Products:**

In 2004 we entered into a thirteen-year supply and technology transfer agreement with FIOCRUZ-Bio-Manguinhos, an affiliate of the Ministry of Health of Brazil relating to our HIV 1/2 STAT-PAK product.

FIOCRUZ-Bio-Manguinhos will supply this product, which will eventually be produced completely in Brazil, to the Brazilian public health market and potentially other markets in the region.

## **Table of Contents**

In September 2005 we were designated as the confirmatory test in Uganda's national rapid testing protocol, and through the offices we have established in East Africa and Nigeria, each staffed with experienced executives, we hope to be selected in more such national testing protocols. In February 2006 our HIV 1/2 STAT-PAK was designated by the Nigerian Ministry of Health in four out of the eight screening protocols in the Nigerian Interim Rapid Testing Algorithm. At the same time, we are identifying and appointing distributors in these regions, and are engaged with the multitude of stakeholders that are responsible for the delivery of rapid testing and related services in the markets. Our focus is on those African countries that are receiving funding from PEPFAR and other large relief programs. In January of 2006 we became one of four recommended global suppliers to Former President Clinton's HIV/AIDS Initiative ( CHAI ), and through that we expect to generate revenues in many of the nearly sixty countries that have agreements with CHAI.

For the U.S. rapid HIV test market, as described in Management's Discussion and Analysis below, we have very recently executed marketing and license agreements with Inverness Medical Innovations, Inc.

### **CHAGAS RAPID TEST**

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

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

### **Other Products**

Prior to 2005, a majority of our revenues were from the contract manufacture of private label pregnancy tests for regional pharmacies, drug stores and mass merchants in the U.S., Europe, Canada and Central America. However, as a result of pricing pressures, regulatory changes and potential patent litigation in this field, and in order to focus our efforts on rapid HIV tests we sold substantially all of the business related to our private label pregnancy test. We have retained a profit share derived from the sales of these products by the buyer. This has resulted in a substantial reduction of our revenues from these products and this is no longer a material part of our revenue stream. We also have other commercially available products, such as rapid tests for Lyme disease and other products, the aggregate of whose revenues are currently not material to us. We also are involved, as described below under Research and Development, in the development of new products.

### **Lateral Flow Technology**

All our current products employ lateral flow technology. Lateral flow, whether single or dual path, 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 a strip downstream from either the point of application of the sample or of another reagent. Single path 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

**Table of Contents**

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 and colloidal gold conjugates and buffer systems. These techniques include the methods we employ in manufacturing and fusing the reagents with the colored latex, or colloidal gold, blocking procedures used to reduce false positives, and methods used in treating the materials used in our tests to obtain maximum stability and resulting longer shelf life. We also have extensive experience with a variety of lateral flow devices, including the sample collection device used in our SURE CHECK HIV rapid test which we believe is easier to use than other finger-stick whole blood rapid tests. SURE CHECK eliminates the need for transferring finger-stick whole blood samples from the fingertip onto a test device, because the collection of the sample is performed within a tubular test chamber that contains the lateral flow test strip. The whole blood sample is absorbed directly onto the test strip through a small opening in one end of the test chamber and an absorbent pad positioned just inside this same end of the test chamber.

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

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

**Target Market****HIV Rapid Tests**

We believe that the prevention and treatment goals that have been established by large programs that are designed to provide greater access to ARVs (Anti-Retroviral Treatments for AIDS) and thwart the spread of HIV will drive the growth and demand for rapid HIV tests in the coming years. Chembio is one of only two U.S.-based manufacturers of rapid HIV tests and the only one with products that it believes can meet the various demands of the global market.

Based upon an analysis done by the Global Business Coalition of HIV/AIDS, approximately 500 million people will need to be tested with at least one rapid test (also a confirmatory rapid test will be needed in the case of a positive result) over the next three years in order to insure that treatment targets are achieved.<sup>5</sup> This is not just because of the continuing growth in the epidemic, but more importantly, because anti-retroviral treatments are available, affordable and are being funded, so that people actually have a reason to be tested.

Because HIV medicines have become much less expensive and more widely available, unprecedented multi-billion dollar financial commitments are being allocated in each of the next few years. Some of these commitments are being made by The Global Fund<sup>6</sup> and the U.S. Presidential Emergency Plan for AIDS Relief ( PEPFAR<sup>7</sup> ). PEPFAR alone has a goal to provide treatment to two million people, and in order to identify these two million people, rapid testing is being implemented on a very large scale. The U.S. is the largest donor, by far, to these programs. Each of these programs recognizes that a massive scale-up in the use of rapid HIV tests is the only way their treatment goals can hope to be achieved.

We further believe that the global demand for rapid HIV testing will increase at very high rates well beyond the next few years and for the foreseeable future. As of the end of 2005, there were an estimated 40 million people infected with HIV/AIDS worldwide, of which an estimated 6 million were in need of antiretroviral therapy. The number of people in need of treatment will continue to grow as infection rates increase significantly worldwide, and there is little expectation for an effective vaccine anytime soon. As such, even with relatively low prevalence rates in Asia, UNAIDS estimates that 12 million new infections could occur in that region alone between 2005 and 2010.<sup>8</sup>

The Company received approval from the FDA for its SURE CHECK(R) HIV 1/2 and HIV 1/2 STAT-PAK(TM) rapid test Pre-Market Applications on May 25, 2006. This approval allows the Company to market its rapid HIV tests to clinical laboratories and hospitals in the U.S., and allows the Company to further expand its international marketing efforts into countries that require regulatory approval in the manufacturer's country of domicile. The U.S. market opportunity has been developing first in the public health and hospital emergency room segments. However, as a result of recently revised and broadly supported recommendations for routine testing issued by the Centers for Disease Control ( CDC ), we expect the U.S. market to expand as this technology is increasingly employed in physicians offices, prisons and other venues. Before the FDA Blood Products Advisory Committee endorsed the FDA's recommendation to provide rapid HIV tests in the over-the-counter markets, and before

<sup>5</sup> [www.businessfightsaids.org/site/pp.asp?c=gwKXJfNVJtF&b=1008825](http://www.businessfightsaids.org/site/pp.asp?c=gwKXJfNVJtF&b=1008825) Policy Documents/Facilitating Access to Testing

<sup>6</sup> [www.theglobalfund.org/en](http://www.theglobalfund.org/en)

<sup>7</sup> [www.usaid.gov/our\\_work/global\\_health/aids/pepfar.html](http://www.usaid.gov/our_work/global_health/aids/pepfar.html)

<sup>8</sup> [www.unaids.org/html/pub/global-reports/bangkok/unaidsglobalreport2004\\_en\\_html.htm](http://www.unaids.org/html/pub/global-reports/bangkok/unaidsglobalreport2004_en_html.htm)

**Table of Contents**

the CDC recommendations were published, the U.S. rapid HIV test market was estimated to become at least a \$50 million market during the next few years.<sup>9</sup> In his State of the Union Address in 2006, President Bush called on Congress to reform and reauthorize the Ryan White CARE Act, which among other things provides counseling and testing for those in greatest need of HIV/AIDS assistance. The President has also proposed to direct a total of more than \$90 million to the purchase and distribution of rapid HIV test kits, facilitating the testing of more than 3 million additional Americans. Test kits would be distributed in areas of the country with the highest rates of newly discovered HIV cases and the highest suspected rates of undetected cases. This legislation is still in negotiation as part of the overall 2007 budget negotiations.

As a result of the non-exclusive licenses we received from Inverness to their lateral flow patents to market our HIV 1/2 STAT-PAK cassette and dipstick products outside the U.S., we will further expand our international marketing efforts beyond developing countries. For example, we intend to begin marketing in several countries where the Inverness lateral flow patents are issued in Europe, Asia and Latin America. Chagas Rapid Test. The Company had developed this test several years ago, but the market for the product was not meaningful, as most prevention efforts, which were minimal, were made using laboratory tests used for blood bank screening of blood. However, there is now a greater interest in Chembio's rapid test because of an important publication that demonstrated the effectiveness of the rapid test in the screening of blood donors (as opposed to the blood in blood banks), and because it can be effectively deployed in rural populations to screen children and pregnant women. Also, studies that have been completed at multiple sites in Central and South America showing sensitivity of between 98.5% and 99.6% and specificity between 94.8% and 99.9%, thus indicating that the test is a good alternative to standard laboratory testing methods. Our Chagas disease test, Chagas STAT-PAK, was deployed this year to screen every child in Bolivia under the age of 14 in rural areas. Intervention efforts with low cost generic drugs have been shown to cure young children as compared with latent and recurring infections afflicting those beyond early ages.

**Other Products Under Development**

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

Tuberculosis ( TB ) is the leading killer of people who have AIDS, yet there is no rapid screening test for TB like there is for HIV. If successful, Chembio's TB product development efforts will leverage the marketing and distribution capability which the Company has been developing for its HIV products. Chembio had its initial human TB product evaluated last year along side several other rapid tests that were evaluated by an organization affiliated with the World Health Organization. Although Chembio's test was among the best performing tests, more work is still required. Current efforts on a next generation rapid TB test are focused on incorporating the Dual Path Platform in order to produce higher sensitivity levels, particularly in HIV-TB co-infected patients and also with respect to antigen candidates. Given the variations in TB strains and the context of latent TB infection in different geographic regions and populations, there are debates as to what the performance standards should be and whether certain tests may in fact be appropriate for use in certain regions.

Tuberculosis is also a problem in a number of animal species either because of potential transmission to humans or from humans to animals (i.e., zoonotic disease), costs in lost agricultural productivity or because of the potential negative impact on the cost of the animal species themselves. For example, nonhuman primates used in research or in zoos are quite costly, and whole colonies can be lost if transmission is not effectively controlled through routine and accurate diagnosis. Bovine (cattle) TB can be transmitted from livestock or deer to humans and to other animals both domestic and wild. Under rules established by the Animal and Plant Health Inspection Service ( APHIS ), a state can lose the right to move cattle across state lines if TB is detected in two or more herds, and such a prohibition, has recently occurred in Minnesota, Texas, New Mexico and Michigan. TB control of meat at slaughterhouses is dependent upon visual inspection. The Company believes that a more accurate and rapid test could conceivably complement or supplant these visual inspections.

Chembio has already completed development of a rapid lateral-flow test for the detection of TB in Non-Human Primates (PrimaTB STAT-PAK), and has a similar test near completion for multiple host species, including cattle (BovidTB STAT-PAK), deer both captive and wild species (CervidTB STAT-PAK), camelids (CamelidTB STAT-PAK), elephant (ElephantTB STAT-PAK) and other exotic wildlife. The tests can use serum, plasma, whole

blood or meat juice, are simple and easy to use, have up to an 18 month shelf life at RT storage, and samples provide definitive results within 20 minutes, permitting easy use of the assay for wild species as a true capture, test and cull assay. The Company believes, subject to USDA approvals, that commercialization of these products may begin in early 2007.

**Non-Human Primate Tuberculosis Test and other Veterinary Tuberculosis Tests**

The Company amended the product license application to the USDA for approval of its PrimaTB STAT-PAK (the detection of active tuberculosis in non-human primates) on July 6, 2006, and the application was accepted by the USDA on August 29, 2006. As a result, the Company is preparing for the next stage of the license process by scheduling the clinical trials to validate reproducibility of results during the fourth quarter of 2006. At the same time, the Company is working toward the establishment license with the USDA, which is required along with the product license requiring an inspection by USDA officials. The

<sup>9</sup> Market  
research  
prepared for  
Chembio.

## **Table of Contents**

inspections of the Company's facility and quality system is anticipated to occur during the fourth quarter of 2006 or first quarter of 2007. The Company anticipates approval of the product upon satisfactory completion of the clinical studies and the facility and quality inspection during the first or second quarter of 2007.

During the fourth quarter of 2006, the Company will apply for a conditional license for approval of its VetTB STAT-PAK, which detects active tuberculosis in elephants. A conditional license is generally granted on a case by case basis, and may be granted without having completed a clinical trial, with the condition of completing the requirements for full licensure within one year of receiving the conditional license. A conditional license will allow the Company to market the product to select customers under the auspices of the USDA. The Company anticipates conditional approval during the first quarter of 2007.

### **Distribution Channels & Marketing Strategy**

Approval from the FDA of our HIV rapid tests not only permits sales in the U.S., but also enhances marketing capability in the international markets. HIV 1/2 STAT-PAK (cassette) and HIV 1/2 STAT-PAK dipstick were recently made part of the World Health Organization (the WHO) 2005 Bulk Procurement Scheme. All of our rapid HIV tests are qualified for procurement by the U.S. Agency for International Development, and our FDA approvals have enabled us to obtain Certificates of Free Sale for those products. The WHO's endorsement is required for virtually all international procurements by governmental and non-governmental organizations. The USAID qualification allows our products to be procured with USAID and the Center for Disease Control funding, and the Certificate of Free Sales is required by certain countries to establish that the product is approved in the country of manufacture. These approvals and qualifications have opened up new markets and sales opportunities.

Our marketing strategy is to:

Expand our international sales effort and strategic partnerships in the developing world for our global health rapid test products, particularly our HIV and Chagas Disease tests. We are actively engaged in expanding HIV test sales and marketing through our recently established East and West African offices. These offices are headed by seasoned professionals that have extensive marketing and/or public health experience in Africa and are establishing distributor relationships throughout the continent. We also have new collaborations and sales opportunities that we are pursuing in Southeast Asia, China, and South America for our HIV and/or Chagas Disease tests, as well as other new tests that we have under development.

Launch our rapid HIV tests in the U.S., Europe and Latin America through our chosen marketing partners. Our agreement with Inverness for the SURE CHECK HIV barrel product is global, and we intend to support their efforts in penetrating all markets where there is an opportunity for this premium product. We also intend to support their marketing efforts with respect to the HIV STAT-PAK in the U.S., while pursuing other marketing partners and distributors for all of our products on a global scale.

Pursue potential over-the-counter marketing opportunities in the U.S. and internationally for our HIV tests. We will determine our strategy for pursuing the over-the-counter market opportunity with one or both of our currently FDA approved (professional market) products. Further, we will analyze whether to focus our efforts for this market with our oral fluid HIV test product, which we are currently developing with our DPP technology.

Launch our initial veterinary TB product, Prima TB Stat Pak, within our growing line of veterinary TB tests. We anticipate USDA approval of our initial product, a nonhuman primate TB test, in the first or second quarter of 2007. During 2007 we expect to obtain revenues from certain other veterinary TB products, at very favorable margins.

### **Strategic Alliances**

Strategic alliances are a key element in the Company's business strategy. As described in more detail below in Management's Discussion and Analysis, on September 29, 2006, the Company executed several agreements by and among the Company, Inverness Medical Innovations, Inc. and StatSure Diagnostic Systems, Inc. Pursuant to these agreements, the Company will engage in marketing, licensing and distribution activities with these two companies.

These agreements contain margin sharing formulae that are designed to provide Inverness, the Company and StatSure with reasonable profit margins after deduction for certain unit costs of the products. In addition, the Company has the exclusive right and duty to manufacture the products marketed by Inverness under all the agreements, and it has the right to subcontract manufacturing, but not sublicense or subcontract its rights or obligations.

**Clinton Foundation HIV/AIDS Initiative** In January 2006 we entered into an agreement with the William J. Clinton Foundation's HIV/AIDS Initiative ( CHAI ) to be recommended by CHAI to receive the procurements from CHAI partner countries (more than 50 countries in the developing world and also including China, Brazil and India) that choose to access CHAI's suppliers products and their preferred pricing in exchange for their sharing information with CHAI and permitting CHAI to fill gaps that will improve and scale up the country's health care delivery systems. We are one of four companies worldwide (and the only U.S.-based manufacturer) to be recommended by CHAI for sales of HIV rapid tests. While CHAI is not a procurer of the tests per se, it is an increasingly major factor in influencing which tests are to be procured. CHAI also has major

## **Table of Contents**

agreements with generic HIV ARV manufacturers and manufacturers of viral load and CD-4 monitoring diagnostic tests, and those agreements have been very successful models.

**Brazilian Ministry of Health** - In addition, the Company is committed to securing alliances and technology-transfer agreements with government agencies and commercial entities. For example, Chembio signed, in early 2004, a thirteen year technology transfer, supply and license agreement with Bio-Manguinhos, an affiliate of the Brazilian Ministry of Health ( MOH ) and the predominant supplier for meeting public health needs in Brazil. Over a three-year period, Chembio will transfer its proprietary technology related to HIV 1/2 STAT-PAK to Bio-Manguinhos in exchange for commitments to purchase at least one million rapid tests. This purchase commitment was met during 2005, though we expect substantial additional procurements prior to the completion of the technology transfer agreement, currently anticipated for early 2007. Thereafter, Bio-Manguinhos will have the right to produce its own rapid tests and Chembio will receive royalties for ten years.

### **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, Chagas disease and tuberculosis (both human and veterinary), are very strong.

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

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

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



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

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

**Table of Contents**

The leading products in the international market are UniGold<sup>®</sup>, produced by Trinity Biotech in Ireland, and Determine<sup>®</sup>, produced by Inverness in Tokyo. Until last year, the Determine business was owned by Abbot Diagnostics before it was sold to Inverness Medical Innovations. In connection with this transaction, Abbott retained the distribution rights to the Determine product for approximately three years. The Determine and UniGold products are well established in many of the developing world markets, often as the screening and confirmatory tests, respectively. Inverness Organics subsidiary in Israel also has a rapid HIV test, Double Check Gold, and this is one of the other three products recommended by CHAI; the other two companies whose products were selected by CHAI are based in India and China, respectively, and they have not yet established apparent marketing efforts outside their countries, although they are qualified by the World Health Organization. In the developed world, particularly the U.S., our competitors are Orasure Technologies with OraQuick<sup>®</sup>, and Trinity with its UniGold<sup>®</sup> product, both of which are FDA-approved, CLIA-waived products. Although we do not believe Inverness plans to submit either the Determine or the Organics product to the FDA, our agreements with Inverness provide that in the event such submissions are made, (or in any case if Inverness markets a competitive product in the U.S.), we have the right to terminate our agreement with Inverness or make their marketing rights non-exclusive. In either case, we can retain a license under the Inverness lateral flow patents to market the products under a Chembio brand and/or through third party distribution partners.

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

Orasure has been focusing on building its brand and market share in the U.S. market, and successfully so. Its non-U.S. sales of their rapid HIV test are not significant, and we believe its product is neither suitable nor cost competitive to participate in the international market. Orasure has been successful in bringing attention to the need and availability of rapid HIV testing in the U.S. Its main advantage is the fact that its test can be used with oral fluid samples, though its FDA approved sensitivity is 99.3% with these samples. OraQuick is not approved for use with serum samples which may limit its marketability in certain settings.

Chembio's HIV products shelf life is 24 months, which is double that of UniGold and four times that of Orasure's product. Our products have been approved by the FDA for finger-stick whole blood, venous whole blood, serum and plasma. We believe that our SURE CHECK barrel format is extremely convenient, easier to use than OraQuick on finger-stick whole blood samples, is much more cost competitive, and provides a safe, closed system.

We believe that having high level executives in the field in East and West Africa that are engaged with public health officials, NGOs and other organizations provides us with a competitive advantage in those markets. To the best of our knowledge, none of our competitors have actually done a technology transfer which we can now replicate in other markets of our choosing.

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

**Research and Development**

We are focusing our research and development efforts on new rapid tests that will leverage our expertise and sales channels. Our research and development activities have been in three disease areas: HIV, Human and Veterinary Tuberculosis, and neglected diseases such as Chagas Disease (See section entitled *General*).

**HIV**

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

**Tuberculosis**

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

**Table of Contents**

particularly true when the test was used on co-infected HIV/TB populations in sub-Saharan Africa, where millions are infected with both diseases.

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) (i.e., PrimaTB STAT-PAK). We submitted an amendment to our product license application for review to the U.S. Department of Agriculture ( USDA ) during the third quarter of 2006, and we hope to obtain a licensure of this product during the first or second quarter of 2007. We are also engaged in collaborations related to the detection of active pulmonary tuberculosis in other animals such as cattle, deer, camels, elephants and other exotic species. We plan on leveraging our current technology for licensure of these additional species TB tests. We do not anticipate any material revenues from these efforts before mid to late 2007.

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

**Employees**

At December 31, 2006, we employed 107 people, including 92 permanent full-time employees. In May 2004, we entered into an employment agreement with Javan Esfandiari, Director of Research and Development. In May 2006, we entered into an employment agreement with Lawrence Siebert, President and Chairman.

**Governmental Regulation**

The Company's existing and proposed diagnostic products are regulated by the U.S. Food and Drug Administration ( FDA ), U.S. Department of Agriculture ( USDA ), certain state and local agencies, and/or comparable regulatory bodies in other countries. This regulation governs almost all aspects of development, production and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing and record keeping. The Company's FDA and USDA regulated products require some form of action by each agency before they can be marketed in the U.S., and, after approval or clearance, the Company must continue to comply with other FDA requirements applicable to marketed products, e.g. CLIA regulations (for medical devices). Both before and after approval or clearance, failure to comply with the FDA's requirements can lead to significant penalties.

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

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

Every company that manufactures medical devices distributed in the U.S. must comply with the FDA's Quality System Regulations. These regulations govern the manufacturing process, including design, manufacture, testing, release, packaging, distribution, documentation and purchasing. Compliance with the Quality System Regulations is required before the FDA will approve an application, and these requirements also apply to marketed products. Companies are

also subject to other post-market and general requirements, including compliance with restrictions imposed on marketed products, compliance with promotional standards, record keeping and reporting of certain adverse reactions or events. The FDA regularly inspects companies to determine compliance with the Quality System Regulations and other post-approval requirements. Failure to comply with statutory requirements and the FDA's regulations can lead to substantial penalties, including monetary penalties, injunctions, product recalls, seizure of products, and criminal prosecution.

