

CHEMBIO DIAGNOSTICS, INC.  
Form POS AM  
April 04, 2007

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Registration No. 333-138266

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**POST EFFECTIVE AMENDMENT NO. 1 TO  
FORM SB-2**

**REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933**

**Chembio Diagnostics, Inc.**

(Name of small business issuer in its charter)

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

**3661 Horseblock Road  
Medford, New York 11763  
(631) 924-1135**

(Address and telephone number of principal executive offices)

**Lawrence A. Siebert  
3661 Horseblock Road  
Medford, New York 11763  
(631) 924-1135**

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

Copy of all communications to:

**Alan Talesnick, Esq.  
James J. Muchmore, Esq.  
Patton Boggs LLP  
1660 Lincoln Street, Suite 1900  
Denver, Colorado 80264  
(303) 830-1776**

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

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

registration statement for the same offering.

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

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

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

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

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## CALCULATION OF REGISTRATION FEE

<b>Title Of Each Class of Securities To Be Registered</b>	<b>Number of Units/Shares To Be Registered</b>	<b>Proposed Maximum Offering Price Per Unit (1)</b>	<b>Proposed Maximum Aggregate Offering Price (1)</b>	<b>Amount Of Registration Fee(3)</b>
Common Stock, \$0.01 par value per share (2)	20,008,319	\$ .80	\$16,006,655	\$1,712.71

(1) Estimated solely for purposes of calculating the registration fee in accordance with Rule 457(c) under the Securities Act of 1933, as amended (the "Act"), based on the average of the bid and ask prices for the Registrant's common stock as reported on the OTC Bulletin Board on October 27, 2006.

- (2) a. Includes (i) up to 9,812,500 shares issuable upon the conversion of 165 shares of the Registrant's 7% Series C Convertible Preferred Stock, (ii) up to 1,953,125 shares issuable upon the exercise of related warrants.
- b. Includes (i) up to 520,000 shares issuable upon the exercise of warrants related to Debentures issued June 29, 2006, and (ii) 156,000 shares of common stock that may be issued to the Selling Stockholders under the anti-dilution provisions of the Debentures.
- c. Includes (i) up to 163,933 shares issuable upon the conversion of 2 shares of the Registrant's 9% Series B Convertible Preferred Stock, (ii) up to 155,737 shares issuable upon the exercise of related warrants.
- d. Represents shares of common stock registered for resale by the holders (the "Selling Stockholders") of shares of 9% Series B Convertible Preferred Stock consisting of (i) 73,770 shares of common stock that may be issued to pay semi-annual dividends to the Selling Stockholders, and (ii) 118,042 shares of common stock that may be issued to the Selling Stockholders under the anti-dilution provisions of the 9% Series B Convertible Preferred Stock.
- e. Represents shares of common stock registered for resale by the holders (the "Selling Stockholders") of shares of 7% Series C Convertible Preferred Stock consisting of (i) 2,734,375 shares of common stock that may be issued to pay semi-annual dividends to the Selling Stockholders, and (ii) 3,750,000 shares of common stock that may be issued to the Selling Stockholders under the anti-dilution provisions of the 9% Series C Convertible Preferred Stock.
- f. Includes (i) up to 172,082 shares currently held by the selling stockholders and (ii) up to 398,755 shares issuable upon the exercise of outstanding warrants.

(3) When the Company filed its initial Form SB-2 on October 27, 2006, it anticipated registering 26,024,217 shares, which resulted in the Company paying a \$2,227.67 registration fee. The Company has since reduced the number of shares it is registering in this Form SB-2 to 20,008,319 shares, resulting in its registration fee being reduced to \$1,712.71.

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

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

**SUBJECT TO COMPLETION, DATED APRIL 4, 2007**

**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 April 2, 2007 the closing bid and ask prices for one share of our common stock were \$.64 and \$.65, respectively, as reported by the OTC Bulletin Board website. These over-the-counter quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

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

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

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The date of this prospectus is \_\_\_\_\_, 2007



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## PROSPECTUS SUMMARY

*The following summary is qualified in its entirety by the more detailed information and the financial statements and notes thereto appearing elsewhere in, or incorporated by reference into, this Prospectus. Consequently, this summary does not contain all of the information that you should consider before investing in our Common Stock. You should carefully read the entire Prospectus, including the “Risk Factors” section, and the documents and information incorporated by reference into this Prospectus before making an investment decision.*

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 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.