The Clinical Laboratory Improvement Act of 1988 ( CLIA ) prohibits laboratories from performing in vitro tests for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of, the health of human beings unless there is in effect for such laboratories a certificate issued by the U.S. Department of Health and Human Services (via the FDA) applicable to the category of examination or procedure performed. Although a certificate is not

## **Table of Contents**

required for the Company, it considers the applicability of the requirements of CLIA in the design and development of its products. The statutory definition of laboratory is very broad, and many of our customers are considered labs. A CLIA waiver will remove certain quality control and other requirements that must be met for certain customers to use the Company's products and this is in fact critical to the marketability of a product into the point of care diagnostics market.

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

The Company is also subject to regulations in foreign countries governing products, human clinical trials and marketing, and may need to obtain approval or evaluations by international public health agencies, such as the World Health Organization, in order to sell diagnostic products in certain countries. Approval processes vary from country to country, and the length of time required for approval or to obtain other clearances may in some cases be longer than that required for U.S. governmental approvals. On the other hand, the fact that our HIV diagnostic tests are of value in the AIDS epidemic may lead to some government process being expedited. The extent of potentially adverse governmental regulation affecting Chembio that might arise from future legislative or administrative action cannot be predicted.

Prior to receiving FDA approval, the Company's HIV rapid tests had been evaluated and approved for marketing in several foreign jurisdictions, including Brazil, Mexico, India and a number of other nations in the developing world. Chembio completed clinical trials for the SURE CHECK HIV and HIV 1/2 STAT PAK rapid tests in 2004 and filed the pre-market approval application with the FDA for approval of these products in February 2005. A facility inspection took place in September 2005 and an amendment was made in October 2005 to add an HIV-2 claim to the application. The Company's pre-market application was approved by the FDA on May 25, 2006, and it filed its CLIA waivers in July, 2006. A CLIA waiver was granted by the FDA for HIV 1/2 STAT-PAK on November 20, 2006. The Company also has its first veterinary tuberculosis rapid test under review by the USDA, and expects to have its facility inspected by this agency in late 2006 or early 2007.

### **Environmental Laws**

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

### **Intellectual Property**

#### *Intellectual Property Strategy*

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

#### *Trade Secrets and Know-How*

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

competitive advantage.

*Lateral Flow Technology and Reagent Licenses*

Although we own no issued patents covering lateral flow technology, we have obtained non-exclusive licenses from Inverness Medical Innovations, Inc. and Abbott Laboratories with respect to their portfolios of lateral flow patents. The issue of potential patent challenges is ongoing for us as well as for our competitors, and we continue to monitor the situation, consult with patent counsel, and seek licenses and/or redesigns of products that we believe to be in the best interests of the Company and our stockholders. Because of the costs and other negative consequences of time-consuming litigation regardless of whether we would ultimately prevail, if we foresee a significant possibility of patent infringement litigation, our first priority will be to attempt to obtain a license on reasonable terms. Nevertheless there is no assurance that Abbott's and/or Inverness' lateral flow patents will

**Table of Contents**

not be challenged or that other patents containing claims relevant to the Company's products will be not be granted and that licenses to such patents if any will be available on reasonable terms, if any.

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

During 2005 and 2006 the Company made substantial additions to its intellectual property portfolio as a result of the development of a new rapid test platform that showed improved sensitivity as compared with conventional platforms in a number of preliminary studies using well characterized HIV, Tuberculosis and other samples. This technology has formed the basis of two patent applications that were filed and will likely result in additional applications covering additional uses of this technology platform. The Company anticipates signing new development projects based upon these new technologies in the near future that will provide new product applications and marketing opportunities. On January 16, 2007, the Company received notice that it is to receive a Notice of Allowance from the United States Patent & Trademark Office which substantially increases the likelihood that a patent for DPP will be issued. The Company believes that this new lateral flow platform is outside of the scope of currently issued patents in the field of lateral flow technology, thereby offering the possibility of a greater freedom to operate. There is no assurance that the patent application will be granted, or that its claims won't be modified upon review, or that the Company's patents or its products incorporating the patent claims will not be challenged at some time in the future.

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

The peptides used in our HIV rapid tests are patented by Adaltis Inc. and are licensed to us under a 10-year non-exclusive license agreement dated August 30, 2002, which was recently amended. We also have licensed the antigens used in our tuberculosis and Chagas disease tests. We have concluded license agreements related to intellectual property rights associated with HIV-1, and are negotiating the terms of a license agreement for HIV-2, which we hope to close during late 2006 or early 2007.

**Our Business Prior to the Merger**

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

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

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

**The Merger**

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

**Glossary**

**AIDS** Acquired Immunodeficiency Syndrome. AIDS is caused by the Human Immunodeficiency Virus, HIV.



ANTIBODY	A protein which is a natural part of the human immune system produced by specialized cells to neutralize antigens, including viruses and bacteria that invade the body. Each antibody producing cell manufactures a unique antibody that is directed against, binds to and eliminates one, and only one, specific type of antigen.
ANTIGEN	Any substance which, upon entering the body, stimulates the immune system leading to the formation of antibodies. Among the more common antigens are bacteria, pollens, toxins, and viruses.
ARVs	Anti-Retroviral Treatments for AIDS
CD-4	The CD4+ T-lymphocyte is the primary target for HIV infection because of the affinity of

**Table of Contents**

the virus for the CD4 surface marker. Measures of CD4+ T-lymphocytes are used to guide clinical and therapeutic management of HIV-infected persons.

CDC	U.S. Centers for Disease Control and Prevention
CHAGAS DISEASE	Chagas Disease is an infection caused by the parasite <i>Trypanosoma cruzi</i> . Worldwide, it is estimated that 16 to 18 million people are infected with Chagas disease; of those infected, 50,000 will die each year.
CHAI	Clinton HIV/AIDS Initiative
CLIA	Clinical Laboratory Improvement Act
DIAGNOSTIC	Pertaining to the determination of the nature or cause of a disease or condition. Also refers to reagents or procedures used in diagnosis to measure proteins in a clinical sample.
EITF	Emerging Issues Task Force
FASB	Financial Accounting Standards Board
FDA	U.S. Food and Drug Administration
FDIC	Federal Deposit Insurance Corporation
HIV	Human Immunodeficiency Virus. HIV (also called HIV-1), a retrovirus, causes AIDS. A similar retrovirus, HIV-2, causes a variant disease, sometimes referred to as West African AIDS. HIV infection leads to the destruction of the immune system.
IgG	IgG or Immunoglobulin are proteins found in human blood. This protein is called an antibody and is an important part of the body's defense against disease. When the body is attacked by harmful bacteria or viruses, antibodies help fight these invaders.
MOH	Ministry of Health
MOU	Memoranda of Understanding
NGO	Non-Governmental Organization
OTC	Over-the-Counter
PEPFAR	The President's Emergency Plan for AIDS Relief
PMA	Pre-Marketing Approval
PROTOCOL	A procedure pursuant to which an immunodiagnostic test is performed on a particular specimen in order to obtain the desired reaction.
REAGENT	

A chemical added to a sample under investigation in order to cause a chemical or biological reaction which will enable measurement or identification of a target substance.

RETROVIRUS	A type of virus which contains the enzyme Reverse Transcriptase and is capable of transforming infected cells to produce diseases in the host such as AIDS.
Ryan White CARE Act	The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act is Federal legislation that addresses the unmet health needs of persons living with HIV disease by funding primary health care and support services. The CARE Act was named after Ryan White, an Indiana teenager whose courageous struggle with HIV/AIDS and against AIDS-related discrimination helped educate the nation.
SAB	Staff Accounting Bulletin
SENSITIVITY	Refers to the ability of an assay to detect and measure small quantities of a substance of interest. The greater the sensitivity, the smaller the quantity of the substance of interest the assay can detect. Also refers to the likelihood of detecting the antigen when present.
SFAS	Statement of Financial Accounting Standards
SPECIFICITY	The ability of an assay to distinguish between similar materials. The greater the specificity, the better an assay is at identifying a substance in the presence of substances of similar makeup.
SPUTUM	Expectorated matter; saliva mixed with discharges from the respiratory passages
TB	Tuberculosis (TB) is a disease caused by bacteria called Mycobacterium tuberculosis. The bacteria usually attack the lungs. But, TB bacteria can attack any part of the body such as the kidney, spine, and brain. If not treated properly, TB disease can be fatal. TB is spread through the air from one person to another. The bacteria are put into the air when a person with active TB disease of the lungs or throat coughs or sneezes. People nearby may breathe in these bacteria and become infected.
ALGORITHM	For rapid HIV testing this refers both to method or protocol for using rapid tests from different manufacturers in combination to screen and confirm patients at the point of care, and may also refer to the specific tests that have been selected by an agency or ministry of health to be used in this way.
UNAIDS	Joint United Nations Program on HIV/AIDS
USAID	U.S. Agency for International Development
USDA	U.S Department of Agriculture
WHO	World Health Organization

**Table of Contents****CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS**

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

**MANAGEMENT'S DISCUSSION AND ANALYSIS AND PLAN OF OPERATION**

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

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

**Overview**

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

The financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern. The Company has sustained significant operating losses in the nine months of 2006 and the years 2005 and 2004. At September 30, 2006, the Company had a Stockholders' Deficiency of \$898,030, and a working capital surplus of \$1,836,636.

Including the funds received from the Series C 7% Convertible Preferred Stock offering, (the Series C Offering see below), the Company believes its resources are sufficient to fund its needs through the end of 2007. The Company's liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenue growth; (2) the extent to which, if any, that revenue growth improves operating cash flows; (3) its investments in research and development, facilities, marketing, regulatory approvals and other investments it may determine to make; and (4) the investment in capital equipment and the extent to which it improves cash flow through operating

**Table of Contents**

efficiencies. If the Company's resources are not sufficient to fund its needs through 2007 there are no assurances that the Company will be successful in raising sufficient capital.

On March 30, 2006, the Company sold \$1 million of additional Series B Preferred Stock to a Series B Preferred shareholder pursuant to provisions of the January 2005 Series B 9% Preferred Stock financing agreements. Such provisions were exclusive to said shareholder.

On May 30, 2006, the Company received approval of its Pre-Market Applications ( PMA's ) from the FDA for its SURE CHECK(R) HIV 1/2 and HIV 1/2 STAT-PAK(TM) rapid tests. The approved PMAs allow the Company to market its rapid HIV tests to clinical laboratories and hospitals in the United States. FDA approval also allows the Company to further expand its international marketing efforts into countries that require regulatory approval in the manufacturer's country of domicile.

On June 29, 2006, the Company borrowed \$1,300,000. The loan was repaid in part on September 29, 2006 and the balance converted on October 5, 2006. The loan was secured by a lien on the assets of the Company. See Note 1 of the financial statements for further details.

On September 29, 2006 and October 5, 2006, the Company completed the Series C Preferred Stock Offering for \$8,150,000. Some of the proceeds were used to repay the loan borrowed on June 29, 2006.

### **Results of Operations for the Year Ended December 31, 2005 as Compared with the Year Ended December 31, 2004**

#### **Revenues:**

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

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

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

#### **Gross Margin:**

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

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

#### **Research and Development:**

Research and development expenses for the year ended December 31, 2005 were \$1,364,898 compared with \$1,508,849 for the year ended December 31, 2004. This category includes costs incurred for regulatory approvals, product evaluations and registrations. Expenses for Clinical & Regulatory Affairs, totaled \$411,000 for the year ended December 31, 2005, a decrease of \$472,000 compared to the year ended December 31, 2004. This category also includes costs for clinical studies which decreased by \$437,000 and a reduction in outside regulatory consultants of

\$77,000. The costs related to the clinical trials and consulting in 2004 were related to the evaluation of the Company's HIV tests in preparation of its FDA Pre-Marketing Approval ( PMA ) application submitted in February of 2005. Expenses other than Clinical & Regulatory increased \$329,000 and were related to increased salaries and wage-related costs of \$211,000 for new hires in the R&D group, increased travel and entertainment of \$46,000 and grant payments to a university of \$35,000.

## **Table of Contents**

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

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

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

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

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

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

### **New Generation Rapid Tests Based Upon Patent Pending Dual Path Platform (DPP )**

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

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

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

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

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

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

### **Results of Operations for the Three Months Ended September 30, 2006 as Compared with the Three Months Ended September 30, 2005**



**Revenues:**

Revenues are comprised of \$ 942,000 in net product sales and \$ 76,000 in grants and development income for the three months ended September 30, 2006 as compared with \$ 843,000 in net product sales and \$ 101,000 in grant and development income for the three months ended September 30, 2005. The increase in net product sales is attributable to increased sales of our Chagas tests of

**Table of Contents**

\$ 231,000 from \$ 28,000 to \$ 259,000, partially offset by decreased sales of our HIV products of \$46,000, pregnancy test kit (a deemphasized product) of \$ 40,000 and decreases in other product sales aggregating \$ 48,000. The decrease in grant and development income of \$25,000 was due to certain grants received in 2005 that weren't continued or awarded in 2006.

Net product sales for the three month period ended September 30, 2006 increased 12 % compared to the same period in 2005. HIV net product sales decreased 8 % in this period compared to the same period in 2005. The Company had a \$465,000 order from Brazil that would have resulted in increased HIV sales in the third quarter of 2006 if our customer had completed the necessary import documentation on a timely basis. The necessary documentation has since been completed and this order was shipped in late October 2006. The Company believes that sales of its HIV products will increase in the fourth quarter of 2006 as compared to the fourth quarter of 2005 as a result of shipping the Brazil order mentioned earlier and the international marketing strategies that were implemented in 2005. The Chagas net product sales increase was a result of the Company obtaining its first significant order for this product, in the amount of \$1.2 million of which it shipped \$ 950,000 in the first half of 2006 and the balance of \$230,000 in the third quarter of 2006.

**Gross Margin:**

Gross margin on net product sales for the three months ended September 30, 2006 was 11.8%, as compared to 20.6% for the three months ended September 30, 2005. The decrease in gross margin percentage is attributable to the decreased sales of HIV products and the delay of the Brazil order mentioned above, which were at a higher margin than other product lines, and because the Company has had to increase overhead expenses due to the FDA approval of its two HIV products.

**Research and Development:**

Research and development expenses for the three months ended September 30, 2006 were \$318,000 compared with \$292,000 for the three months ended September 30, 2005.

This category includes costs incurred for regulatory approvals, product evaluations and registrations. Expenses for Clinical & Regulatory Affairs totaled \$71,000 for the three months ended September 30, 2006, a decrease of \$1,000 compared to the three months ended September 30, 2005. While the overall change was immaterial the components changed. There was also a decrease due to reductions in costs for clinical studies of \$14,000. This decrease was offset by increases in salaries and related expenses. The costs related to the clinical trials and consulting in 2005 were related to the evaluation of the Company's HIV tests in relation of its FDA Pre-Marketing Approval ( PMA ) application which was submitted in February of 2005.

Expenses other than Clinical & Regulatory Affairs increased \$27,000 and were related to increased salaries and wage-related costs of \$ 41,000 for new hires in the R&D group and the cost related to employee stock options vesting in the period of \$ 6,000, additional temporary labor of \$15,000, increase in travel and entertainment costs of \$2,000 offset by a reduction in the cost of materials of \$25,000, and a reduction in grant funding of \$10,000.

The Company presently plans to increase its spending on research and development because it believes such spending will result in the development of new and innovative products that will drive revenue growth. The Company will continue to focus its development efforts on its HIV and tuberculosis rapid test products, some of which incorporate patent-pending technologies.

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

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

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

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

Chembio has completed development and is in final validation stage on a series of rapid lateral-flow assays for the detection of veterinary TB in multiple host species including; cattle, cervids, badgers, camels, elephants, and exotic wildlife species. The family name for the technology is VetTB STAT-PAK . Application to the USDA is targeted for the fourth quarter of 2006 for the ElephantTB STAT-PAK Assay with the other to follow in early 2007. The Company anticipates commercialization of these products to start in the second quarter of 2007 for at least the ElephantTB STAT-PAK to be followed by veterinary tests for cervids (CervidTB STAT-PAK), cattle (BovidTB STAT-PAK) and camelids (CamelidTB STAT-PAK), although there are no assurances that it will be successful.

**Table of Contents****Dual Path Platform (DPP )**

During the third quarter of 2006 significant additional progress was made in developing prototypes of the Dual Path Platform, including the testing of our current HIV test strip with DPP and identifying an oral fluid collection system that would be used with an oral fluid HIV test incorporating DPP. We have also generated interest in this platform as a result of our initial business development efforts for collaborative and licensing opportunities for this technology, and we are in preliminary discussions with several parties in this regard. We believe we can extend this technology to many applications within the infectious disease field, as well as other medical fields.

**Selling, General and Administrative Expense:**

Selling, general and administrative expense increased \$288,000 to \$1,110,000 in the three months ended September 30, 2006 compared with \$822,000 for the same period in 2005. This increase was attributable to increased staff costs in the accounting, administration and sales and marketing departments of \$126,000 and the cost related to employee stock options vesting in the period of \$15,000. In addition, there was an increase of \$71,000 in costs classified as investor relations, \$21,000 of which resulted from an increase in the number of members of the Company's Board of Directors, \$27,000 from increased travel and entertainment costs, \$16,000 from increased trade show costs, \$16,000 in increased license fees, increased legal expenses of \$44,000 related to patent litigation, \$65,000 related to general patent and other legal services offset by a reduction in royalties and commissions of \$101,000. As the Company's sales of its HIV rapid test products increase, it expects selling, general and administrative expense to also increase. This will be in large measure due to increased costs for commissions and royalties on intellectual property licenses. At the end of 2005, the Company renegotiated one of its license agreements to provide for a decrease of 50% in the royalty rate, from 10% to 5% of sales of HIV products, in exchange for \$350,000 in cash payments (of which \$100,000 was paid in 2005, \$50,000 paid in June 2006, and the balance accrued as of September 30, 2006). Such payment is being amortized over the life of the royalty agreement as licensing fees.

**Other Income and Expense:**

Interest expense increased by \$358,000 for the three months ended September 30, 2006 compared with the three months ended September 30, 2005. Almost all of this increase was due to the valuation of the warrants associated with debentures issued on June 29, 2006 and amortized over the three month life which totaled \$331,000. In addition, the accrued interest on this debt was \$26,000. Interest income for the three months ended September 30, 2006 decreased \$8,000 due to less availability of funds to invest. In addition the Company received \$25,000 from a New York State grant related to marketing research.

**Results of Operations for the Nine Months Ended September 30, 2006 as Compared with the Nine Months Ended September 30, 2005****Revenues:**

Revenues are comprised of \$ 3,684,000 in net product sales and \$ 209,000 in grants and development income for the nine months ended September 30, 2006 as compared with \$ 2,004,000 in net product sales, \$250,000 in license revenue and \$ 328,000 in grant and development income for the nine months ended September 30, 2005. The increase in net product sales is attributable to increased sales of our HIV tests of \$ 793,000 and increased sales of our Chagas tests of \$ 1,137,000 from \$ 64,000 to \$ 1,201,000, partially offset by decreased sales of our pregnancy test kit (a deemphasized product) of \$ 150,000 and decreases in other product sales aggregating \$ 100,000. The decrease in license revenue of \$250,000 is due to a technology transfer agreement which took place in 2005. The Company does not expect that this particular license revenue will continue in the future. The decrease in grant and development income of \$ 119,000 was due to certain grants received in 2005 that weren't continued or awarded in 2006.

Net product sales for the nine month period ended September 30, 2006 increased 84 % compared to the same period in 2005. HIV net product sales increased 67 % in this period compared to the same period in 2005. The Company had a \$465,000 HIV product order from Brazil that it would have shipped in the third quarter but for a delay in our customer completing required import documentation on a timely basis. The documentation was completed in October and this order was shipped in late October 2006. The Company believes that sales of its HIV products will continue to increase in 2006 as compared to 2005 both as a result of the international marketing strategies that were implemented in 2005 and from the sales in the United States market due to the approval from the U.S. Food and Drug Administration (FDA). The Chagas net product sales increase was a result of the Company obtaining its first significant order for this

product, in the amount of \$1.2 million, which it shipped in the nine months of 2006.

**Gross Margin:**

Gross margin on net product sales for the nine months ended September 30, 2006 was 26.5%, as compared to 11.6% for the nine months ended September 30, 2005. The increase in gross margin percentage is attributable to the increased sales of HIV products, which were at a higher margin than other product lines, and because sales volume in 2005 was significantly lower, fixed overhead expenses per dollar of sales were disproportionately high.

**Table of Contents****Research and Development:**

Research and development expenses for the nine months ended September 30, 2006 were \$1,062,000 compared with \$1,054,000 for the nine months ended September 30, 2005.

This category includes costs incurred for regulatory approvals, product evaluations and registrations. Expenses for Clinical & Regulatory Affairs, totaled \$250,000 for the nine months ended September 30, 2006, a decrease of \$132,000 compared to the nine months ended September 30, 2005. Most of this decrease is due to reductions in costs for clinical studies of \$105,000, outside regulatory consultants of \$32,000, and an increase in salary and related expenses of \$8,000. The costs related to the clinical trials and consulting in 2005 were related to the evaluation of the Company's HIV tests in relation of its FDA Pre-Marketing Approval ( PMA ) application which was submitted in February of 2005.

Expenses other than Clinical & Regulatory Affairs increased \$141,000 and were related to increased salaries and wage-related costs of \$93,000 for new hires in the R&D group, the cost related to employee stock options vesting in the period of \$54,000, increased cost of materials of \$25,000, additional temporary labor of \$30,000, net of a reduction in travel and entertainment costs of \$19,000 and a reduction in grant funding of \$45,000.

The Company presently plans to increase its spending on research and development because it believes such spending will result in the development of new and innovative products. The Company currently plans to continue to focus its development efforts on its HIV and tuberculosis related products, some of which incorporate patent-pending technologies.

**Selling, General and Administrative Expense:**

Selling, general and administrative expense increased \$1,632,000 to \$3,741,000 in the nine months ended September 30, 2006 compared with \$2,109,000 for the same period in 2005. This increase was attributable to increased staff costs in the accounting, administration and sales and marketing departments of \$374,000 and the cost related to employee stock options vesting in the period of \$118,000. Increased sales also resulted in an increase in royalties and commissions of \$208,000. In addition there was an increase of \$261,000 in costs regarding investor relations, \$94,000 of which resulted from an increase in the number of members of the Company's Board of Directors, \$81,000 from increased travel and entertainment costs, \$67,000 related to marketing consultants, \$38,000 from increased trade show costs, \$50,000 in increased license fees, increased legal expenses of \$200,000 related to patent litigation and \$110,000 related to general patent and other legal services.

**Other Income and Expense:**

Interest expense increased by \$371,000 for the nine months ended September 30, 2006 compared with the nine months ended September 30, 2005. Most of this increase was due to the valuation of the warrants associated with debentures issued on June 29, 2006 and amortized over the three month life which totaled \$331,000. In addition the accrued interest on this debt was \$26,000. Interest income for the nine months ended September 30, 2006 decreased \$30,000 due to less availability of funds to invest. In addition the Company sold a piece of equipment which was fully depreciated for \$5,000 as well as receiving \$25,000 from New York State grant related to marketing research.

**LIQUIDITY AND CAPITAL RESOURCES**

The Company had a working capital surplus of \$1,837,000 at September 30, 2006 and a working capital surplus of \$650,000 at December 31, 2005. On September 29, 2006 and October 5, 2006, the Company completed the Series C Preferred Stock Offering for \$8,150,000. On June 29, 2006, the Company borrowed \$1,300,000 which was partially repaid from the Series C Preferred Stock Offering proceeds, as described in the Overview section above and more fully in Note 1 of the financial statements. On March 30, 2006, the Company completed a transaction related to the Series B Preferred Stock Offering which raised \$1,000,000 before costs in the form of 9% Convertible Series B Preferred Stock and associated warrants ( Series B Offering ). The proceeds from the Series C Offering, the June 29, 2006 bridge loan and the Series B Offering have been and are being used primarily for general corporate purposes including for sales and marketing, research and development, intellectual property, and also for working capital, investor relations and capital expenditures.

The Company believes its resources are sufficient to fund its needs through the end of 2007. Its liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenue growth; (2) the extent to which, if any, that revenue growth improves operating cash flows; (3) its investments in research and development,

facilities, marketing, regulatory approvals, and other investments it may determine to make; and (4) the investment in capital equipment and the extent to which it improves cash flow through operating efficiencies. There are no assurances that it will be successful in raising sufficient capital.

The following table lists the future payments required on the Company's debt and any other contractual obligations as of September 30, 2006:

**Table of Contents**

<b>OBLIGATIONS</b>	<b>Total</b>	<b>Less than</b>			<b>Greater than</b>
		<b>1 Year</b>	<b>1-3 Years</b>	<b>4-5 Years</b>	<b>5 Years</b>
Long Term Debt(1)	\$ 923,160	\$ 920,000	\$ 3,160	\$	\$
Capital Leases (2)	\$ 54,407	\$ 41,293	\$ 13,113	\$	\$
Operating Leases	\$ 50,225	\$ 50,225	\$	\$	\$
Other Long Term Obligations(3)	\$ 1,085,000	\$ 820,000	\$ 177,500	\$ 25,000	\$ 62,500
<b>Total Obligations</b>	<b>\$ 2,112,792</b>	<b>\$ 1,831,518</b>	<b>\$ 193,773</b>	<b>\$ 25,000</b>	<b>\$ 62,500</b>

(1) This includes the balance of \$800,000 still due from the funds borrowed on June 29, 2006 (see Note 1) and accrued interest (see Note 3).

(2) This represents capital leases used to purchase capital equipment.

(3) This represents contractual obligations for fixed cost licenses and employment contracts.

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

Please see section entitled Overview above.

On September 29, 2006, the Company executed several agreements by and among the Company, Inverness Medical Innovations, Inc. ( Inverness ) and StatSure Diagnostic Systems, Inc. ( StatSure ). Pursuant to these agreements, as described below, the Company will engage in marketing, licensing and distribution activities with these two companies. These agreements contain gross margin sharing formulae among Inverness, the Company and StatSure. In addition, the Company has the exclusive right and duty to manufacture the products marketed by Inverness under all the agreements, and it has the right to subcontract manufacturing, but not sublicense or subcontract its rights or obligations.

First, the Company executed an HIV Barrel License, Marketing and Distribution Agreement between the Company, Inverness and StatSure. This agreement covers the Company s FDA-approved SURE CHECK® HIV 1/2 ( SURE



CHECK ), a lateral flow rapid HIV test employing a proprietary barrel system that is an integrated single-use rapid HIV antibody detection screening test. Some terms of the agreement are:

Inverness will market the SURE CHECK product under Inverness brands globally [subject only to certain existing international agreements that the Company and StatSure may keep in place for up to one year];

Inverness will exclusively market SURE CHECK under the agreement as well as any new HIV products in the barrel field that are developed, and may not compete with any products in this field worldwide as defined;

The Company and StatSure have each granted Inverness exclusive rights to their intellectual property in the HIV barrel field; and

Inverness has a first right to negotiate any agreements to market and distribute any of the Company's new HIV antibody detection tests, including products that may incorporate the Company's patent-pending Dual Path Platform (DPP(TM))

In addition, the Company executed an HIV Cassette License, Marketing and Distribution Agreement with Inverness. This agreement covers the Company's FDA-approved STAT-PAK(TM) HIV 1/2, a lateral flow rapid HIV test employing a cassette system that is a single-use rapid HIV antibody detection screening test. Some of the terms of the agreement are:

Inverness will market this product in the U.S. market only, and the Company has a non-exclusive license under the Inverness lateral flow patents to continue to market the product under the Company's brand in the rest of the world; and

Inverness may bring a competitive HIV cassette product to the U.S. market, but in that event the Company may expand its lateral flow license for this product to the U.S. and have other options under the agreement.

The Company and Inverness also executed a Non-Exclusive License, Marketing and Distribution Agreement, which covers the Company's FDA-approved STAT-PAK(TM) HIV 1/2. Some of the terms of this agreement are as follows:

The Company received a non-exclusive license under the Inverness lateral flow patents for its HIV 1/2 Dipstick for marketing outside the U.S.;

**Table of Contents**

The Company received a worldwide non-exclusive license to manufacture and market a number of other Company-branded products, including all the Company's rapid tests for human and veterinary and tuberculosis, Chagas disease, and tests for other defined emerging and neglected diseases; and Inverness has the right to market each of these products (except the HIV 1/2 STAT PAK Dipstick) under an Inverness brand pursuant to an agreed-upon pricing and margin sharing formula similar to the other agreements.

The Company and StatSure also entered into a Settlement Agreement pursuant to which all matters in their litigation regarding StatSure's barrel patent and other matters were settled. Under the terms of this agreement, the parties will equally share in the profits relating to SURE CHECK after reimbursement to the Company of its manufacturing and related costs, as defined, and the parties will act jointly in the HIV barrel field. The settlement combines each company's HIV barrel intellectual property, including an exclusive manufacturing license from StatSure to the Company of its barrel patent for all HIV applications, thereby ensuring the Company's exclusive right to manufacture, as well as Inverness' right to market through the marketing license that StatSure granted Inverness under the three way agreement. In addition, pursuant to this Agreement, StatSure and the Company will share equally the net sales to Inverness of SURE CHECK after these deductions.

In July 2006 the Company submitted to the FDA CLIA ( Clinical Laboratory Improvement Act ) waiver applications for its HIV 1/2 STAT-PAK® and SURE CHECK® HIV 1/2 products. These waivers are essential in order to market FDA approved products to the physician office laboratory and public health segments of the United States market. A CLIA waiver was granted by the FDA for HIV 1/2 STAT PAK in November of 2006. The application concerning SURE CHECK HIV 1/2 is still pending at the FDA.

Upon receipt of a CLIA waiver, the Company will then submit proposed labeling changes that it will have agreed upon with Inverness principally related to the brand name changes. The Company currently anticipates that this process will be completed to enable Inverness to launch the CLIA-waived products in the United States during the first quarter of 2007.

There have been many developments recently regarding the market for HIV testing in the United States. For example, the United States Centers for Disease Control recently issued final revised recommendations advocating routine HIV testing for all Americans between the ages of 13 and 64, a White House 2007 budget request for \$90 million to test an additional three million Americans using rapid HIV tests is being negotiated by Senate and House conference committees, and the FDA adopted guidelines recommended by its Blood Products Advisory Committee that set forth the conditions under which rapid HIV tests could be approved for direct over-the-counter sales to U.S. consumers. All of these developments bode well for the expansion of the U.S. rapid HIV test market. However, there are still many obstacles and uncertainties which must be overcome before these developments become a reality that will result in realizable opportunities for the Company, and there is no assurance that any of these developments will be realized. During 2005, the Company established offices in Nigeria and Tanzania which it believes will be significant in its continuing efforts to become part of the national testing protocols in many countries in Africa. The Company's STAT-PAK is designated as the confirmatory test in all of the national rapid HIV testing protocols in the Republic of Uganda, and in February of 2006 STAT-PAK was designated in four of the eight parallel testing algorithms (two tests used on each patient) adopted by the Nigerian Ministry of Health in its Interim National Testing Algorithm. The Company is making good progress towards having its HIV products designated in other countries where it has focused its efforts. The Company has registered its products and has arrangements with distribution partners in certain of these countries and is in negotiations for similar arrangements in other countries. The Company believes that its strategy of establishing offices in these challenging markets is a very effective way to obtain sustainable and supportable business.

In 2006, Chembio was one of four companies selected by the Clinton Foundation HIV/AIDS Initiative ( CHAI ) to make available low-cost rapid HIV tests in order to more quickly and cost effectively achieve treatment objectives. Under the CHAI agreement, the Company has agreed to offer its HIV STAT-PAK Dipstick, Chembio's lowest cost HIV rapid test product, at a reduced price in the expectation that the Company will receive significant order volume not otherwise obtainable. If these order volumes are not realized, the Company has the right to terminate the agreement or renegotiate pricing. Chembio is the only U.S.-based manufacturer of the four companies in this agreement. The CHAI Procurement Consortium is currently comprised of more than 50 countries in Africa, Asia,

Eastern Europe, Latin America and the Caribbean that have Memoranda of Understanding (MOUs) with CHAI. Consequently, the Company is now actively engaged with CHAI in developing sales opportunities in many of these countries. Although in some of these countries the Company has already made substantive sales efforts, there are many more where this is not the case. There is no commitment or assurance that either the Company's direct efforts to establish additional distributors and/or local assembly, or its activities through CHAI will materialize into meaningful sales.

The Company's technology transfer and supply agreement in Brazil is moving forward. The Company shipped \$670,000 of HIV rapid test components to this customer in the nine months ended September 30, 2006, a 20% decrease over the same period in 2005. However, the Company delivered another \$841,000 of HIV rapid test components to their Brazilian customer in the fourth quarter of 2006.

**Table of Contents**

The Company also received, in January of 2006, an order for \$1.2 million to supply its Chagas Disease rapid test. The Company shipped approximately \$930,000 in the nine months ended September 30, 2006, with the balance delivered in the third quarter of 2006. This procurement is being made by the Pan American Health Organization, headquartered in Washington D.C., which is affiliated with the World Health Organization. The procurement will be used to implement a nationwide Chagas screening program for all children under the age of 10 in endemic regions of Bolivia. The Company is actively looking at developing additional business opportunities for this product in Bolivia, and other markets in Latin America that are impacted by this disease.

In September 2005, the Company hired a senior diagnostics marketing executive to focus on its Tuberculosis products, both for veterinary and human TB. The Company's non-human primate Tuberculosis product is currently under review by the United States Department of Agriculture (USDA), and the Company hopes to receive USDA approval during the first quarter of 2007 provided its tests meet certain performance and other criteria. The Company plans to submit additional veterinary TB products to the USDA, including a cattle TB test, subject to having the necessary performance data.

During the third quarter of 2006, the Company made significant progress in developing prototypes of the Dual Path Platform (DPP(TM)). In addition to our internal product development efforts in the infectious disease area, based on significant interest for a number of different applications of this technology from various potential users, we believe we can also extend this technology to other medical fields.

**Critical Accounting Policies and Estimates**

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

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

*Revenue Recognition*

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

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

*Research & Development Costs*

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

*Valuation of Inventories*

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

*Allowance for doubtful accounts*

The Company's policy is to review its accounts receivable on a periodic basis, no less than monthly. On a quarterly basis an analysis is made of the adequacy of its allowance for doubtful accounts and adjustments are made accordingly. The current allowance is approximately 3.99% of accounts receivable.

*Income Taxes*

Income taxes are accounted for under SFAS No. 109, Accounting for Income Taxes. SFAS No. 109 requires the asset and liability method of accounting for deferred income taxes. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities. Deferred tax assets or liabilities at the end of each period are determined using the tax rate expected to be in effect when taxes are actually

paid or recovered. For example, if the Company does not become profitable it may be unable to utilize its deferred tax asset, which approximates \$6,128,000 at December 31, 2005.

**Table of Contents**

SFAS 109 also requires that a valuation allowance be established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence needs to be considered, including a company's current and past performance, the market environment in which the company operates, length of carryback and carryforward periods and existing contracts that will result in future profits. Forming a conclusion that a valuation allowance is not needed is difficult when there is negative objective evidence such as cumulative losses in recent years. Cumulative losses weigh heavily in the overall assessment. As a result, the Company determined that it was appropriate to establish a valuation allowance for the full amount of its deferred tax assets.

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

**DESCRIPTION OF PROPERTY**

Our administrative offices and research facilities are located in Medford, New York. We lease approximately 14,000 square feet of industrial space for \$8,167 per month. The space is utilized for research and development (approximately 1,600 square feet), offices (approximately 4,700 square feet) and production (approximately 7,700 square feet). The lease term expires on April 30, 2007 with a right to renew for an additional two years. Additional space may be required as we expand our research and development activities. We do not foresee any significant difficulties in obtaining any required additional facilities.

**CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

Mark L. Baum, our former president prior to the merger and a former director of Chembio Diagnostics, Inc., entered into a nine-month employment agreement with Chembio Diagnostics, Inc., effective upon the closing of the merger, pursuant to which Mr. Baum received 400,000 shares of our common stock as well as a warrant to acquire 425,000 shares of common stock at \$.60 per share and a warrant to acquire an additional 425,000 shares of common stock at \$.90 per share. The warrants expire five years after the date of grant. Pursuant to the employment agreement, Mr. Baum was to advise Chembio Diagnostics, Inc. concerning management, marketing, strategic planning, corporate structure, business operations, expansion of services, acquisitions and business opportunities, matters related to our public reporting obligations, and our overall needs through February 5, 2005. Mr. Baum also invested \$65,000 in the private placement of series A preferred stock, pursuant to which he received 2.167 shares of series A preferred stock convertible into 108,350 shares of common stock, and a warrant to purchase 130,020 shares of common stock. Mr. Baum also owns 300,000 shares of our common stock in addition to the stock and warrants described above. In November of 2004 as payment of dividends on the series A preferred, Mr. Baum received 4,333 shares of common stock. Prior to the merger, Mr. Baum was the sole director and officer of Chembio Diagnostics, Inc. On March 18, 2005, as compensation for Mr. Baum's service on the Board of Directors of Chembio Diagnostics, Inc., the exercise price of Mr. Baum's warrant to acquire 425,000 shares of common stock at \$.90 per share was reduced to \$.75 per share. Mr. Baum received no other compensation for his services on the Board of Directors.

Lawrence A. Siebert, the president and chairman of the board of directors of the Company beginning at the time of and after the merger, and the president and chairman of Chembio Diagnostic Systems Inc. since May 2002, held two promissory notes issued by Chembio Diagnostic Systems Inc. One note was issued on August 1, 1999 in the original principal amount of \$338,125, bearing interest at a rate of 11% per annum. The other was issued on April 25, 2001 in the original principal amount of \$795,937, bearing interest at a rate of 12% per annum. Mr. Siebert converted the entire outstanding principal amount of the 11% note and \$561,875 principal amount of the 12% note into 30 shares of the Company's series A preferred stock, together with warrants to acquire 1,800,000 shares of common stock at \$.90 per share, pursuant to the Company's private placement of its series A preferred stock on May 5, 2004. The shares of series A preferred stock held by Mr. Siebert are convertible into 1,547,100 shares of the Company's common stock. The remaining debt of \$234,062 held by Mr. Siebert was exchanged on December 29, 2004 into 7.80208 shares of the Company's series A preferred stock, together with warrants to acquire 468,125 shares of common stock at \$.90 per

share, pursuant to the terms of the Company's private placement of its series A preferred stock on May 5, 2004. As of September 30, 2006, \$126,501.94 of accrued interest on the debt is also due to Mr. Siebert, but is not accruing interest. The accrued interest will be paid out according to the terms of the Company's private placement of its series B preferred stock on January 28, 2005. Mr. Siebert also invested \$50,000 in our series B preferred stock private placement pursuant to which he received 1 share of series B preferred stock convertible into 81,967 shares of common stock and a warrant to purchase 77,868 shares of common stock.

Mr. Siebert also invested \$18,700 in Chembio Diagnostic Systems Inc. pursuant to a private placement of convertible notes on March 22, 2004. Mr. Siebert converted the entire principal amount of the note that he received, together with accrued interest

**Table of Contents**

thereon, into .942 shares of the Company's series A preferred stock, together with warrants to acquire 56,520 shares of common stock at \$.90 per share, pursuant to the Company's private placement of its series A preferred stock on May 5, 2004. In November of 2004 as payment of dividends on the series A preferred he received 61,884 shares of common stock. Mr. Siebert exercised a warrant to purchase 66,869 shares of common stock on December 30, 2004 at a price of \$.45 per share. These shares were gifted by Mr. Siebert to a third party. In May of 2005 as payment of dividends on the series A preferred he received 72,234 shares of common stock. In July of 2005 as payment of dividends on the series B preferred he received .03871 shares of series B preferred stock. In November of 2005 as payment of dividends on the series A preferred he received 77,488 shares of common stock. In January of 2006 as payment of dividends on the series B preferred he received .04674 shares of series B preferred stock. In May of 2006 as payment of dividends on the series A preferred, Mr. Siebert received 77,488 shares of common stock. In June of 2006 as payment of dividends on the series A preferred and series B preferred, Mr. Siebert received 22,714 shares of common stock. In July and August of 2006 as payment of dividends on the series B preferred, Mr. Siebert received 3,295 shares of common stock. In November of 2006 as payment of dividends on the series A preferred, Mr. Siebert received 55,860 shares of common stock. In January 2007 as payment of dividends on the series B preferred, Mr. Siebert received 3,292 shares of common stock.

Mr. Siebert prior to March 22, 2004 had either advanced funds to Chembio Diagnostic Systems, Inc. or paid vendors directly on Chembio Diagnostic Systems, Inc.'s behalf. The total amount so paid or advanced and not repaid totaled \$182,181 as of September 30, 2006.

Richard J. Larkin, the Chief Financial Officer of the Company, invested \$10,000 in Chembio Diagnostic Systems Inc. pursuant to the March 22, 2004 private placement of convertible notes. Mr. Larkin converted the entire principal amount of the note that he received, together with accrued interest thereon, into .504 shares of the Company's series A preferred stock, together with warrants to acquire 30,240 shares of common stock at \$.90 per share, pursuant to the Company's private placement of its series A preferred stock on May 5, 2004. In November of 2004 as payment of dividends on the series A preferred he received 1,007 shares of common stock. In May of 2005 as payment of dividends on the series A preferred he received 999 shares of common stock. In November of 2005 as payment of dividends on the series A preferred he received 1,007 shares of common stock. In May of 2006 as payment of dividends on the series A preferred, Mr. Larkin received 1,077 shares of common stock. In June of 2006 as payment of dividends on the series A preferred and series B preferred, Mr. Larkin received 265 shares of common stock. In November of 2006 as payment of dividends on the series A preferred, Mr. Larkin received 726 shares of common stock.

Avi Pelosof, the vice president of sales and marketing of the Company, invested \$4,000 in the Company pursuant to the March 22, 2004 private placement of convertible notes. Mr. Pelosof converted the entire principal amount of the note that he received, together with accrued interest thereon, into .202 shares of the Company's series A preferred stock, together with warrants to acquire 22,555 shares of common stock at \$.90 per share, pursuant to the Company's private placement of its series A preferred stock on May 5, 2004. In November of 2004 as payment of dividends on the series A preferred he received 403 shares of common stock. In May of 2005 as payment of dividends on the series A preferred he received 399 shares of common stock. In November of 2005 as payment of dividends on the series A preferred he received 403 shares of common stock. In May 2006, as payment of dividends on the series A preferred, Mr. Pelosof received 403 shares of common stock. In June of 2006 as payment of dividends on the series A preferred and series B preferred he received 106 shares of common stock. In November of 2006 as payment of dividends on the series A preferred, Mr. Pelosof received 290 shares of common stock. Mr. Pelosof voluntarily resigned from the Company on December 6, 2006, effective January 31, 2007.

Dr. Gary Meller, a non-employee director of the Company, currently serves as a limited partner and a member of the Advisory Board of Crestview Capital Master LLC, referred to herein as Crestview, which was the lead investor, investing \$3 million, in our series B preferred stock private placement in January 2005, and which subsequently invested an additional \$1 million in our series B preferred in March 2006. Crestview also invested \$2 million in our series C preferred stock private placement. in September 2006.