### **Our Corporate Information**

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 that detect a number of infectious 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, manufacturer and marketer of rapid diagnostic tests that detect infectious diseases. Our main products presently commercially available are three rapid tests for the detection of HIV antibodies in whole blood, serum and plasma samples, two of which were approved by the FDA last year. These products employ single path lateral flow technology which we have licensed from Inverness Medical Innovations, Inc. (“Inverness”), who is also our exclusive marketing partner for those two products in the United States under its Clearview® brand. Inverness launched its marketing of these products in the United States in February, 2007. Chembio’s two HIV STAT-PAK® rapid HIV tests are marketed outside the United States through different partners and channels under license from Inverness. We also have a rapid test for Chagas disease (a parasitic disease endemic in Latin America) as well as a line of rapid tests for tuberculosis, including tests for tuberculosis in animals for which USDA approval is pending.

On March 13, 2007, we were issued United States patent # 7,189,522 for our Dual Path Platform (“DPP™”) rapid test system. We believe that as a result of the patent protection we now have with DPP™, we have a significant opportunity to develop and license many new rapid tests in a number of fields including but not limited to infectious diseases. We have already completed initial development on some products in this new platform. We believe the DPP™ provides significant advantages over standard single path lateral flow assays, and we are developing most of our new products using this platform.

Our products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments. Our products are sold either under our STAT-PAK® or SURE CHECK® registered trademarks and/or the private labels of our marketing partners, such as the Inverness Clearview® label.



We have a history of losses, and we continue to incur operating and net losses. 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.

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

We also are in the process of developing rapid tests employing our patented 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.

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.

### Summary Financial Data

The following table presents summary historical financial information for the fiscal years ended December 31, 2006 and 2005. The financial statements are set forth beginning on page F-1 of this prospectus, and you should read this information for a more complete understanding of the presentation of this information.

	<u>Year Ended</u> <u>December 31,</u> <u>2006</u>	<u>Year Ended</u> <u>December 31,</u> <u>2005</u>
Revenue	\$ 6,502,480	\$ 3,940,730
Operating Expenses	6,596,761	4,630,133
Net Loss	(4,995,020)	(3,252,000)
Current Assets	6,953,668	2,468,193
<b>Total Assets</b>	<b>7,906,577</b>	<b>3,016,406</b>
Current Liabilities	1,840,435	1,818,474
<b>Total Liabilities</b>	<b>2,297,193</b>	<b>1,963,703</b>
<b>Convertible Redeemable Preferred Stockholders' Equity (Deficit)</b>	<b>6,549,191</b>	<b>n/a</b>
	<b>(939,807)</b>	<b>(1,052,703)</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.

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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 our 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 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 single path 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, we made substantial additions to our 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 formed the basis of two patent applications that we filed, and may result in additional applications covering additional uses of this technology platform. On March 13, 2007, one of these patent applications was approved by the United States Patent & Trademark Office, which issued United States patent no. 7,189,522 for our DPP™ rapid test system. Also, we believe 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 our patents or our 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.

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**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 our revenues and gross margins increased significantly in recent periods, we sustained significant operating losses in 2006, 2005 and 2004. At December 31, 2006, we had a stockholders' deficiency of \$940,000 and a working capital surplus of \$5,113,000. Including the funds received from the Series C 7% Convertible Preferred Stock offering, we believe our resources are sufficient to fund our needs through the end of 2007 and into early 2008. Our 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) our investments in research and development, facilities, marketing, regulatory approvals and other investments we may determine to make; and (4) our investment in capital equipment and the extent to which this investment improves cash flow through operating efficiencies. If our resources are not sufficient to fund our needs through 2007, there are no assurances that we will be successful in raising sufficient capital.

On March 30, 2006, we 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, we 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 our assets. See Note 1 of the financial statements for further details.