As referred to above, in January 2005, for a purchase price of \$3 million, we issued Crestview 60 shares of our series B preferred stock, and warrants to purchase 4,672,130 shares of our common stock at a warrant exercise price of \$.61



per share. In July 2005, we issued Crestview dividends on these series B preferred shares in the form of 2.32274 additional series B preferred shares.

In March 2006, for a purchase price of \$1 million, we issued Crestview 20 shares of series B preferred shares with warrants to purchase 1,557,377 shares of common stock at a warrant exercise price of \$.61 per share. These shares were issued in connection with the Company's January 2005 private placement as described herein. Subsequently, in July 2006, we issued dividends on all of Crestview's shares in the form of 220,301 shares of common stock. In September 2006, for a purchase price of \$2 million, we issued 40 shares of series C preferred shares to Crestview together with warrants to purchase 625,000 shares of common stock at an exercise price of \$1.00 per share.

In January 2007, because of comments from the staff of the SEC concerning the registration statement of which this prospectus is a part, Crestview agreed to reduce the number of its shares of common stock covered by this prospectus to 2,000,000. Crestview also agreed to waive any penalties that the Company would otherwise owe Crestview because of the failure to register all of Crestview's shares in the current registration statement. In return, the Company has agreed that, upon request by Crestview, the

**Table of Contents**

Company will file one or more registration statements with the SEC in order to register the resale of other shares beneficially owned by Crestview. The cost of any such registration statements shall be borne by the Company. The series B preferred shares owned by Crestview are convertible into a total of 6,747,748 shares of common stock, and the series C preferred shares owned by Crestview are convertible into a total of 2,500,000 shares of common stock.

Crestview invested \$2,000,000 in our series C preferred stock private placement on September 29, 2006. We also received an investment of \$2,000,000 on that date from Inverness. A certificate of designation for the series C preferred was filed with the Secretary of State of Nevada reflecting the agreed upon conversion price of \$.85. The series C preferred stock private placement for an aggregate of \$8,150,000 (including the \$2,000,000 invested by each of Crestview and Inverness) was completed on October 5, 2006. During the period between September 29, 2006 and October 5, 2006, we requested the assistance of Crestview and others in identifying to us prospective investors. A representative of Crestview informed Mr. Siebert on October 3, 2006 of a conversation he had earlier that day with a fund manager that the fund would be interested in investing a substantial amount in the offering, but only at a conversion price of no more than \$.80.

At a board of directors meeting on October 4, 2006, Mr. Siebert expressed his recommendation that the board approve lowering the conversion price to \$.80 in order to be able to obtain the additional funds. The board discussed the bridge financing of \$1,300,000 in promissory notes which had been completed in June 2006, the noteholders who expected to convert their notes into the series C preferred stock, and the restrictions on future equity sales by us in the bridge financing purchase agreement that necessitated finalizing promptly the series C preferred stock offering. After discussion, Mr. Siebert made a motion to approve the funding. The motion was approved unanimously, with the exception of Gerald Eppner, a director who resigned from the board of directors on January 31, 2007, who abstained. Mr. Eppner stated that he understood the benefits of the economics of the transaction and the Company's need to proceed so quickly, but that he did not wish to vote in favor.

At a board meeting held on October 11, 2006, the board members discussed the series C preferred stock private placement. Mr. Eppner, a director who resigned from the board of directors on January 31, 2007, stated in his view that it would be desirable to review the sequence of events in this transaction to assure proper guidelines for corporate governance and to determine if disclosure or other issues needed to be considered. At a board meeting held on October 26, 2006, it was discussed that a subcommittee of the audit committee, whose members would be Mr. Eppner and Alan Carus, would review certain issues related to the series C preferred stock private placement.

The first meeting of the audit committee to review the series C preferred stock offering was held on October 27, 2006. The audit committee decided it would review the role of Crestview in the series C preferred stock offering, Crestview's status as a possible control person, the role of Gary Meller in the offering and his relationship with Crestview, and whether the audit committee should recommend new corporate governance procedures to be implemented or any action to be taken by the Board. The audit committee utilized legal counsel to assist in its review. The audit committee held seven meetings during the period from October 27, 2006 to January 10, 2007. Messrs. Carus and Eppner attended all of the meetings. Mr. Carus concluded that: (i) he was satisfied with the review, and (ii) although with fewer time constraints, there could have been more deliberation regarding the change in the conversion price, he believed there was no inappropriate conduct, that the Company had not suffered any damage and that the matter should be closed. Mr. Eppner stated his concerns that: (i) Crestview is an affiliate of the Company, (ii) there was no participation by the Company in the reduction in the conversion price from \$.85 to \$.80, (iii) although he agreed with Mr. Carus that the \$.80 price may have been acceptable to the Company, it was not as good as a higher price, (iv) Mr. Siebert should not have allowed this to happen, and that because he did, it was evidence of control by Crestview, and (v) disclosure of the review of the audit committee should be made in this registration statement.

## **MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS**

### **Market Information**

Our common stock is quoted on the OTC Bulletin Board under the symbol CEMI. Prior to May 14, 2004, our common stock was traded on the OTC Bulletin Board under the symbol TSUN. For the periods indicated, the following table sets forth the high and low bid prices per share of our common stock. These prices represent inter-dealer quotations without retail markup, markdown, or commission and may not necessarily represent actual

transactions. We completed a 1 for 17 reverse stock split on March 12, 2004, and all of the prices in this table have been adjusted to reflect this split.

<b>Fiscal Year 2006</b>	<b>High Bid</b>	<b>Low Bid</b>
First Quarter	\$0.75	\$0.33
Second Quarter	\$1.15	\$0.65
Third Quarter	\$0.85	\$0.68
Fourth Quarter	\$0.92	\$0.63

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

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

Trades of our common stock are subject to Rule 15c-9 of the Securities and Exchange Commission, known as the Penny Stock Rule. This rule imposes requirements on broker/dealers who sell securities subject to the rule to persons other than established customers and accredited investors. For transactions covered by the rule, brokers/dealers must make a special suitability determination for purchasers of the securities and receive the purchaser's written agreement to the transaction prior to sale. The Securities and Exchange Commission also has rules that regulate broker/dealer practices in connection with transactions in penny stocks. Penny stocks generally are equity securities with a price of less than \$5.00 (other than securities registered on certain national securities exchanges or quoted on the NASDAQ system, provided that current price and volume information with respect to transactions in that security is provided by the exchange or system), except for securities of companies that have tangible net assets in excess of \$2,000,000 or average revenue of at least \$6,000,000 for the previous three years. The Penny Stock Rule requires a broker/ dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document prepared by the Commission that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker/dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker/dealer and its salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker/dealer and salesperson compensation information, must be given to the customer orally or in writing prior to effecting the

**Table of Contents**

transaction and must be given to the customer in writing before or with the customer's confirmation. These disclosure requirements have the effect of reducing the level of trading activity in the secondary market for our common stock. As a result of these rules, investors may find it difficult to sell their shares.

**Holders**

As of January 4, 2007 there were approximately 815 record owners of our common stock.

**Dividends**

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

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

the corporation would not be able to pay its debts as they become due in the usual course of business; or

except as otherwise specifically allowed by the corporation's articles of incorporation, the corporation's total assets would be less than the sum of its total liabilities plus the amount that would be needed, if the corporation were to be dissolved at the time of distribution, to satisfy the preferential rights upon dissolution of stockholders whose preferential rights are superior to those receiving the distribution.

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

**Equity Compensation Plan Information as of September 30, 2006**

## Equity Compensation Plan Information

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders	1,629,750	\$ 0.69	1,372,250
Equity compensation plans not approved by security holders			
<b>Total</b>	<b>1,629,750</b>	<b>\$ 0.69</b>	<b>1,372,250</b>

**EXECUTIVE COMPENSATION**

The following table summarizes all compensation recorded by the Company in each of the last two completed fiscal years for our principal executive officer, our two most highly compensated executive officers other than our principal executive officer whose annual compensation exceeded \$100,000, and up to two additional individuals for whom disclosure would have been made in this table but for the fact that the individual was not serving as an executive officer of our company at December 31, 2006.

**Table of Contents**

<b>Name and Principal Position</b>	<b>Year</b>	<b>Salary (\$)<sup>1</sup></b>	<b>Bonus (\$)<sup>2</sup></b>	<b>Option Awards (\$)<sup>3</sup></b>	<b>All Other Compensation</b>	<b>Total (\$)</b>
Lawrence A. Siebert, CEO and Director <sup>4</sup>	2006	\$207,115	\$	\$18,364	\$ 7,200	\$232,679
	2005	155,998			4,154	160,152
Richard J. Larkin, CFO	2006	\$140,385	\$	\$19,660		\$160,045
	2005	122,773	900	24,833		148,506
Avi Pelossof, Vice President of Sales and Marketing	2006	\$156,538	\$	\$40,648	\$ 6,120	\$203,306
	2005	133,899	16,500	24,833	3,766	178,998
Javan Esfandiari, Director of Research and Development	2006	\$150,385	\$	\$30,448	\$ 4,800	\$185,633
	2005	133,380	18,712	24,833	2,954	179,879
Les Stutzman Vice President of Marketing	2006	\$116,539	\$11,500	\$ 7,754	\$20,075 <sup>5</sup>	\$155,868

**Employment Agreements**

**Mr. Siebert.** On June 15, 2006, Mr. Siebert and the Company entered into an employment agreement, effective May 10, 2006, which terminates on May 10, 2008. Pursuant to the employment agreement, Mr. Siebert serves as the President and Chief Executive Officer of the Company and is entitled to receive a base compensation of \$240,000 per year, subject to review by the board of directors of the Company at the end of the first twelve months. Mr. Siebert also shall be eligible for a bonus of up to 50% of his salary, consisting of (i) a bonus of up to 25% of his salary that is at the complete discretion and determination of the board of directors, and (ii) a bonus of up to an additional 25% of his salary that will be determined based upon revenue and earnings performance criteria established each year by the board of directors. Mr. Siebert is eligible to participate in any profit sharing, stock option, retirement plan, medical and/or hospitalization plan, and/or other benefit plans except for disability and life insurance that the Company may from time to time place in effect for the Company's executives during the term of Mr. Siebert's employment agreement. If Mr. Siebert's employment agreement is terminated by the Company without cause, or if Mr. Siebert terminates his employment agreement for a reasonable basis, including within 12 months of a change in control, the Company is required to pay as severance Mr. Siebert's salary for six months. Mr. Siebert has agreed for a period of two years after the termination of his employment with the Company not to induce customers, agents, or other sources of distribution of the Company's business under contract or doing business with the Company to terminate, reduce, alter, or divert business with or from the Company.

**Mr. Pelossof.** On May 5, 2004, Mr. Pelossof and the Company entered into an employment agreement, effective May 10, 2004, which terminates on May 10, 2007. Pursuant to the employment agreement, Mr. Pelossof serves as the Vice President of Sales, Marketing and Business Development of the Company. On June 15, 2006, the board of directors amended this agreement, and increased Mr. Pelossof's salary from a base compensation of \$120,000 per year, to a base salary of \$170,000 per year. Mr. Pelossof is also eligible for a bonus of up to 25% of his salary, consisting of (i) a bonus of up to 12.5% of his salary that is at the complete discretion and determination of the board of directors, and (ii) a bonus of up to an additional 12.5% of his salary that will be determined based upon revenue and earnings performance criteria established each year by the board of directors. Mr. Pelossof is eligible to participate in any profit sharing, stock option, retirement plan, medical and/or hospitalization plan, and/or other benefit plans except for disability and life insurance that the Company may from time to time place in effect for the

<sup>1</sup> Salary is total base salary.

<sup>2</sup>

Any bonus earned was paid solely on a discretionary basis, and not pursuant to any bonus plan.

<sup>3</sup> The estimated fair value of any option granted was determined at the date of grant by using the Black-Scholes option pricing model. All options cancelled in 2006 and subsequently reissued were valued at the delta incremental fair value, computed as of the repricing or modification date in accordance with FAS 123R, with respect to any cancelled option.

<sup>4</sup> Mr. Siebert also serves as a director on the Company's board of directors. Mr. Siebert does not receive any compensation for this director role.

<sup>5</sup> This amount represents the rental payments

the Company  
makes for the  
apartment Mr.  
Stutzman rents  
when he visits  
the Company.



**Table of Contents**

Company's executives during the term of Mr. Pelossof's employment agreement. If Mr. Pelossof's employment agreement is terminated by the Company without cause, or if Mr. Pelossof terminates his employment agreement for a reasonable basis, including within 12 months of a change in control, the Company is required to pay as severance Mr. Pelossof's salary for six months. Mr. Pelossof has agreed for a period of two years after the termination of his employment with the Company not to induce customers, agents, or other sources of distribution of the Company's business under contract or doing business with the Company to terminate, reduce, alter, or divert business with or from the Company. Mr. Pelossof voluntarily resigned from the Company on December 6, 2006, effective January 31, 2007.

**Mr. Esfandiari.** On May 5, 2004, Mr. Esfandiari and the Company entered into an employment agreement, effective May 10, 2004, which terminates on May 10, 2007. Pursuant to the employment agreement, Mr. Esfandiari serves as the Director of Research & Development for the Company. On June 15, 2006, the board of directors amended this agreement, and increased Mr. Esfandiari's salary from a base compensation of \$115,000 per year, subject to periodic review by the Board of Directors of the Company 120,000 per year, to a base salary of \$160,000 per year.

Mr. Esfandiari is also eligible for a bonus of up to 25% of his salary, consisting of (i) a bonus of up to 12.5% of his salary that is at the complete discretion and determination of the board of directors, and (ii) a bonus of up to an additional 12.5% of his salary that will be determined based upon revenue and earnings performance criteria established each year by the board of directors. Mr. Esfandiari is eligible to participate in any profit sharing, stock option, retirement plan, medical and/or hospitalization plan, and/or other benefit plans except for disability and life insurance that the Company may from time to time place in effect for the Company's executives during the term of Mr. Esfandiari's employment agreement. If Mr. Esfandiari's employment agreement is terminated by the Company without cause, or if Mr. Esfandiari terminates his employment agreement for a reasonable basis, including within 12 months of a change in control, the Company is required to pay as severance Mr. Esfandiari's salary for six months. Mr. Esfandiari has agreed for a period of two years after the termination of his employment with the Company not to induce customers, agents, or other sources of distribution of the Company's business under contract or doing business with the Company to terminate, reduce, alter, or divert business with or from the Company.

Neither Mr. Larkin nor Mr. Stutzman has an employment contract with the Company.

**OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END 2006**

Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price	Option Expiration Date	Option Vesting Date
	(#)	(#)	(\$)		
Lawrence A. Siebert	50,000 <sub>2</sub>		0.75	11/19/2007	4/17/2006
	10,000 <sub>2</sub>		0.75	12/31/2008	4/17/2006
	10,000 <sub>2</sub>		0.75	5/4/2011	4/17/2006
	50,000 <sub>2</sub>		0.75	5/28/2011	4/17/2006
		50,000 <sub>2</sub>	0.75	5/28/2011	1/1/2007
	50,000 <sub>3</sub>		0.75	5/4/2011	5/5/2004

<sup>1</sup> All options issued with a \$.62 exercise price were issued during 2006 as part of the Company's

1999 Option Plan. Pursuant to this plan, the Company granted 244,000 options to all employees.

- 2 All options issued with a \$.75 exercise price and an April 17, 2006 vesting date were issued on April 17, 2006 as part of the Company's 1999 Option Plan. Pursuant to this plan, the Company granted 244,000 options to all employees. On April 17, 2006, the Company's Compensation Committee approved the cancellation of each employee stock option award issued under the 1999 Equity Incentive Plan where the exercise price was greater than \$0.75 per share of the Company's common stock, and the issuance of a new stock option award under the 1999 Equity Incentive Plan, for the same number of shares of the

Company's common stock, with an exercise price of \$0.75 per share of the Company's common stock for each cancelled stock option award. The market price of the common stock of the Company on April 17, 2006 was \$0.72 per share. In total, stock option awards to acquire 795,000 shares of Company common stock were cancelled, and stock option awards to acquire 795,000 shares of Company common stock were issued. Other than the change in the exercise price, all of the terms and conditions in each newly issued stock option award are identical to the cancelled stock option award it replaces, with the following exceptions:

(i) Lawrence A. Siebert's stock option award for 50,000 shares of the Company's

common stock, exercisable on May 28, 2006 and terminating on May 28, 2011 was replaced with a stock option award for 50,000 shares of the Company's common stock, exercisable on January 1, 2007 and terminating on May 28, 2011; (ii) Avi Pelosof's stock option awards for 72,500 shares of the Company's common stock, exercisable on May 28, 2005 and on May 28, 2006 and both terminating on May 28, 2011 was replaced with a stock option award for 72,500 shares of the Company's common stock, exercisable on January 1, 2007 and terminating on May 28, 2011.

- <sup>3</sup> All other options shown were issued prior to 2006 as part of the Company's 1999 Option Plan.

**Table of Contents**

<b>Name</b>	<b>Number of Securities Underlying Unexercised Options Exercisable (#)</b>	<b>Number of Securities Underlying Unexercised Options Unexercisable (#)</b>	<b>Option Exercise Price (\$)</b>	<b>Option Expiration Date</b>	<b>Option Vesting Date</b>
<b>Richard J. Larkin</b>	25,000 <sub>2</sub>		0.75	5/17/2010	4/17/2006
		25,000 <sub>2</sub>	0.75	5/17/2010	4/17/2006
	18,750 <sub>1</sub>		0.62	3/24/2011	3/24/2006
		18,750 <sub>1</sub>	0.62	3/24/2011	1/1/2007
	50,000 <sub>3</sub>		0.45	9/15/2010	5/5/2004
<b>Avi Pelossof</b>	40,000 <sub>2</sub>		0.75	11/19/2007	4/17/2006
	10,000 <sub>2</sub>		0.75	12/31/2008	4/17/2006
	25,000 <sub>2</sub>		0.75	5/17/2010	4/17/2006
		25,000 <sub>2</sub>	0.75	5/17/2010	1/1/2007
	25,000 <sub>1</sub>		0.62	3/24/2011	3/24/2006
		25,000 <sub>1</sub>	0.62	3/24/2011	1/1/2007
	10,000 <sub>2</sub>		0.75	5/4/2011	4/17/2006
	27,500 <sub>2</sub>		0.75	5/27/2011	4/17/2006
		50,000 <sub>2</sub>	0.75	5/27/2011	1/1/2007
	40,000 <sub>3</sub>	22,500 <sub>2</sub>	0.75	5/27/2011	1/1/2007
		0.75	5/4/2011	5/5/2004	
<b>Javan Esfandiari</b>	30,000 <sub>2</sub>		0.75	3/31/2008	4/17/2006
	5,000 <sub>2</sub>		0.75	12/31/2008	4/17/2006
	25,000 <sub>2</sub>		0.75	5/17/2010	4/17/2006
		25,000 <sub>2</sub>	0.75	5/17/2010	1/1/2007
	18,750 <sub>1</sub>		0.62	3/24/2011	3/24/2006
		18,750 <sub>1</sub>	0.62	3/24/2011	1/1/2007
	5,000 <sub>2</sub>		0.75	5/4/2011	4/17/2006
	25,000 <sub>2</sub>		0.75	5/28/2011	4/17/2006
	25,000 <sub>2</sub>		0.75	5/28/2011	4/17/2006
	30,000 <sub>3</sub>	25,000 <sub>2</sub>	0.75	5/28/2011	5/28/2007
		0.75	5/4/2011	5/5/2004	
<b>Les Stutzman</b>	15,000 <sub>1</sub>		0.62	3/24/2011	3/24/2006
	10,000 <sub>3</sub>		0.57	9/19/2010	9/19/2006
		10,000 <sub>3</sub>	0.57	9/19/2010	9/19/2007

**Table of Contents****DIRECTOR COMPENSATION**

Name	Fees Earned or	Stock	Option	Total
	Paid in Cash (\$) <sup>1</sup>	Awards (\$) <sup>2</sup>	Awards (\$) <sup>3</sup>	
Alan Carus	\$ 40,000	\$ 10,650	\$ 14,663	\$ 65,313
Gerald Eppner <sup>4</sup>	37,500		16,504	54,004
Gary Meller	34,750		16,504	51,254

**Director Compensation**

All non-employee directors are paid an \$18,000 annual retainer, semi-annually, and 36,000 stock options, with an exercise price equal to the market price on the date of the grant. One-third of each non-employee director's stock options are exercisable on the date of grant, one-third become exercisable on the first anniversary of the date of grant, and one-third become exercisable on the second anniversary of the date of grant. The audit committee chairman is paid an annual retainer of \$2,500, paid semi-annually. In addition, the non-employee directors are paid \$1,000 in cash for each board of directors meeting attended, and paid \$500 in cash for each telephonic board of directors meeting. The non-employee directors who are members of a committee of the board of directors are paid \$500 in cash for each committee meeting attended, or \$750 in cash for each committee meeting attended if that non-employee director is the committee chairman. In addition, in December 2005, each of the three non-employee directors was granted options to purchase 15,000 shares of the Company's common stock at an exercise price equal to the market price of the underlying common stock on the date of grant.

**FINANCIAL STATEMENTS**

See the Consolidated Financial Statements beginning on page F-1, Index to Consolidated Financial Statements.

<sup>1</sup> Fees earned or paid in cash represents a yearly fee and fees for meeting expenses:  
(a) Mr. Carus received an \$18,000 annual fee as a member of the board of directors, a \$2,500 annual fee as audit committee chairman and \$19,500 in meeting fees paid during 2006;  
(b) Mr. Eppner, who resigned from the board of directors

effective  
January 30,  
2007, received  
an \$18,000  
annual fee as a  
member of the  
board of  
directors for the  
period ending  
December 31,  
2006, and  
\$19,500 in  
meeting fees  
paid during  
2006;  
(c) Mr. Meller  
received an  
\$18,000 annual  
fee as a member  
of the board of  
directors, and  
\$16,750 in  
meeting fees.

- 2 Alan Carus was  
awarded 15,000  
shares of  
common stock  
as compensation  
for services as  
the Audit  
Committee  
Chairman. The  
shares were  
awarded on  
July 18, 2006  
and 5,000 of  
these shares  
vested  
immediately,  
5000 vest on  
July 1, 2007,  
and 5,000 vest  
on July 1, 2008.  
This stock was  
valued based on  
the market  
closing price on  
the date of the  
grant at  
\$10,650.

3 Each outside member of the board of directors is granted the right to purchase 36,000 shares of the company's common stock with an exercise price equal to the market price on the date of the grant as part of their annual compensation. One-third of these options are exercisable on the date of grant, one-third become exercisable on the first anniversary of the date of grant, and one-third become exercisable on the second anniversary of the date of grant. In connection with Mr. Eppner's resignation from the board of directors effective January 30, 2007, the Company accelerated the exercise date for all of Mr. Eppner's options to January 30, 2007. The fair



value of options  
at the date of  
grant was  
estimated using  
the  
Black-Scholes  
option pricing  
model.

- 4 Mr. Eppner  
resigned from  
his position as a  
director of the  
Company on  
January 30,  
2007, effective  
January 30,  
2007.

**Table of Contents**

**EXPERTS**

Lazar, Levine & Felix LLP, a registered independent public accounting firm, have audited our consolidated balance sheet of Chembio Diagnostics, Inc. and subsidiaries as of December 31, 2005 and the consolidated statements of operations, stockholders' equity (deficit), and cash flows for the two years in the period ended December 31, 2005 as set forth in this Prospectus. The financial statements are included in reliance on such report given upon the authority of Lazar, Levine & Felix LLP as experts in accounting and auditing. Lazar, Levine & Felix LLP does not have any ownership interest in us.

**LEGAL MATTERS**

The validity of the issuance of the shares of common stock offered hereby and other legal matters in connection herewith have been passed upon for us by Patton Boggs LLP. A partner of Patton Boggs LLP owns 82,101 shares of common stock, 1,44731 shares of series A preferred stock (which are convertible into 72,365 shares of common stock) and a warrant to purchase 94,930 shares of our common stock. Patton Boggs LLP owns 37,319 shares of common stock.

**DISCLOSURE OF COMMISSION POSITION OF INDEMNIFICATION  
FOR SECURITIES ACT LIABILITIES**

Our directors and officers are indemnified by our bylaws against amounts actually and necessarily incurred by them in connection with the defense of any action, suit or proceeding in which they are a party by reason of being or having been directors or officers of Chembio Diagnostics, Inc. or of our subsidiary. Our articles of incorporation provide that none of our directors or officers shall be personally liable for damages for breach of any fiduciary duty as a director or officer involving any act or omission of any such director or officer. Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, may be permitted to such directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

In the event that a claim for indemnification against such liabilities, other than the payment by Chembio Diagnostics, Inc. of expenses incurred or paid by such director, officer or controlling person in the successful defense of any action, suit or proceeding, is asserted by such director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

**CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS  
ON ACCOUNTING AND FINANCIAL DISCLOSURE**

On June 1, 2004, our Board of Directors voted to replace Madsen & Associates, CPA's, Inc., certified public accountants, and to retain Lazar, Levine & Felix LLP as our principal accountant. Lazar, Levine & Felix LLP had been the principal accountant of Chembio Diagnostic Systems Inc. since 2000. There were no disagreements between us and Madsen, whether resolved or not resolved, on any matter of accounting principles or practices, financial statement disclosure or auditing, scope or procedure which, if not resolved, would have caused them to make reference to the subject matter of the disagreement in connection with their reports. During its tenure, Madsen's audit opinion on our financial statements did not contain an adverse opinion or a disclaimer of opinion, nor was it modified as to audit scope or accounting principles. Madsen's reports did include an explanatory paragraph where they expressed substantial doubt about our ability to continue as a going concern.

Prior to retaining Lazar, Levine & Felix, LLP, management did not consult Lazar, Levine & Felix LLP regarding the application of accounting principles to a specific completed or contemplated transaction or the type of audit opinion that might be rendered, nor concerning any matter that was the subject of any disagreement or event.

**ADDITIONAL INFORMATION**

We have filed with the SEC a registration statement on Form SB-2 under the Securities Act for the common stock offered by this prospectus. This prospectus, which is a part of the registration statement, does not contain all of the information in the registration statement and the exhibits filed with it, portions of which have been omitted as permitted by SEC rules and regulations. For further information concerning us and the securities offered by this

prospectus, please refer to the registration statement and to the exhibits filed with it. Statements contained in this prospectus as to the content of any contract or other document referred to are not necessarily complete. In each instance, we refer you to the copy of the contracts and/or other documents filed as exhibits to the registration statement and these statements are qualified in their entirety by reference to the contract or document.

**Table of Contents**

The registration statement, including all exhibits, may be inspected without charge at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Copies of these materials may also be obtained from the SEC's Public Reference at 100 F Street, NE, Washington D.C. 20549, upon the payment of prescribed fees. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The registration statement, including all exhibits and schedules and amendments, has been filed with the SEC through the Electronic Data Gathering, Analysis and Retrieval system, and is publicly available through the SEC's Website located at <http://www.sec.gov>.

**Table of Contents**

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS  
INDEX**

	<b>Page(s)</b>
<b>CONSOLIDATED FINANCIAL STATEMENTS FOR DECEMBER 31, 2005</b>	
<u>Report of Registered Independent Public Accounting Firm</u>	F-2
Financial Statements:	
<u>Consolidated Balance Sheet December 31, 2005</u>	F-3
<u>Consolidated Statements of Operations Years ended December 31, 2005 and 2004</u>	F-4
<u>Consolidated Statements of Changes in Stockholders Equity (Deficit) Year ended December 31, 2004</u>	F-5
<u>Consolidated Statements Of Changes in Stockholders Equity (Deficit) Year ended December 31, 2005</u>	F-6
<u>Consolidated Statements of Cash Flows Years ended December 31, 2005 and 2004</u>	F-7
<u>Notes to Consolidated Financial Statements</u>	F-8 - F-17
 <b>CONSOLIDATED FINANCIAL STATEMENTS FOR SEPTEMBER 30, 2006</b>	
<u>Consolidated Balance Sheets as of September 30, 2006 (unaudited) and December 31, 2005</u>	F-18
<u>Consolidated Statements of Operations (unaudited) for the Six and Nine Months ended September 30, 2006 and 2005</u>	F-19
<u>Consolidated Statements of Cash Flows (unaudited) for the Nine Months ended September 30, 2006 and 2005</u>	F-20
<u>Notes to Consolidated Financial Statements (unaudited)</u>	F-21 - F-31
F-1	

---

**Table of Contents**

**REPORT OF REGISTERED INDEPENDENT PUBLIC ACCOUNTING FIRM**

To The Board of Directors

Chembio Diagnostics, Inc. and Subsidiaries

Medford, New York

We have audited the consolidated balance sheet of Chembio Diagnostics, Inc. and Subsidiaries (the Company) as of December 31, 2005 and the consolidated statements of operations, stockholders' equity (deficit) and cash flows for the two years in the period ended December 31, 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Chembio Diagnostics, Inc. and Subsidiaries as of December 31, 2005, and the consolidated results of its operations and its cash flows for the two years in the period ended December 31, 2005 in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that Chembio Diagnostics, Inc. and Subsidiaries will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations. If such losses continue and the Company is unable to raise sufficient capital, its ability to continue as a going concern would be in doubt. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**LAZAR LEVINE & FELIX LLP**

**/s/ LAZAR LEVINE & FELIX LLP**

New York, New York

February 3, 2006

F-2

---

**Table of Contents**

**CHEMBIO DIAGNOSTIC SYSTEMS, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEET  
AS OF DECEMBER 31, 2005**

**- ASSETS -**

**CURRENT ASSETS:**

Cash	\$ 232,148
Accounts receivable, net of allowance for doubtful accounts of \$20,488	1,255,073
Inventories	687,983
Prepaid expenses and other current assets	292,989

**TOTAL CURRENT ASSETS** **2,468,193**

**FIXED ASSETS, net of accumulated depreciation** **438,632**

**OTHER ASSETS:** **109,581**

**\$ 3,016,406**

**- LIABILITIES AND STOCKHOLDERS EQUITY-**

**CURRENT LIABILITIES:**

Accounts payable and accrued liabilities	\$ 1,477,925
Current portion of accrued interest payable	120,000
Current portion of obligations under capital leases	38,368
Payable to related party	182,181

**TOTAL CURRENT LIABILITIES** **1,818,474**

**OTHER LIABILITIES:**

Obligations under capital leases, net of current portion	44,417
Accrued interest, net of current portion	100,812

**TOTAL LIABILITIES** **1,963,703**

**COMMITMENTS AND CONTINGENCIES****STOCKHOLDERS EQUITY**

Preferred Stock 10,000,000 shares authorized:	
Series A 8% Convertible \$\$.01 par value: 158.68099 shares issued and outstanding. Liquidation preference \$4,822,957	2,628,879
Series B 9% Convertible \$.01 par value: 102.19760 shares issued and outstanding. Liquidation preference-\$5,341,896	3,173,239
Common stock \$.01 par value; 100,000,000 shares authorized 8,491,429 shares issued and outstanding	84,914
Additional paid-in capital	14,034,099
Accumulated deficit	(18,868,428)

<b>TOTAL STOCKHOLDERS EQUITY</b>	<b>1,052,703</b>
	<b>\$ 3,016,406</b>

The accompanying notes are an integral part of these financial statements.

F-3

---



Table of Contents

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF OPERATIONS**

	December 31, 2005	December 31, 2004
<b>REVENUES:</b>		
Net sales	\$ 3,359,532	\$ 2,749,143
License revenue	250,000	
Research grants and development income	331,198	556,789
<b>TOTAL REVENUES</b>	<b>3,940,730</b>	<b>3,305,932</b>
Cost of sales	2,608,584	2,601,847
<b>GROSS PROFIT</b>	<b>1,332,146</b>	<b>704,085</b>
<b>OVERHEAD COSTS:</b>		
Selling, general and administrative expenses	3,265,235	2,298,598
Research and development expenses	1,364,898	1,508,849
	<b>4,630,133</b>	<b>3,807,447</b>
<b>LOSS FROM OPERATIONS</b>	<b>(3,297,987)</b>	<b>(3,103,362)</b>
<b>OTHER INCOME (EXPENSES):</b>		
Settlement of accounts payable	21,867	209,372
Interest income	39,803	8,126
Interest (expense)	(15,683)	(190,558)
Loss on retirement of fixed assets		(22,469)
<b>LOSS BEFORE INCOME TAXES</b>	<b>(3,252,000)</b>	<b>(3,098,891)</b>
Income taxes		
<b>NET LOSS</b>	<b>(3,252,000)</b>	<b>(3,098,891)</b>
Dividends payable in stock to preferred stockholders	818,321	240,001
Dividend accreted to preferred stock for associated costs and a beneficial conversion feature	2,698,701	1,703,072
<b>NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS</b>	<b>\$ (6,769,022)</b>	<b>\$ (5,041,964)</b>

<b>Basic and diluted loss per share</b>	<b>\$</b>	<b>(0.88)</b>	<b>\$</b>	<b>(0.85)</b>
---	-----------	---------------	-----------	---------------

<b><i>Weighted number of shares outstanding, basic and diluted</i></b>	<b>7,705,782</b>	<b>5,966,769</b>
--	------------------	------------------

The accompanying notes are an integral part of these financial statements.

F-4

---

Table of Contents

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIT)**  
**FOR THE YEAR ENDED DECEMBER 31, 2004**

	Series A Preferred Stock		Common Stock		Additional paid in capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Amount	Amount	Amount
<b>Balance at December 31, 2003</b>		\$	4,902,608	\$ 49,026	\$ 4,550,975	\$ (7,057,442)	\$ (2,457,441)
<b>Preferred Stock</b>							
<b>Issued:</b>							
For cash	73.33330	2,200,000			(418,862)		(418,862)
Conversion of debt	90.29853	2,372,958					-
Allocation of fair value to warrants		(1,920,460)			1,920,460		1,920,460
Allocation of value of beneficial conversion		(1,964,740)			1,964,740		1,964,740
Accretion of preferred dividend		58,114				(240,001)	(240,001)
Accretion of beneficial conversion		1,703,072				(1,703,072)	(1,703,072)
<b>Common Stock</b>							
<b>Issued:</b>							
Conversion of debt			826,741	8,267	322,430		330,697
For Fees			65,667	657	(657)		-
Upon conversion of Preferred	(1.25942)	(21,914)	62,971	630	21,284		21,914
Preferred dividend			303,145	3,031	178,856		181,887
For services			679,142	6,791	358,454		365,245
<b>Warrants and options:</b>							
Issued for services					91,589		91,589
Exercised To debt holders, pre-merger			66,869	669	29,422		30,091
					60,650		60,650

**Net loss for  
2004**

**(3,098,891) (3,098,891)**

**Balance at  
December 31,  
2004**

**162.37241 \$ 2,427,030 6,907,143 \$ 69,071 \$ 9,079,341 \$(12,099,406) \$(2,950,994)**

The accompanying notes are an integral part of these financial statements.

F-5

---

Table of Contents

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)**  
**FOR THE YEAR ENDED DECEMBER 31, 2005**

	Series A Preferred		Series B Preferred		Common Stock		Additional	Accumulated	Total
	Shares	Amount	Shares	Amount	Shares	Amount	paid in capital Amount	Deficit Amount	Amount
<b>Balance at December 31, 2004</b>		\$		\$	6,907,143	\$ 69,071	\$ 9,079,341	\$ (12,099,406)	\$ (2,950,999)
Adjustment to reflect reclassification of Series A Preferred to Permanent Equity	162.37241	2,427,030							2,427,030
<b>Preferred Stock Issued:</b>									
for cash			100.95000	5,047,500			(321,639)		4,725,861
for fees			4.98000	249,000			(249,000)		
exchanged from Series A Preferred to Series B Preferred	(0.66666)	(11,600)	0.40000	20,000			(8,400)		
allocation of fair value to warrants				(2,349,893)			2,349,893		
allocation of value of beneficial conversion Series B Preferred				(2,437,035)			2,437,035		
dividend accrual of beneficial conversion		261,666	4.06988	435,509				(435,509)	
				2,437,035				(2,698,701)	
<b>Common Stock Issued:</b>									
upon conversion of Preferred	(3.02476)	(52,631) 4,414	(8.20228)	(228,877)	823,654 630,632	8,237 6,306	273,271 372,092	(382,812)	

Series A Preferred Dividend for services				<b>95,000</b>	<b>950</b>	<b>52,300</b>			<b>53,250</b>
<b>Warrants and Options:</b>									
Issued for services						<b>90,288</b>			<b>90,288</b>
Exercised				<b>35,000</b>	<b>350</b>	<b>24,850</b>			<b>25,200</b>
Cancelled						<b>(65,932)</b>			<b>(65,932)</b>
<b>Net loss for 2005</b>								<b>(3,252,000)</b>	<b>(3,252,000)</b>
<b>Balance at December 31, 2005</b>	<b>158.68099</b>	<b>\$ 2,628,879</b>	<b>102.19760</b>	<b>\$ 3,173,239</b>	<b>8,491,429</b>	<b>\$ 84,914</b>	<b>\$ 14,034,099</b>	<b>\$(18,868,428)</b>	<b>\$ 1,052,700</b>

The accompanying notes are an integral part of these financial statements.

F-6

**Table of Contents**

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<b>FOR THE YEARS ENDED:</b>	
	<b>December 31, 2005</b>	<b>December 31, 2004 (REVISED)</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (3,252,000)	\$ (3,098,891)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	98,508	109,965
Loss on retirement of fixed assets		22,469
Provision for doubtful accounts	4,120	(1,136)
Increase in accrued interest		93,918
Expenses related to shares, options and warrants issued for services	77,606	451,622
Changes in:		
Accounts receivable	(1,094,137)	118,814
Restricted cash	250,000	(250,000)
Inventory	(149,336)	(72,149)
Accounts payable and accrued expenses	212,939	(26,632)
Grant and other current liabilities		(12,648)
Other	(153,060)	16,861
<b>Net cash used in operating activities</b>	<b>(4,005,360)</b>	<b>(2,647,807)</b>
 <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Acquisition of fixed assets	(348,741)	(60,552)
<b>Net cash used in investing activities</b>	<b>(348,741)</b>	<b>(60,552)</b>
 <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Sale of Series B Preferred Stock and associated warrants, net of cash cost of financing of \$321,639	4,725,861	
Payment of obligations to bank		(67,434)
Payment of capital lease obligation	(42,511)	(55,410)
Payment of accrued interest	(112,138)	
Proceeds from working capital loan	161,917	295,000
Payment of working capital loan	(206,917)	(250,000)
Proceeds from sale of common stock including bridge loan		330,698
Exercise of warrants	25,200	30,091
Sale of Series A Preferred Stock including bridge loan, net of the cost of financing of \$418,856		2,460,251
<b>Net cash provided by financing activities</b>	<b>4,551,412</b>	<b>2,743,196</b>
 <b>NET INCREASE IN CASH</b>	<b>197,311</b>	<b>34,837</b>
Cash beginning of the period	34,837	

<b>CASH end of the period</b>	<b>\$ 232,148</b>	<b>\$ 34,837</b>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid during the period for interest	<b>\$ 124,805</b>	<b>\$ 1,985</b>
Cash paid during the period for corporate taxes	<b>3,763</b>	<b>1,693</b>
<b>Supplemental disclosures for non-cash investing and financing activities:</b>		
Common Stock issued as payment for financing fees	<b>\$</b>	<b>\$ 39,400</b>
Warrants/Options issued as payment for consulting services	<b>24,363</b>	<b>42,237</b>
Warrants issued for shareholder consent to merger		<b>144,643</b>
Warrants issued as payment for financing fees	<b>364,268</b>	<b>337,973</b>
Long term debt converted to Series A Preferred Stock		<b>1,693,851</b>
Series B Preferred issued as payment for financing fees	<b>249,000</b>	
Series A Preferred and associated warrants exchanged for Series B Preferred and associated warrants	<b>20,000</b>	
Dividend and beneficial conversion accreted to Series A and Series B Preferred Stock	<b>3,517,022</b>	<b>1,373,750</b>
Series B Preferred issued as payment of Series B dividend	<b>203,493</b>	
Common Stock issued as payment of Series A Preferred dividend	<b>378,398</b>	<b>181,887</b>

The accompanying notes are an integral part of these financial statements.

F-7



**Table of Contents**

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2005 AND 2004**

**NOTE 1 DESCRIPTION OF BUSINESS:**

Chembio Diagnostics, Inc. (the Company) and its subsidiaries develop, manufacture, and market lateral flow rapid diagnostic tests that detect infectious diseases. These tests are sold in the U.S. and/or internationally to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments. The products are made under the label of Chembio Diagnostic Systems, Inc. (CDS) or the private labels of its distributors or their customers. The products are used in the diagnosis of infectious diseases and other conditions in humans and animals. The Companies main products presently commercially available are its three HIV Rapid Tests (SURE CHECK® HIV, HIV 1/2 STAT-PAK and HIV 1/2 STAT-PAK Dipstick) and its rapid test for Chagas Disease.

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern. Although the Company's revenues and gross margins increased significantly in 2005 as compared to 2004, it has sustained significant operating losses in 2005 and 2004. At December 31, 2005, the Company had a positive stockholders' equity of \$1,053,000 and working capital of \$650,000. The Company believes its resources are sufficient to fund its needs through early 2006 and it is considering alternatives to provide for its capital requirements for the balance of 2006 and beyond in order to continue as a going concern. The Company's liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenue growth; (2) the extent to which, if any, that revenue growth improves operating cash flows; (3) its investments in research and development, facilities, marketing, regulatory approvals, and other investments it may determine to make, and (4) the investment in capital equipment and the extent to which it improves cash flow through operating efficiencies. There are no assurances that the Company will be successful in raising sufficient capital.

**RECENT DEVELOPMENTS:**

On March 30, 2006, the Company sold \$1 million of additional Series B Preferred stock to a Series B Preferred shareholder pursuant to provisions of the January 2005 Series B 9% Preferred Stock financing agreements. Such provisions were exclusive to said shareholder. The Company is continuing to pursue additional financing opportunities in order to provide for its longer term financing needs. Approximately \$140,000 of these proceeds will be used to pay cash dividends which were accrued as of December 31, 2005.

**NOTE 2 SERIES B FINANCING:**

On January 28, 2005, the Company completed a private placement of 9% Series B Convertible Preferred Stock and associated warrants for \$5,047,500. The purchase price per unit (one share plus associated warrants) was \$50,000 and a total of 100.95 shares and warrants to purchase 7,860,846 shares of Common Stock were issued in the transaction. In addition one Series A Preferred stockholder exercised its right to exchange \$20,000 worth of Series A 8 % Preferred Stock and associated warrants for .40 shares of 9% Series B Preferred Stock and warrants to purchase 31,146 shares of Common Stock.

Placement Agents were paid a cash commission of 5% of the gross cash proceeds and 4.98 shares of 9 % Series B Preferred Stock and warrants to purchase 388,588 shares of Common Stock. In addition, they received warrants to purchase 737,712 shares of Common Stock at an exercise price of \$0.80 per share. The warrants may not be exercised until the majority investor in the Series B financing has given notice of its intent to exercise its warrants. See also note 13.

**NOTE 3 MERGER TRANSACTION:**

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

Chembio Diagnostics, Inc. with CDS, as the acquiror. The earnings per share presented in the statement of operations for periods prior to 2005 reflect the shares outstanding as if the merger had taken place as of January 1, 2004. Trading Solutions.com, Inc. had no assets, liabilities or transactions (other than a 1:17 reverse split of its Common Stock) in the fiscal year preceding the merger. Prior to the merger, Trading Solutions.com, Inc. s fiscal year ended

F-8

---

**Table of Contents**

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2005 AND 2004**

September 30. After the merger, Chembio Diagnostics, Inc. adopted a fiscal year ending on December 31, the fiscal year-end of CDS.

**NOTE 4 SIGNIFICANT ACCOUNTING POLICIES:**

**(a) *Principles of Consolidation:***

The consolidated financial statements include the accounts of the Company, and its subsidiaries all wholly owned. All intercompany transactions and balances have been eliminated in consolidation.

**(b) *Inventories:***

Inventories are stated at the lower of cost or market. Cost is determined on the first-in, first-out method.

**(c) *Fixed Assets:***

Fixed assets are stated at cost less accumulated depreciation. Depreciation is computed using the straight line method over the estimated useful lives of the respective assets, which range from three to seven years. Leasehold improvements are amortized over the useful life of the asset or the lease term, whichever is shorter.

**(d) *Use of Estimates:***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

**(e) *Income Taxes:***

The Company accounts for income taxes under the provisions of Statement of Financial Accounting Standards No. 109, Accounting for Income Taxes (SFAS 109). Under SFAS 109, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and the tax bases of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse.

**(f) *Research and Development:***

Research and development costs are charged to expense as incurred.

**(g) *Stock Based Compensation:***

The Company accounts for stock-based employee compensation under Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and its related interpretations. The Company has adopted the disclosure-only provisions of SFAS No. 123, as amended, Accounting for Stock-Based Compensation. See also note 4(m).

**(h) *Statement of Cash Flows:***

For purposes of the statements of cash flows the Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents.

**(i) *Revenue Recognition:***

The Company recognizes revenue in accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 104, Revenue Recognition ( SAB 104 ). Under SAB 104, revenue is recognized when there is persuasive evidence of an arrangement, delivery has occurred or services have been rendered, the sales price is determinable, and collectibility is reasonably assured. Revenue typically is recognized at time of shipment. Sales are recorded net of discounts, rebates and returns.

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

**(j) *Comprehensive Income:***

The Company adopted SFAS No. 130 Reporting Comprehensive Income , which prescribes standards for reporting other comprehensive income and its components. The Company currently does not have any items of other comprehensive income and accordingly no separate statements are required.

F-9

---

**Table of Contents**

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2005 AND 2004**

**(k) *Concentrations of Credit Risk:***

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of temporary cash investments and trade receivables. The Company places its temporary cash instruments with well-known financial institutions and, at times, may maintain balances in excess of the \$100,000 FDIC Insurance limit. The Company monitors the credit ratings of the financial institutions to mitigate this risk. Concentration of credit risk with respect to trade receivables is principally mitigated by the Company's obtaining of letters of credit from certain foreign customers, and its diverse customer base both in number of customers and geographic locations.

**(l) *Fair Value:***

Fair values of cash, accounts receivable, prepaid expenses and other current assets and accounts payable reflected in these financial statements approximate carrying value as these are short-term in nature.

**(m) *Recent Accounting Pronouncements Affecting the Company:***

SFAS No. 154, Accounting Changes and Error Corrections—a replacement of APB Opinion No. 20 (Accounting Changes) and FASB No. 3 (Reporting Accounting Changes in Interim Financial Statements) was issued in June 2005. It changes requirements for the accounting for and reporting of a change in accounting principle. This Statement requires retrospective application to prior periods' financial statements of changes in accounting principle unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. When it is impracticable to determine the period-specific effects of an accounting change on one or more individual prior periods presented, this Statement requires that the new accounting principle be applied to the balances of assets and liabilities as of the beginning of the earliest period for which retrospective application is practicable and that a corresponding adjustment be made to the opening balance of retained earnings (or other appropriate components of equity or net assets in the statement of financial position) for that period rather than being reported in an income statement. When it is impracticable to determine the cumulative effect of applying a change in accounting principle to all prior periods, this Statement requires that the new accounting principle be applied as if it were adopted prospectively from the earliest date practicable.

SFAS No. 154 is effective for accounting changes and error corrections made in fiscal years beginning after December 15, 2005 (calendar year 2006). Early adoption is permitted.

A revision of SFAS No. 123—Share-Based Payment (No. 123R) was issued in December of 2004. The revised statement establishes standards for the accounting for transactions in which an entity exchanges its equity investments for goods and services. It also addresses transactions in which an entity receives goods or services that are exchanged for or that may be settled by the issuance of equity instruments. The statement does not change the accounting guidance for share-based payments with parties other than employees. The statement requires a public entity to measure the cost of employee service received in exchange for an award of equity instruments based on the grant-date fair value of the award (with limited exception). That cost will be recognized over the period during which an employee is required to provide service in exchange for the award (usually the vesting period). A public entity will initially measure the cost of employee services received in exchange for an award of an equity instrument based on its current fair value; the fair value of that award will be remeasured subsequently at each reporting date through the settlement date. Changes in fair value during the requisite service period will be recognized as compensation over that period. The

grant-date fair value of employee share options and similar instruments will be estimated using option-pricing models adjusted for the unique characteristics of these instruments. The Company will be required to comply with this pronouncement for periods beginning after December 15, 2005. The adoption of SFAS 123R in 2006, is expected to have an impact on the results of operations of the Company which will be calculated starting in the first reporting period of 2006.

**(n) Preferred Stock:**

The Company's Series A and Series B Preferred Stock both contained provisions whereby, under certain conditions outside of the control of management, the holders could have required redemption; accordingly, they were initially classified outside of permanent equity. At December 31, 2005, such conditions no longer apply; accordingly, the Series A and Series B Preferred have been reclassified to permanent equity at December 31, 2005.

**(o) Reclassifications**

Prior year's financial statements have been reclassified to conform with current year presentation.

F-10

---

**Table of Contents**

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2005 AND 2004**

**(p) Geographic Information:**

SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information establishes standards for the way that business enterprises report information about operating segments in financial statements and requires that those enterprises report selected information. It also establishes standards for related disclosures about product and services, geographic areas, and major customers.

The Company produces only one group of similar products known collectively as rapid medical tests. As per the provisions of SFAS 131, management believes that it operates in a single business segment. Net sales by geographic area are as follows:

	For the years ended	
	December 31, 2005	December 31, 2004
Africa	\$ 802,925	\$ 120,002
Asia	124,467	215,131
Australia	10,585	25,478
Europe	125,135	157,516
Middle East	55,652	69,737
North America	503,456	994,540
South America	1,737,312	1,166,739
	<b>\$ 3,359,532</b>	<b>\$ 2,749,143</b>

**(q) Accounts payable and accrued liabilities**

Accounts payable and accrued liabilities as of December 31, 2005 consisted of:

Accounts payable – suppliers	\$ 550,247
Accrued commissions	171,587
Accrued royalties	381,510
Accrued payroll and other taxes	63,146
Accrued vacation	145,566
Accrued legal and accounting	50,024
Accrued expenses – other	115,845
<b>TOTAL</b>	<b>\$ 1,477,925</b>

**(r) Earnings Per Share**

The following weighted average shares were used for the computation of basic and diluted earnings per share:

	For the years ended	
	December 31, 2005	December 31, 2004
Basic	7,705,782	5,966,769

Diluted

**7,705,782**

5,966,769

Basic loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted loss per share reflects the potential dilution from the exercise or conversion of other securities into Common Stock, but only if dilutive. Diluted loss per share for the years ended December 31, 2005 and December 31, 2004 is the same as basic loss per share, since the effects of the calculation were anti-dilutive due to the fact that the Company incurred losses for all periods presented. The following securities, presented on a common share equivalent basis, have been excluded from the per share computations:

F-11

---



Table of Contents

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2005 AND 2004**

	<b>For the years ended</b>	
	<b>December 31, 2005</b>	December 31, 2004
<b>Stock Options</b>	<b>1,430,375</b>	1,300,250
<b>Warrants</b>	<b>21,327,972</b>	12,226,054
<b>Preferred Stock</b>	<b>16,311,602</b>	8,118,611

**NOTE 5 EMPLOYEE STOCK OPTION PLAN:**

As part of the merger (see note 3), the Company adopted the 1999 Stock Option Plan (the Plan) of CDS covering 1,500,000 shares of Common Stock. Under the terms the Plan, the Compensation Committee of the Company's board is authorized to grant incentive options to key employees and to grant non-qualified options to key employees and key individuals. The options become exercisable at such times and under such conditions as determined by the Compensation Committee. The Plan was amended at the Company's 2005 stockholders' meeting. The number of options under the Plan was increased to cover 3,000,000 shares of common stock. It was also amended to allow independent directors to be eligible for grants under the portion of the Plan concerning non-qualified options. The Company applies Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees and related Interpretations to account for the options issued to employees and or directors using the intrinsic value method. Had compensation cost for the options been determined using the fair value based method, as defined in Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation (SFAS 123), the Company's net loss and loss per share would have been adjusted to the pro forma amounts indicated below. The Company adopted Statement of Financial Accounting Standards No. 148, Accounting for Stock-Based Compensation Transition and Disclosure an amendment of FASB Statement No. 123 requiring interim period disclosure for the years ending after December 15, 2002. The effect of the fair value method allowed under SFAS 123 is shown below.

	<b>For the years ended</b>	
	<b>December 31, 2005</b>	December 31, 2004
Net loss attributable to common stockholders, as reported	<b>\$ (6,769,022)</b>	\$ (5,041,964)
Add: Stock-based compensation included in reported net loss		969
Deduct: Total stock based compensation expense determined under the fair value based method for all awards (no tax effect)	<b>(180,195)</b>	(490,348)
Pro forma net loss attributable to common stockholders	<b>\$ (6,949,217)</b>	\$ (5,531,343)
Net loss per share:		
Basic and diluted loss per share as reported	<b>\$ (0.88)</b>	\$ (0.85)
Basic and diluted loss per share pro forma	<b>\$ (0.90)</b>	\$ (0.93)

The fair value of each option grant was estimated on the date of the grant using the Black-Scholes option-pricing model with the following weighted-average assumptions:

For the year ended December 31, 2005: expected volatility of 110.28%; risk-free interest rate of 3.69% to 4.46%; expected lives of 3 to 5 years and no dividends.

For the year ended December 31, 2004: expected volatility of 82.6%; risk-free interest rate of 3.31%; expected lives of 4 to 7 years and no dividends.

The effects of applying SFAS 123 in the above pro forma disclosures are not indicative of future amounts since future amounts will be affected by the number of grants awarded and additional awards are generally expected to be made at

varying prices.

The Company granted 481,500 options under the Plan during the year ended December 31, 2005 at exercise prices ranging from \$0.35 per share to \$0.80 per share.

F-12

---

**Table of Contents**

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2005 AND 2004**

Plan activity is summarized as follows:

	Number of Shares	Weighted Average Exercise Price
Options outstanding at December 31, 2003	365,000	\$ 2.75
Granted	740,000	0.95
Canceled		
Exercised		
Options outstanding at December 31, 2004	1,105,000	\$ 1.55
Granted	481,500	0.74
Canceled	(300,750)	1.75
Exercised		
Options outstanding at December 31, 2005	1,285,750	\$ 1.20

Additional Plan information as of December 31, 2005 is as follows:

Range of Exercise Prices	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Life (yrs)	Options Exercisable	Weighted Average Exercise Price
\$2.17 4.00	202,500	\$3.12	2.05	202,500	\$3.08
\$0.90 1.50	310,000	\$1.20	5.40	160,000	\$1.02
\$0.75 1.50	530,750	\$0.79	4.60	176,000	\$0.76
\$0.35 0.60	242,500	\$0.52	5.12	222,500	\$0.51
	1,285,750	\$1.20	4.49	761,000	\$1.36

**NOTE 6 RELATED PARTIES:**

The Company's former president, also a former director received, in March 2005, as compensation for his service on the Board of Directors, a reduction from \$.90 per share to \$.75 per share in the exercise price of a warrant to acquire 425,000 shares of Common Stock. The Company is accounting for these warrants as variable from the date of the modification to the date the award is exercised, forfeited, or expires unexercised. At December 31, 2005 the stock price was less than the revised exercise price; therefore there was no adjustment to compensation is required. Such warrants remain unexercised as of December 31, 2005.

The Company has a liability to its President for i) funds advanced by him to it or paid directly by him to vendors on its behalf of \$182,000 (non-interest bearing and payable on demand) and ii) \$165,000 of accrued interest on prior debt that is not accruing additional interest. The accrued interest is being repaid according to the terms related to the Series B offering (see notes 2 and 9).

**NOTE 7 INVENTORIES:**

Inventories consist of:

Raw Materials	\$ 425,758
---------------	------------

Work in Process	86,001
Finished Goods	176,224
	<b>\$ 687,983</b>

**NOTE 8 FIXED ASSETS:**

Fixed assets consist of:

F-13

---

**Table of Contents**

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2005 AND 2004**

Machinery and equipment	\$ 604,243
Furniture and fixtures	126,277
Computer and telephone equipment	94,283
Leasehold improvements	131,157
Tooling	41,900
	<b>997,860</b>
Less accumulated depreciation and amortization	(559,228)
	<b>\$ 438,632</b>

Included in the above fixed assets is \$74,183, net of accumulated depreciation of \$84,058, of assets held under capital leases as of December 31, 2005. Depreciation for the 2005 and 2004 years aggregated \$98,508 and \$109,965, respectively.

**NOTE 9 LONG-TERM DEBT:**

In connection with the Series B offering (see note 2) interest payable on certain debt was agreed to be paid over 33 months in installments of \$10,000 per month and a final payment of \$2,950 in the 34<sup>th</sup> month. These payments are subordinate to the redemption rights of the Series B Preferred stockholders. No interest accrues on this payable.

**NOTE 10 OBLIGATIONS UNDER CAPITAL LEASES:**

The Company is obligated under capitalized leases for certain computer and telephone equipment.

Future minimum lease payments under these capitalized lease obligations, including interest as of December 31, 2005 were as follows:

Year ending December 31,

2006	\$ 45,546
2007	40,113
2008	7,260
	92,919
Less: imputed interest	10,134
	82,785
Less: current maturities	38,368
	<b>\$ 44,417</b>

These leases have interest rates ranging from 8% - 15%.

**NOTE 11 RESEARCH GRANTS AND DEVELOPMENT CONTRACTS:**

In 2005 and 2004 the Company received research grants and development contracts in the amount of \$331,198 and \$556,789 respectively. A substantial portion of the revenues realized in 2005 is not expected to recur in 2006.

**NOTE 12 INCOME TAXES:**

No provision for Federal income taxes was required for the years ended December 31, 2005 or 2004, due to the Company's operating losses. At December 31, 2005, the Company has unused net operating loss carryforwards of approximately \$14,500,000 which expire at various dates through 2024. Most of this amount is subject to annual limitations under certain provisions of the Internal Revenue Code related to changes in ownership. In addition the

Company has a research and development credit carryforward of approximately \$288,000.

As of December 31, 2005 and 2004, the deferred tax assets related to the aforementioned carryforwards have been fully offset by valuation allowances, since significant utilization of such amounts is not presently expected in the foreseeable future.

F-14

---

**Table of Contents**

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2005 AND 2004**

Deferred tax assets and valuation allowances consist of:

	<b>December 31, 2005</b>	December 31, 2004
Net operating loss carryforwards	\$ <b>5,800,000</b>	\$ 4,424,000
Research and development credit	<b>288,000</b>	230,000
Other	<b>40,000</b>	73,000
Gross deferred tax assets	<b>6,128,000</b>	4,727,000
Valuation allowances	<b>(6,128,000)</b>	(4,727,000)
Net deferred tax assets	\$	\$

**NOTE 13 STOCKHOLDERS EQUITY:****(a) Common Stock**

During 2005 the Company issued 95,000 shares of its Common Stock to consultants as compensation. The shares were valued from \$0.43 to \$0.75 per share and were expensed over the lives of the related contracts.

In 2005 Series A Preferred shareholders converted 3.02476 shares into 151,237 shares of Common Stock. Series B Preferred shareholders converted 8.20228 shares into 672,417 shares of Common Stock and warrants were exercised to purchase 35,000 shares of Common Stock at an exercise price of \$0.72 per share.

On May 14, 2005 and November 15, 2005 the Company issued 312,773 and 317,859 shares, respectively, of its Common Stock as payment of dividends on its series A preferred stock.

**(b) Warrants**

The warrants to purchase 8,280,550 shares of Common Stock issued in connection with the Series B offering were assigned a value of \$2,349,893.

Warrants were issued in January 2005 to placement agents in connection with the Series B Preferred Stock financing to purchase a total of 737,712 shares of Common Stock at an exercise price of \$0.80. The fair values of these warrants are \$364,268. The effect of this transaction was reflected in Additional Paid in Capital.

In March 2005, the Company re-priced certain warrants see note 6.

During 2005, the Company issued warrants to purchase 133,656 shares of Common Stock at exercise prices from \$0.55 to \$0.70 per share to a distributor as payment for commissions. The value of these warrants was expensed.

**(c) Other Common Stock Options**

During 2005 the Company issued options to purchase 20,000 shares of Common Stock to advisory board members. These options were valued at \$6,969 and are being expensed over the vesting periods.

(d) ***Series A 8% Convertible Preferred Stock:***

The Series A Preferred Stock was issued at a face value of \$30,000 per share and came with detachable warrants. The recorded amount of the preferred shares was calculated using a fair value allocation between the preferred shares and detachable warrants. Some key features include:

**Dividends:** The 8% per annum dividend is payable semi-annually, in cash or, at the Company's option, in Common Stock. To date all dividends have been paid in Common Stock.

**Conversion:** Series A Preferred stock is convertible, at the option of the holders, into shares of Common Stock at a conversion price of \$0.60 per share. Based on its original purchase price of \$30,000 per share, each share of Series A Preferred Stock is convertible into 50,000 shares of Common Stock.

**Redemption:** The holders have the right, under certain conditions, to require redemption of all or a portion of such holder's shares of Series A Preferred Stock. The Series A Preferred Stock is not currently redeemable and there is no likelihood that it will become redeemable; accordingly, no accretion is being made to bring the value up to its redemption value (The liquidation preference is \$30,000 per share plus accrued and unpaid dividends, presently \$394.05 per share, an aggregate for all such shares of \$4,822,957). Accrued but unpaid dividends of \$62,528 are included in the preferred stock carrying value as at December 31, 2005.

F-15

---



**Table of Contents**

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2005 AND 2004**

As per EITF 00-27 Application of Issue 98-5 to Certain Convertible Instruments the Company evaluated the series A preferred stock transaction and found that there was an associated beneficial conversion feature totaling \$1,635,416; the preferred stock was further discounted by this amount. The beneficial conversion amount was then accreted back to the preferred stock in accordance with the conversion provision which allowed for 20% to be converted immediately and 100% after the earlier of ten months from the merger or 6 months after the registration statement registering the underlying common shares became effective. The amount accreted back to the preferred and charged to dividends in 2005 was \$261,666.

(e) ***Series B 9% Convertible Preferred Stock:***

The Series B Preferred Stock was issued at a face value of \$50,000 per share and came with detachable warrants. The recorded amount of the preferred shares was calculated using a fair value allocation between the preferred shares and detachable warrants. Some key features of the Series B Preferred Stock (see note 2) are as follows:

**Dividends:** The 9% Series B Preferred Stock accrues dividends at 9% per annum, payable semi-annually. Dividends are payable in either Series B Preferred Stock (plus associated warrants) or cash. The majority investor in the Series B financing has the option as it pertains to its dividend payment to choose cash or preferred shares. The Company has the option to choose cash or preferred shares as to the balance of the dividends. To date all dividends have been paid in Preferred Shares.

**Conversion:** The Series B Preferred Stock is convertible, at the option of the holders, into shares of Common Stock at a conversion price of \$.61 per share. Based on the original purchase price of \$50,000 per share, each share of Series B Stock is convertible into 81,967 shares of Common Stock.

**Redemption:** The holders have the right, under certain conditions, to require redemption of all or a portion of such holder's shares of Series B Preferred Stock. The Series B Preferred is not currently redeemable and there is no likelihood that it will become redeemable; accordingly, no accretion is being made to bring the value up to its redemption value (The liquidation preference is \$50,000 per share plus accrued and unpaid dividends, presently \$2,270.27 per share, an aggregate for all such shares of \$5,341,896). Accrued but unpaid dividends of \$232,016 are included in the preferred stock carrying value as at December 31, 2005. The accrued but unpaid dividend was paid on January 2, 2006 by the issuance of 4.60249 shares Series B Preferred Stock.

On July 1, 2005, the Company issued 4.06988 shares of Series B Preferred Stock as payment of dividends on the Company's Series B Preferred Stock. No cash was exchanged in this issuance.

As per EITF 00-27 Application of Issue 98-5 to Certain Convertible Instruments the Company evaluated the series B preferred stock transactions and found that there was an associated beneficial conversion feature totaling \$2,437,035; the preferred stock was further discounted by this amount. The beneficial conversion amount was then accreted back to the preferred stock in accordance with the conversion provision which allowed for 100% to be converted immediately.

**NOTE 14 COMMITMENTS AND CONTINGENCIES:**

***Employment Contracts:***

The Company has contracts with three key employees. The contracts call for salaries presently aggregating \$420,000 per year. Two contracts expire in May of 2006 and one contract expires in May of 2007.

***Pension Plan:***

The Company has a 401(k) plan established for its employees. The Company has the option to make matching contributions to the plan. The Company has not elected to make any matching contributions for the years ended December 31, 2005 and 2004 and accordingly no expense has been recorded.

***Obligations Under Operating Leases:***

The Company leases office and manufacturing facilities. The following is a schedule of future minimum rental commitments:

Year ending December 31,

2006	99,837
2007	25,113
	\$ 124,950

**Table of Contents**

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2005 AND 2004**

Rent expense aggregated \$97,000 and 88,000 for the years ended December 31, 2005 and 2004, respectively.

***Economic Dependency:***

The Company had sales to three customers in excess of 10% of total sales in the year ended December 31, 2005. Sales to these customers aggregated approximately \$1,125,000, \$474,000 and \$412,000, respectively.

The Company had sales to two customers in excess of 10% of total sales in the year ended December 31, 2004. Sales to these customers aggregated approximately \$1,071,000 and \$309,000, respectively.

The Company had no purchases from any vendor in excess of 10% of total purchases for the years ended December 31, 2005 and 2004.

***Governmental Regulation:***

All of the Company's existing and proposed diagnostic products are regulated by the Food and Drug Administration (FDA), U.S. Department of Agriculture, certain state and local agencies, and/or comparable regulatory bodies in other countries. Most aspects of development, production, and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing, and record keeping are subject to review. After marketing approval has been granted, Chembio must continue to comply with governmental regulations. Failure to comply with these regulations can result in significant penalties.

**NOTE 15 LITIGATION:**

The Company is involved in a patent litigation with Saliva Diagnostic Systems, Inc. ( SDS ), the assignee of a patent related to a method for collecting samples. The Company has requested relief from the court that its Sure Check HIV test does not infringe SDS's patent, that such patent is invalid, and that it is unenforceable due to inequitable procurement. SDS has answered and counterclaimed, alleging that the Company has infringed the patent, which the Company has denied. In the years 2001 through 2003, the Company paid royalties to SDS and took several other actions based upon SDS's representations regarding its alleged patent.

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

**NOTE 16 SUBSEQUENT EVENTS**

- (a) During January of 2006, holders of Series B Preferred shares converted 6.70680 shares into approximately 550,000 shares of Common Stock.
  
- (b) Please see note 1 *Recent Developments*.

**Table of Contents****Item 1. FINANCIAL STATEMENTS****CHEMBIO DIAGNOSTIC SYSTEMS, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS**

	<b>September 30, 2006 (Unaudited)</b>	December 31, 2005
<b>- ASSETS -</b>		
<b>CURRENT ASSETS:</b>		
Cash	\$ 3,474,030	\$ 232,148
Accounts receivable, net of allowance for doubtful accounts of \$35,312 and \$20,488 for 2006 and 2005, respectively	870,435	1,255,073
Inventories	1,091,024	687,983
Prepaid expenses and other current assets	177,451	292,989
<b>TOTAL CURRENT ASSETS</b>	<b>5,612,940</b>	<b>2,468,193</b>
<b>FIXED ASSETS</b> , net of accumulated depreciation of \$604,887 and \$559,228 for 2006 and 2005, respectively	<b>613,036</b>	<b>438,632</b>
<b>OTHER ASSETS:</b>		
Deposits and other assets	361,125	109,581
	<b>\$ 6,587,101</b>	<b>\$ 3,016,406</b>
<b>- LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIENCY)-</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$ 2,632,830	\$ 1,477,925
Accrued interest payable	120,000	120,000
Loan payable	800,000	
Current portion of obligations under capital leases	41,293	38,368
Payable to related party	182,181	182,181
<b>TOTAL CURRENT LIABILITIES</b>	<b>3,776,304</b>	<b>1,818,474</b>
<b>OTHER LIABILITIES:</b>		
Obligations under capital leases net of current portion	13,113	44,417
Liabilities in respect to warrants	331,114	
Derivative liability	218,025	
Accrued interest, net of current portion	3,160	100,812
<b>TOTAL LIABILITIES</b>	<b>4,341,716</b>	<b>1,963,703</b>
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>PREFERRED STOCK</b> Series C 7% Convertible \$.01 par value: 80 and none shares issued and outstanding as of 2006 and 2005,	<b>3,143,415</b>	

respectively net of derivative liability of \$218,025. Liquidation preference of \$4,000,000

**STOCKHOLDERS EQUITY (DEFICIENCY)**

Preferred Stock 10,000,000 shares authorized:

Series A 8% Convertible \$.01 par value: 149.92119 and 158.68099 shares issued and outstanding as of 2006 and 2005, respectively.

Liquidation preference of \$4,644,882	<b>2,591,591</b>	2,628,879
---------------------------------------	------------------	-----------

Series B 9% Convertible \$.01 par value: 113.93591 and 102.19760 shares issued and outstanding as of 2006 and 2005, respectively.

Liquidation preference of \$5,822,663	<b>3,414,868</b>	3,173,239
---------------------------------------	------------------	-----------

Common stock \$.01 par value; 100,000,000 shares authorized 11,036,246 and 8,491,429 shares issued and outstanding as of 2006 and 2005, respectively

<b>110,363</b>	84,914
----------------	--------

Additional paid-in capital

<b>17,462,415</b>	14,034,099
-------------------	------------

Accumulated deficit

<b>(24,477,267)</b>	(18,868,428)
---------------------	--------------

**TOTAL STOCKHOLDERS EQUITY (DEFICIENCY)**

<b>(898,030)</b>	1,052,703
------------------	-----------

<b>\$ 6,587,101</b>	\$ 3,016,406
---------------------	--------------

*See notes accompanying the financial statements.*

F-18

**Table of Contents**

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(UNAUDITED)**

	<b>Three months ended</b>		<b>Nine months ended</b>	
	<b>September</b>	September	<b>September</b>	September
	<b>30,</b>	30,	<b>30,</b>	30,
	<b>2006</b>	2005	<b>2006</b>	2005
<b>REVENUES:</b>				
Net sales	\$ 942,088	\$ 843,435	\$ 3,683,599	\$ 2,003,868
License revenue				250,000
Research grants and development income	76,102	101,277	209,494	328,419
<b>TOTAL REVENUES</b>	<b>1,018,190</b>	944,712	<b>3,893,093</b>	2,582,287
Cost of sales	830,819	669,817	2,705,749	1,770,747
<b>GROSS PROFIT</b>	<b>187,371</b>	274,895	<b>1,187,344</b>	811,540
<b>OVERHEAD COSTS:</b>				
Research and development expenses	318,048	292,198	1,062,319	1,053,731
Selling, general and administrative expenses	1,109,797	822,010	3,740,765	2,109,030
	<b>1,427,845</b>	1,114,208	<b>4,803,084</b>	3,162,761
<b>LOSS FROM OPERATIONS</b>	<b>(1,240,474)</b>	(839,313)	<b>(3,615,740)</b>	(2,351,221)
<b>OTHER INCOME (EXPENSES):</b>				
Other income	25,000		25,000	
Sale of fixed asset			5,000	400
Interest income	2,094	10,135	2,980	33,456
Interest (expense)	(360,606)	(2,804)	(382,316)	(11,269)
<b>LOSS BEFORE INCOME TAXES</b>	<b>(1,573,986)</b>	(831,982)	<b>(3,965,076)</b>	(2,328,634)
Income taxes				
<b>NET LOSS</b>	<b>(1,573,986)</b>	(831,982)	<b>(3,965,076)</b>	(2,328,634)
Dividends payable in stock to preferred stockholders	220,909	206,256	641,769	600,495
Dividend accreted to preferred stock for associated costs and a beneficial conversion feature	538,560		1,001,994	2,698,701

<b>NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS</b>	<b>\$ (2,333,455)</b>	<b>\$ (1,038,238)</b>	<b>\$ (5,608,839)</b>	<b>\$ (5,627,830)</b>
<b>Basic and diluted loss per share</b>	<b>\$ (0.21)</b>	<b>\$ (0.13)</b>	<b>\$ (0.56)</b>	<b>\$ (0.75)</b>
<i>Weighted number of shares outstanding, basic and diluted</i>	<b>10,961,662</b>	8,137,727	<b>10,014,207</b>	7,500,167

*See notes accompanying the financial statements.*

F-19

---

**Table of Contents**

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(UNAUDITED)**

	Nine months ended	
	September 30, 2006	September 30, 2005
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>	<b>\$ (3,965,076)</b>	<b>\$ (2,328,634)</b>
Net loss		
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	146,346	79,429
Provision for doubtful accounts	7,945	(4,278)
Non-cash interest expense	331,114	
Common stock, options and warrants issued as compensation	458,412	26,240
Changes in:		
Accounts receivable	376,693	(559,878)
Restricted cash		250,000
Inventories	(403,041)	(32,215)
Prepaid expenses and other current assets	115,538	90,189
Other assets and deposits	(251,544)	(100,212)
Payment of accrued interest	(97,652)	(89,790)
Accounts payable and accrued expenses	1,178,931	(365,326)
<b>Net cash used in operating activities</b>	<b>(2,102,334)</b>	<b>(3,034,475)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Acquisition of fixed assets	(320,750)	(324,642)
<b>Net cash used in investing activities</b>	<b>(320,750)</b>	<b>(324,642)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Sale of Series C Preferred Stock and associated warrants, net of cash cost of financing of \$50,000	3,950,000	
Sale of Series B Preferred Stock and associated warrants, net of cash cost of financing for the periods ended in 2006 and 2005 of \$2,750 and \$321,639, respectively	997,250	4,725,861
Proceeds from bridge loan	1,300,000	
Payment on bridge loan	(500,000)	
Proceeds from exercise of warrants	86,321	25,196
Payment of capital lease obligation	(28,379)	(28,402)
Proceeds from working capital loan		161,917
Payment of working capital loan		(206,917)
Payment of dividends	(140,226)	
<b>Net cash provided by financing activities</b>	<b>5,664,966</b>	<b>4,677,655</b>



<b>NET INCREASE IN CASH</b>	<b>3,241,882</b>	1,318,538
Cash beginning of the period	<b>232,148</b>	34,837
<b>CASH end of the period</b>	<b>\$ 3,474,030</b>	\$ 1,353,375
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid during the period for interest	<b>\$ 112,302</b>	\$ 118,531
<b>Supplemental disclosures for non-cash investing and financing activities:</b>		
Warrants issued as payment for fees	<b>\$</b>	\$ 366,559
Preferred B issued as payment for financing fees	<b>100,000</b>	249,000
Preferred A and associated warrants exchanged for Preferred B and associated warrants		20,000
Value of warrants issued allocated to additional paid in capital	<b>1,120,030</b>	2,349,893
Accreted beneficial conversion to preferred stock	<b>1,001,994</b>	2,698,701
Accreted dividend to preferred stock	<b>641,769</b>	600,495
Common stock issued as payment of dividend	<b>522,794</b>	187,679
Preferred B issued as payment of dividend	<b>89,899</b>	203,493
Preferred A converted to common stock	<b>122,006</b>	52,631
Preferred B converted to common stock	<b>360,651</b>	228,877

*See notes accompanying the financial statements.*

F-20

**Table of Contents**

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**SEPTEMBER 30, 2006**  
**(UNAUDITED)**

**NOTE 1 DESCRIPTION OF BUSINESS:**

Chembio Diagnostics, Inc. and its subsidiaries (the Company) develop, manufacture, and market lateral flow rapid diagnostic tests that detect infectious diseases and other conditions in humans and animals. These tests are sold in the U.S. and/or internationally to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments. The products are made under the label of Chembio Diagnostic Systems, Inc. (CDS) or the private labels of its distributors or their customers. The Company's main products presently commercially available are its three HIV Rapid Tests (SURE CHECK® HIV 1/2, HIV 1/2 STAT-PAK and HIV 1/2 STAT-PAK Dipstick) and its rapid test for Chagas Disease (Chagas STAT-PAK®). The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern. The Company has sustained significant operating losses in the nine months of 2006 and the years 2005 and 2004. At September 30, 2006, the Company had a Stockholders' Deficiency of \$898,030 and a working capital surplus of \$1,836,636. On September 29, 2006 and October 5, 2006, the Company completed a private offering which raised \$8,150,000 (please see Recent Developments below for a more complete discussion of this financing). The Company believes its resources are sufficient to fund its needs through the end of 2007. The Company's liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenue growth; (2) the extent to which, if any, that revenue growth improves operating cash flows; (3) its investments in research and development, facilities, marketing, regulatory approvals, and other investments it may determine to make, and (4) the investment in capital equipment and the extent to which it improves cash flow through operating efficiencies. If the Company's resources are not sufficient to fund its needs through 2007 there are no assurances that the Company will be successful in raising sufficient capital.

**RECENT DEVELOPMENTS:**

On May 30, 2006, the Company received approval of its Pre-Market Applications (PMAs) from the U. S. Food and Drug Administration (FDA) for its SURE CHECK® HIV 1/2 and HIV 1/2 STAT-PAK rapid tests. The approved PMAs allow Chembio to market its rapid HIV tests to clinical laboratories and hospitals in the United States. FDA approval also allows Chembio to further expand its international marketing efforts into countries that require regulatory approval in the manufacturer's country of domicile.

*Bridge Loan payable*

On June 29, 2006, the Company entered into Agreements for the private placement of up to \$1,800,000 of secured debentures, of which \$1,300,000 was then borrowed. The principal and accrued interest under this obligation was due on September 29, 2006 and was secured by a lien on all assets of the Company. The Company also issued warrants for the purchase of its Common Stock in connection with this transaction; each \$1,000 of debenture entitles the lender to a warrant to purchase 400 shares of common stock at an exercise price of \$0.75 per share with a term of exercise of five years. See footnote 4(b) for further information on the valuation and terms of the warrants.

The lenders also had a right to participate in future equity financings on the same terms and conditions as the offer, up to the lesser of \$2,000,000 or 40% of the offering amount. The lenders could convert the outstanding secured debentures and accrued interest into securities being offered in the future by the Company on the same terms and conditions as the other participants, at a discounted rate of 12.5%. Subsequent to September 30, 2006, \$600,245, plus interest, of the secured debentures were converted into the Series C Offering (see below) at a discount of 12.5% and the balance amount of \$199,755 was repaid from the proceeds of the Series C Offering.

The Agreements related to the June 2006 financing require the Company to register and maintain the registration of the shares underlying the aforementioned warrants. The Company will incur cash penalties if it fails to do so.

**Table of Contents**

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
SEPTEMBER 30, 2006  
(UNAUDITED)**

Pursuant to the provisions of Statement of Financial Accounting Standards No. 133, *Accounting for Derivative Instruments and Hedging Activities* and EITF 00-19: *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock* (EITF 00-19), the Company has recorded the value (calculated on a Black-Scholes option pricing model) of the warrants in connection to the June 29, 2006 private placement, \$328,341, as deferred financing costs with a corresponding credit to a long term derivative liability on the Consolidated Balance Sheet as of September 30, 2006. The deferred financing cost was amortized on a straight-line basis over the life of the underlying debt. Accordingly, as at September 30, 2006, the deferred financing cost was fully amortized.

The liability for the value of the warrants will be marked to market in future accounting periods until such time as the warrants are exercised or they meet the criteria for equity classification.

*CLIA Waiver*

In July 2006 the Company submitted to the FDA CLIA (Clinical Laboratory Improvement Act) waiver applications for its HIV 1/2 STAT-PAK® and SURE CHECK® HIV 1/2 products. These waivers are essential in order to market FDA approved products to the POL (physician office laboratory) and public health segments of the United States market. These applications are pending at the FDA.

*Series C Preferred Stock Offering*

On September 29, 2006, the Company sold 80 shares of its 7% series C convertible preferred stock, together with warrants to purchase 1,250,000 shares of common stock, exercisable at \$1.00 per share. This issuance was made in connection with the Company's private placement for \$8,150,000, consisting of 165 shares of 7% series C convertible preferred stock (at a stated value of \$50,000 per share), together with warrants to purchase 2,578,125 shares of its common stock (the Series C Offering). \$500,000 of the proceeds were used during September 2006, to repay part of the bridge loan borrowed on June 29, 2006. The balance was either repaid (\$199,755) or converted into Series C in October of 2006 (\$600,245). The Company believes this Series C Offering will be enough to supply the Company's cash needs through the end of 2007. Refer to footnote 4(e) for a description of selected terms and the accounting of the Series C Offering.

**NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:**

***(a) Basis of Presentation:***

The consolidated interim financial information as of September 30, 2006 and for the three and nine-month periods ended September 30, 2006 and 2005 has been prepared without audit, pursuant to the rules and regulations of the Securities and Exchange Commission (the SEC). Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations, although we believe that the disclosures made are adequate to provide for fair presentation. The interim financial information should be read in conjunction with the Financial Statements and the notes thereto, included in the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2005, previously filed with the SEC.

In the opinion of management, all adjustments (which include normal recurring adjustments) necessary to present a fair statement of consolidated financial position as of September 30, 2006, and consolidated results of operations for the three and nine-month periods, and cash flows for the nine month periods ended September 30, 2006 and 2005, as applicable, have been made. The interim results of operations are not necessarily indicative of the operating results for the full fiscal year or any future periods.

Table of Contents

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**SEPTEMBER 30, 2006**  
**(UNAUDITED)**

*(b) Inventories:*

Inventory consists of the following at:

	<b>September 30, 2006</b>	December 31, 2005
<b>Raw Materials</b>	\$ 475,077	\$ 425,758
<b>Work in Process</b>	93,422	86,001
<b>Finished Goods</b>	522,525	176,224
	<b>\$ 1,091,024</b>	<b>\$ 687,983</b>

*(c) Fixed Assets*

In June 2006, the Company retired fully depreciated fixed assets with an original cost of \$100,687.

*(d) Earnings Per Share*

The following weighted average number of shares were used for the computation of basic and diluted loss per share:

	<b>For the three months ended</b>		<b>For the nine months ended</b>	
	<b>September 30, 2006</b>	September 30, 2005	<b>September 30, 2006</b>	September 30, 2005
<b>Basic</b>	<b>10,961,662</b>	8,137,727	<b>10,014,207</b>	7,500,167
<b>Diluted</b>	<b>10,961,662</b>	8,137,727	<b>10,014,207</b>	7,500,167

Basic loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted loss per share reflects the potential dilution from the exercise or conversion of other securities into Common Stock, but only if dilutive. Diluted loss per share for the three and nine months ended September 30, 2006 and 2005 is the same as basic loss per share, since the effect of including such potential Common Stock equivalents was anti-dilutive as the Company incurred losses for all periods presented. Such securities, shown below, presented on a common share equivalent basis and outstanding as at September 30, 2006 and 2005, have been excluded from the per share computations:

	<b>September 30, 2006</b>	September 30, 2005
<b>1999 Plan Stock Options</b>	<b>1,629,750</b>	1,256,500
<b>Other Stock Options</b>	<b>144,625</b>	144,625
<b>Warrants</b>	<b>24,713,994</b>	21,263,966
<b>Convertible Preferred Stock</b>	<b>16,835,036</b>	16,311,602

*(e) Employee Stock Option Plan:*

Effective January 1, 2006, the Company's Plan is accounted for in accordance with the recognition and measurement provisions of Statement of Financial Accounting Standards (FAS) No. 123 (revised 2004), Share-Based Payment (FAS 123(R)), which replaces FAS No. 123, Accounting for Stock-Based Compensation, and supersedes Accounting Principles Board Opinion (APB) No. 25, Accounting for Stock Issued to Employees, and related interpretations. FAS 123(R) requires compensation costs related to share-based payment transactions, including employee stock options, to be recognized in the financial statements. In addition, the Company adheres to the guidance set forth within Securities

and Exchange Commission ( SEC ) Staff Accounting Bulletin No. 107 ( SAB 107 ), which provides the Staff 's views regarding the interaction between SFAS No. 123(R) and certain SEC rules and regulations and provides interpretations with respect to the valuation of share-based payments for public companies.

F-23

---

**Table of Contents**

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**SEPTEMBER 30, 2006**  
**(UNAUDITED)**

Prior to January 1, 2006, the Company accounted for similar transactions in accordance with APB No. 25 which employed the intrinsic value method of measuring compensation cost. Accordingly, compensation expense was not recognized for fixed stock options if the exercise price of the option equaled or exceeded the fair value of the underlying stock at the grant date.

While FAS No. 123 encouraged recognition of the fair value of all stock-based awards on the date of grant as expense over the vesting period, companies were permitted to continue to apply the intrinsic value-based method of accounting prescribed by APB No. 25 and disclose certain pro-forma amounts as if the fair value approach of SFAS No. 123 had been applied. In December 2002, FAS No. 148, Accounting for Stock-Based Compensation-Transition and Disclosure, an amendment of SFAS No. 123, was issued, which, in addition to providing alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based employee compensation, required more prominent pro-forma disclosures in both the annual and interim financial statements. The Company complied with these disclosure requirements for all applicable periods prior to January 1, 2006.

In adopting FAS 123(R), the Company applied the modified prospective approach to transition. Under the modified prospective approach, the provisions of FAS 123(R) are to be applied to new awards and to awards modified, repurchased, or cancelled after the required effective date. Additionally, compensation cost for the portion of awards for which the requisite service has not been rendered that are outstanding as of the required effective date shall be recognized as the requisite service is rendered on or after the required effective date. The compensation cost for that portion of awards shall be based on the grant-date fair value of those awards as calculated for either recognition or pro-forma disclosures under FAS 123.

As a result of the adoption of FAS 123(R), the Company's results for the three and nine month periods ended September 30, 2006 include share-based compensation expense totaling approximately \$33,100 and \$247,000, respectively. Such amounts have been included in the Consolidated Statements of Operations within cost of goods sold (\$3,100 and \$25,000), research and development (\$6,300 and \$62,000) and selling, general and administrative expenses (\$23,700 and \$160,000). No income tax benefit has been recognized in the income statement for share-based compensation arrangements due to the history of operating losses.

Stock option compensation expense in the nine months of 2006 represent the estimated fair value of options outstanding which are being amortized on a straight-line basis over the requisite vesting period of the entire award. The weighted average estimated fair value of stock options granted in the three and nine months ended September 30, 2006 and 2005 was none and \$.53 and \$.38 and \$.49 per share, respectively. The fair value of options at the date of grant was estimated using the Black-Scholes option pricing model. During 2006, the Company took into consideration guidance under SFAS 123(R) and SAB 107 when reviewing and updating assumptions. The expected volatility is based upon historical volatility of our stock and other contributing factors. The expected term is determined using the simplified method as permitted by SAB 107, as the Company has no history of employee exercise of options to-date. The assumptions made in calculating the fair values of options are as follows:

	Three Months Ended		Nine Months Ended	
	September 30, 2006	September 30, 2005	September 30, 2006	September 30, 2005
Expected term (in years)	n/a	5	4 to 5	5
Expected volatility	n/a	89.82%	116.20% to 118.03%	95.56% to 114.94%
Expected dividend yield	n/a	0%	0%	0%

Risk-free interest rate	n/a	4.08%	4.66% to 4.92%	3.72% to 4.18%
-------------------------	-----	-------	----------------------	----------------

There were no awards issued during the three months ended September 30, 2006.

The following table addresses the additional disclosure requirements of 123(R) in the period of adoption. The table illustrates the effect on net income and earnings per share as if the fair value recognition provisions of FAS No. 123 had been applied to all outstanding and unvested awards in the prior year comparable period.

F-24

---

Table of Contents

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**SEPTEMBER 30, 2006**  
**(UNAUDITED)**

	<b>For the three months ended September 30, 2005</b>	<b>For the nine months ended September 30, 2005</b>
Net loss attributable to common stockholders, as reported	(1,038,238)	(5,627,830)
Add: Stock-based compensation included in reported net loss		
Deduct: Total stock based compensation expense determined under the fair value based method for all awards (no tax effect)	(59,435)	(130,906)
Pro forma net loss attributable to common stockholders	\$ (1,097,673)	\$ (5,758,736)
Net loss per share:		
Basic and diluted loss per share as reported	\$ (0.13)	\$ (0.75)
Basic and diluted loss per share pro forma	\$ (0.13)	\$ (0.77)

The Company did not grant any options in the three months ended September 30, 2006. The Company granted 831,250 new options under the Plan during the three months ended June 30, 2006 at an exercise price of \$0.75 per share. The Company granted 316,000 new options under the Plan during the three months ended March 31, 2006 at exercise prices ranging from \$0.55 per share to \$0.62 per share.

The following table provides stock options activity for the nine months ended September 30, 2006:

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Stock Options				
Outstanding at January 1, 2006	1,285,750	\$1.20		
Granted	1,147,250	\$0.71		
Cancelled	(795,250)	\$1.56		
Exercised				
Forfeited/expired	(8,000)	\$0.75		
Outstanding at September 30, 2006	1,629,750	\$0.69	3.90 years	\$148,179
Exercisable at September 30, 2006	1,164,250	\$0.68	3.75 years	\$114,219

As of September 30, 2006, there was \$51,363 of net unrecognized compensation cost related to stock options that are not vested, which is expected to be recognized over a weighted average period of approximately .40 years. The total fair value of shares vested during the three months ended September 30, 2006 and 2005, was \$3,647 and none, respectively. The total fair value of shares vested during the nine months ended September 30, 2006 and 2005, was \$401,381 and \$66,252, respectively.

On April 17, 2006 the Compensation Committee of the Company's Board of Directors approved the cancellation of all employee options where the exercise price was greater than \$.75 per share (an aggregate of 795,250 options) and issued new options at an exercise price of \$.75 per share with the same vesting schedule and expiration dates (except



for 122,500 new options that were issued with a vesting date of January 1, 2007 which is later than the vesting date of the options they replaced). The expense related to this modification in the second quarter of 2006 was \$58,000. No options were exercised during the nine months ended September 30, 2006 or September 30, 2005. For the three and nine months ended September 30, 2006, 7,500 and 8,000 options expired, respectively.

F-25

---

**Table of Contents**

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**SEPTEMBER 30, 2006**  
**(UNAUDITED)**

**(f) Geographic Information:**

SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information establishes standards for the way that business enterprises report information about operating segments in financial statements and requires that those enterprises report selected information. It also establishes standards for related disclosures about product and services, geographic areas, and major customers.

The Company produces only one group of similar products known collectively as rapid medical tests. As per the provisions of SFAS 131, management believes that it operates in a single business segment. Net sales by geographic area are as follows:

	<b>For the three months ended</b>		<b>For the nine months ended</b>	
	<b>September 30, 2006</b>	<b>September 30, 2005</b>	<b>September 30, 2006</b>	<b>September 30, 2005</b>
Africa	\$ 493,922	\$ 95,550	\$ 1,229,083	\$ 313,261
Asia	53,945	37,640	205,234	113,729
Australia	1,180	520	1,180	13,598
Europe	16,313	20,460	62,642	75,303
Middle East	5,505	8,720	13,245	106,036
North America	130,349	138,452	279,620	374,132
South America	240,874	542,093	1,892,595	1,007,809
	\$ 942,088	\$ 843,435	\$ 3,683,599	\$ 2,003,868

**(g) Accounts payable and accrued liabilities**

Accounts payable and accrued liabilities consists of:

	<b>September 30, 2006</b>	<b>December 31, 2005</b>
Accounts payable – suppliers	\$ 1,220,443	\$ 550,247
Accrued commissions	160,734	171,587
Accrued royalties / licenses	509,261	381,510
Accrued payroll and other taxes	135,392	63,146
Accrued vacation	185,355	145,566
Accrued legal and accounting	59,595	50,024
Accrued expenses – other	362,050	115,845
<b>TOTAL</b>	<b>\$ 2,632,830</b>	<b>\$ 1,477,925</b>

**(h) Recent Accounting Pronouncements**

SEC Staff Accounting Bulletin 108 ( SAB 108 ), Considering the Effects of Prior Year Misstatements when Qualifying Misstatements in Current Year Financial Statements

In September 2006, the SEC staff issued Staff Accounting Bulletin No. 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements. SAB 108 was issued in order to eliminate the diversity of practice surrounding how public companies quantify financial statement misstatements.



**Table of Contents**

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
SEPTEMBER 30, 2006  
(UNAUDITED)**

In SAB 108, the SEC staff established an approach that requires quantification of financial statement misstatements based on the effects of the misstatements on each of the company's financial statements and the related financial statement disclosures. This model is commonly referred to as a "dual approach" because it requires quantification of errors under both the iron curtain and the roll-over methods.

SAB 108 permits existing public companies to initially apply its provisions either by (i) restating prior financial statements as if the "dual approach" had always been used or (ii) recording the cumulative effect of initially applying the "dual approach" as adjustments to the carrying values of assets and liabilities as of January 1, 2006 with an offsetting adjustment recorded to the opening balance of retained earnings.

We will adopt the provisions of SAB 108 in connection with the preparation of our annual financial statements for the year ending December 31, 2006. We currently do not believe that its adoption will have any impact on our financial statements.

Statement of Financial Accounting Standard 158, Fair Value Measurements (SFAS 158)

On September 15, 2006, the Financial Accounting Standard Board issued a standard that provides enhanced guidance for using fair value to measure assets and liabilities. The standard applies whenever other standards require (or permit) assets or liabilities to be measured at fair value. The standard does not expand the use of fair value in any new circumstances.

This Statement is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. Earlier application is encouraged, provided that the reporting entity has not yet issued financial statements for that fiscal year, including financial statements for an interim period within that fiscal year. The Company will adopt this pronouncement effective periods beginning January 1, 2008. We currently do not believe that its adoption will have any impact on our financial statements.

FSP FAS 123(R)-5, Amendment of FASB Staff Position FAS 123(R)-1

FSP FAS 123(R)-5 was issued on October 10, 2006. The FSP provides that instruments that were originally issued as employee compensation and then modified, and that modification is made to the terms of the instrument solely to reflect an equity restructuring that occurs when the holders are no longer employees, no change in the recognition or the measurement (due to a change in classification) of those instruments will result if both of the following conditions are met: (a). There is no increase in fair value of the award (or the ratio of intrinsic value to the exercise price of the award is preserved, that is, the holder is made whole), or the antidilution provision is not added to the terms of the award in contemplation of an equity restructuring; and (b). All holders of the same class of equity instruments (for example, stock options) are treated in the same manner. The provisions in this FSP shall be applied in the first reporting period beginning after the date the FSP is posted to the FASB website. We will adopt this FSP from its effective date. We currently do not believe that its adoption will have any impact on our financial statements.

**NOTE 3 LONG-TERM DEBT:**

In connection with the Series B offering, interest that had accrued on certain debt through December 29, 2004 was agreed to be paid over 33 months in installments of \$10,000 per month and a final payment of \$3,160 in the 34<sup>th</sup> month. These payments are subordinate to the redemption rights of the Series B preferred stockholders. No interest accrues on this accrued liability. As of September 30, 2006 the total remaining outstanding interest was \$123,160.

**NOTE 4 STOCKHOLDERS' EQUITY:**

**(a) Common Stock**

During the three and nine months ended September 30, 2006 the Company issued 25,000 and 147,082 shares, respectively of its Common Stock to a consultant as compensation. The number of shares issued was a fixed number set forth in the consultant's contract, with specific issue dates and without regard to the market price of the stock on the date of issuance. For accounting purposes, the shares were valued based on the closing market price on date of issuance from \$0.55 to \$0.91 per share and the related compensation expense for the three and nine months ended September 30, 2006 was \$20,167 and \$115,028 respectively.

In July 2006, the Company issued to a member of the Board of Directors 15,000 shares of common stock as additional compensation for services as the audit committee chair. This stock was valued based on the market closing price on the date of the grant and \$10,650 was charged to expense.

F-27

---

**Table of Contents**

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**SEPTEMBER 30, 2006**  
**(UNAUDITED)**

There was no conversion activity in the three months ended September 30, 2006. During the nine months ended September 30, 2006 Series A Preferred shareholders converted 8.75980 shares into 437,989 shares of Common Stock and Series B Preferred shareholders converted 12.05966 shares into 988,494 shares of Common Stock.

During the nine months ended September 30, 2006 the Company issued 140,691 shares of its Common Stock upon the exercise of warrants and received cash of \$86,321.

In the nine months ended September 30, 2006 the Company issued 399,121 shares of its Common Stock as payment of dividends on its Series A Preferred Stock and 416,440 shares of its Common Stock as payment of dividends on its Series B Preferred Stock. These shares were valued using a 10 day volume weighted average price for the ten trading days immediately preceding the issue date.

***(b) Warrants***

The warrants to purchase 1,713,114 shares of Common Stock issued in connection with the March 2006 Series B offering were assigned a value of \$481,470. These warrants have an exercise price of \$0.61 per share and a five year life.

Warrants to purchase 520,000 shares of Common Stock were issued in connection with the bridge loan and were assigned an initial value of \$328,341. As of September 30, 2006, the warrants were revalued at \$331,114 and were charged to interest expense in the three months ended September 30, 2006. These warrants have an exercise price of \$0.75 per share and a five year life.

Warrants to purchase 1,250,000 shares of Common Stock were issued in connection with the completed Series C Offering and were assigned a value of \$638,560. These warrants have an exercise price of \$1.00 per share and a five year life.

During the three and nine months ended September 30, 2006, the Company issued warrants to purchase 25,000 and 183,599 shares, respectively of Common Stock at exercise prices from \$0.55 to \$0.883 per share to a sales agent as payment for commissions (value \$34,100) and commissions accrued at year end 2005 (value \$24,000) and to consultants as compensation for 2006 (value for the three and nine months ended September 30, 2006 was \$15,500 and \$38,324, respectively). These warrants have a five year life.

All of the above warrants were valued using a Black-Scholes option pricing model based on assumptions for expected volatilities from 116.2% to 118.03%, expected lives of 5 years and expected risk free interest rates from 4.55% to 5.13%.

***(c) Series A 8% Convertible Preferred Stock:***

**Redemption:** The holders have the right, under certain conditions, to require redemption of all or a portion of such holder's shares of Series A Preferred Stock. The Series A Preferred Stock is not currently redeemable and there is no likelihood that it will become redeemable; accordingly, no accretion is being made to bring the value up to its redemption value. The liquidation preference is \$30,000 per share plus accrued and unpaid dividends, presently \$982.15 per share, an aggregate for all such shares of \$4,644,882. Accrued but unpaid dividends of \$147,246 are included in the preferred stock carrying value as at September 30, 2006.

**Dividends:** The 8% per annum dividend is payable semi-annually, in cash or, at the Company's option, in Common Stock, except as to Vicis Capital which is to be paid in cash unless it opts to take its dividends in Common Stock. In June 2006, the Series A Preferred Stock was amended to provide, among other matters, that dividends in Preferred or Common Stock would be based on a 10 day volume weighted average market price at the time of the dividend. To date all dividends have been paid in Common Stock.

***(d) Series B 9% Convertible Preferred Stock:***

On March 30, 2006, the Company sold \$1 million of additional Series B Preferred Stock to a Series B Preferred shareholder pursuant to provisions of the January 2005 Series B 9% Preferred Stock financing agreements. Such provisions were exclusive to said shareholder. Approximately \$140,000 of these proceeds was used to pay cash dividends which were accrued as of December 31, 2005.

Redemption: The holders have the right, under certain conditions, to require redemption of all or a portion of such holder's shares of Series B Preferred Stock. The Series B Preferred is not currently redeemable and there is no likelihood that it will become redeemable; accordingly, no accretion is being made to bring the value up to its redemption value. The liquidation preference is \$50,000 per share plus accrued and unpaid dividends, presently \$1,104.72 per share, an aggregate for all such shares of \$5,822,663. Accrued but unpaid dividends of \$125,867 are

F-28

---

**Table of Contents**

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**SEPTEMBER 30, 2006**  
**(UNAUDITED)**

included in the preferred stock carrying value as at September 30, 2006. The accrued but unpaid dividend was paid on January 2, 2006 by the issuance of 4.60249 shares Series B Preferred Stock valued at the stated value of \$50,000 per share. Subsequent to this issuance a Series B shareholder asserted its right, which is exclusive to such shareholder, to receive its dividend in cash; the certificate for 2.80452 shares of Series B was surrendered and the equivalent amount of \$140,226 was paid in April 2006.

As per EITF 00-27 Application of Issue 98-5 to Certain Convertible Instruments, the Company evaluated the Series B Preferred Stock transaction that occurred in January 2005 and found that there was an associated beneficial conversion feature totaling \$2,437,035; the preferred stock was further discounted by this amount. The beneficial conversion amount was then accreted back to the preferred stock in accordance with the conversion provision which allowed for 100% to be converted immediately. The Company also evaluated the Series B Preferred Stock transaction that occurred on March 30, 2006, see above, and found that there was an associated beneficial conversion feature totaling \$463,434; the preferred stock was further discounted by this amount. The beneficial conversion amount was then accreted back to the preferred stock in accordance with the conversion provision which allowed for 100% to be converted immediately.

**Dividends:** The 9% Series B Preferred Stock accrues dividends at 9% per annum, payable semi-annually. Dividends are payable in Series B Preferred Stock, Common Stock or in cash. In June 2006, the Series B Preferred Stock was amended to provide, among other amendments, that the dividend could be paid in Common Stock (in addition to Preferred Stock or cash) and that dividends in Preferred or Common Stock would be based on a 10 day volume weighted average market price at the time of the dividend. The majority investor in the Series B financing has the option as it pertains to its dividend payment to choose cash or Preferred or Common shares. The Company has the option to choose cash or Preferred or Common shares as to the balance of the dividends. To date all dividends have been paid in Preferred or Common Shares, except \$140,226 which was paid in cash at the option of the majority investor.

***(e) Series C 7% Convertible Preferred Stock:***

On September 29, 2006, the Company sold \$4 million of Series C Preferred Stock (see note 6) pursuant to provisions of the September 29, 2006 Series C 7% Preferred Stock financing agreements. In addition the Company issued 1,250,000 warrants to the investors. See note 4(b) for information on the warrants. See note 1- Recent Developments for additional information. A summary of the significant terms as amended on October 5, 2006 are as follows:

**Dividends.** Holders of series C preferred stock are entitled to a 7% per annum dividend per share. The dividend accrues and is payable semi-annually in cash or in shares of common stock, at our option. Accrued but unpaid dividends are also payable upon the conversion or redemption of the shares of series C preferred stock and upon a liquidation event.

**Conversion.** The series C preferred stock is convertible, at the option of the holders, into shares of our common stock at a conversion price of \$.80 per share. Based on the original purchase price of \$50,000 per share, each share of series C preferred stock is convertible into 62,500 shares of our common stock.

**Redemption:** The holders have the right, under certain conditions, to require redemption of all or a portion of such holder's shares of Series C Preferred Stock. The redemption value is greater of (i) 130% of the stated value or \$65,000 and (ii) the product of (a) daily volume weighted average price of the Company's common stock and (b) a quotient of \$65,000 divided by the then existing conversion price, plus accrued and unpaid dividends and all liquidated damages.

**Liquidation preference:** The liquidation preference is \$50,000 per share plus accrued and unpaid dividends and all liquidated damages. There are no accrued but unpaid dividends at September 30, 2006. The aggregate liquidation preference as of September 30, 2006 is \$4,000,000

The Company has accounted for the Series C Offering pursuant to the provisions of Statement of Financial Accounting Standards No. 133, Accounting for Derivative Instruments and Hedging Activities and EITF 00-19:

Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock (EITF



00-19 ). The Company has allocated the value received between the preferred stock and the related warrants. The allocated value for the preferred stock and the related warrants were \$3,361,440 and \$638,560, respectively. Further, the Company has determined the redemption feature in the Series C Preferred Stock needs to be bifurcated and has valued the same at \$218,025. The warrant value and the value of the redemption feature is treated as discount and the preferred stock is reflected net of this discount. Due to the contingent redemption feature, the Series C Preferred Stock is reflected as temporary equity. The Series C Preferred Stock is not currently

F-29

---

**Table of Contents**

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
SEPTEMBER 30, 2006  
(UNAUDITED)**

redeemable and there is no likelihood that it will become redeemable; accordingly, no accretion is being made to bring the carrying value up to its redemption value. The liability for the value of the redemption feature will be marked to market in future accounting periods until such time as the redemption is exercised or the feature meets the criteria for equity classification. See footnote 4(b) for the valuation of warrants.

In addition, as per EITF 00-27 Application of Issue 98-5 to Certain Convertible Instruments, the Company evaluated the Series C Preferred Stock transaction that occurred in September 2006 and found that there were associated beneficial conversion features totaling \$538,560; the preferred stock was further discounted by this amount. The beneficial conversion amount related to the valuation of the preferred stock (\$538,560) was then accreted back to the preferred stock in accordance with the conversion provision which allowed for 100% to be converted immediately. The accretion was reflected as dividend expense.

**NOTE 5 COMMITMENTS AND CONTINGENCIES:**

***(a) Economic Dependency:***

The Company had sales to two customers in excess of 10% of total sales in the three months ended September 30, 2006. Sales to these customers approximated \$363,000 and \$232,000, respectively.

The Company had sales to one customer in excess of 10% of total sales in the three months ended September 30, 2005. Sales to this customer approximated \$510,000.

The Company had sales to three customers in excess of 10% of total sales in the nine months ended September 30, 2006. Sales to these customers approximated \$1,197,000, \$685,000 and \$640,000, respectively.

The Company had sales to one customer in excess of 10% of total sales in the nine months ended September 30, 2005. Sales to this customer approximated \$862,000.

The Company had purchases from one vendor in excess of 10% of total purchases for the three months ended September 30, 2006. Purchases from this vendor approximated \$70,000

The Company had purchases from one vendor in excess of 10% of total purchases for the nine months ended September 30, 2006. Purchases from this vendor approximated \$202,000.

The Company had no purchases from any vendor in excess of 10% of total purchases for the three and nine months ended September 30, 2005.

***(b) Governmental Regulation:***

All of the Company's existing and proposed diagnostic products are regulated by the U.S. Food and Drug Administration (FDA), U.S. Department of Agriculture, certain state and local agencies, and/or comparable regulatory bodies in other countries. Most aspects of development, production, and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing, and record keeping are subject to review. After marketing approval has been granted, Chembio must continue to comply with governmental regulations. Failure to comply with these regulations can result in significant penalties.

***(c) Litigation:***

On September 29, 2006, the Company and StatSure Diagnostic Systems, Inc. (StatSure) entered into a Settlement Agreement pursuant to which all matters in their litigation regarding StatSure barrel patent and other matters were settled. In addition the parties entered into the Joint HIV Barrel Product Commercialization Agreement, which provides that the parties will equally share in the profits relating to all SURE CHECK® HIV 1/2 after reimbursement to the Company of its manufacturing and related costs, as defined, and that they will act jointly in the HIV barrel field. The settlement combines each company's HIV barrel intellectual property, including an exclusive manufacturing license from StatSure to the Company of its barrel patent for all HIV applications, thereby ensuring the Company's exclusive right to manufacture.

**NOTE 6 SUBSEQUENT EVENTS:**

***Series C Financing:***

On October 5, 2006 the Company completed its private offering by selling \$4,150,000 of its Series C Preferred Stock. \$600,245 of the debentures sold on June 29, 2006 was converted into the Series C Offering at a discount of 12.5% pursuant to the terms of the debenture offering. Some of the proceeds from this offering were used to pay

F-30

---

**Table of Contents**

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
SEPTEMBER 30, 2006  
(UNAUDITED)**

the \$199,755 balance of remaining debentures with interest. The Company paid \$50,000 and issued 62,500 warrants (at an exercise price of \$1.00 per share with a five year life) to an investment banker in connection with \$1.0 million of the financing.

**NOTE 7 COMPARATIVE INFORMATION:**

Certain amounts for fiscal 2005 have been reclassified to conform with the current year's financial statement presentation.

F-31