On September 29, 2006 and October 5, 2006, we completed the Series C Offering for \$8,150,000. Some of the proceeds were used to repay the loan borrowed on June 29, 2006. We believe this Series C offering will be enough to supply our 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.

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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 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 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.

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**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 interests 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, 2006, we have incurred net losses. As of December 31, 2006, we have an accumulated deficit of \$(27,073,494). We incurred net losses of \$(4,995,020) and \$(3,252,000) in 2006 and 2005, respectively.

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

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

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

#### *Risks related to our Common Stock*

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

Our Common Stock is classified as penny stock. Penny stocks generally are equity securities with a price of less than \$5.00 and trade on the over-the-counter market. As a result, an investor may find it more difficult to dispose of or obtain accurate quotations as to the price of the Shares being registered in this Prospectus. 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 that 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 36,000 shares per day over the three months ended March 31, 2007. 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.

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**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 the entire obligation to issue 704,000 common shares upon the exercise of the options outstanding as of the merger date. On January 28, 2005, we completed a private placement in which we issued 100 shares of our 9% Series B Convertible Preferred Stock, which we refer to as the "Series B Stock," together with warrants to purchase 7,786,960 shares of our Common Stock. For each \$.61 invested in this private placement, an investor received (a) \$.61 of face amount of Series B Stock, which is convertible into one share of our Common Stock, and (b) a five-year warrant to acquire .95 of a share of our Common Stock. Each full share of the Series B Stock was purchased for \$50,000, with fractional shares of Series B Stock being purchased by investments of less than \$50,000. In connection with the January 28, 2005 offering, we also issued to the placement agent Series B Stock in an aggregate amount equal to 5% of the amount of cash proceeds from the private placement, together with accompanying warrants to purchase our Common Stock. We also issued to the placement agent warrants to purchase 737,712 shares of our Common Stock. As of March 31, 2006, there were 1,529,750 options issued and outstanding under the stock option plan and 1,470,250 options available for issuance under the stock option plan. As a result, the conversion of the outstanding preferred stock and the exercise of the outstanding warrants and options will result in substantial dilution to the holders of our Common Stock.

On March 30, 2006, we issued to an investor 20 shares (face amount \$1,000,000) of the Company's series B preferred stock with warrants to purchase a total of 1,557,377 shares of our Common Stock at an exercise price of \$0.61 per share for a period of five years. We 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 our achievement, as of the fourth fiscal quarter of 2005, certain financial milestones. As compensation for services rendered to the Company by Midtown Partners & Co., LLC for the second closing, we agreed to issue to Midtown two shares (face amount \$100,000) of our Series B Preferred Stock and warrants to purchase a total of 155,738 shares of our 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.

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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 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 we 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 March 31, 2007, our named executive officers, directors and 5% stockholders beneficially owned approximately 21.49% of our voting power. For the foreseeable future, to the extent that our current stockholders vote similarly, they will be able to exercise control over many matters requiring approval by the board of directors or our stockholders. As a result, they will be able to:

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

**USE OF PROCEEDS**

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

**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 stock 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 and 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.

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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.

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.

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 to an investor 20 shares of its series B preferred stock. In connection with this issuance, the Company also issued to 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 the Company's common stock issuable upon the exercise of the warrants that it holds. In addition, as compensation for services rendered to the Company for the private placement of these series B preferred shares, the Company issued to 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 \$.61 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 \$8,250,000, including \$7,550,286 in cash and \$699,714 purchased through debt conversion at a previously agreed 12.5% discount to the price paid by other investors 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 pursuant to a required time schedule, 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.

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

<b>Selling security holders (C)</b>	<b>Number of Shares of Common Stock Owned Before Offering (A)</b>	<b>Number of Shares to be Offered (B)</b>	<b>Number of Shares Owned After Offering</b>	<b>Percentage of Shares of Common Stock Owned After Offering</b>
Alpha Capital AG <sup>1</sup>	2,057,539	746,875	1,310,664	10.73%
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	327,721	252,923	74,798	0.00%
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	46.93%
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	0.00%
Iroquois Master Fund, Ltd.	40,000	40,000	-	0.00%
Jordan, Bruce <sup>3</sup>	107,006	35,092	71,914	0.47%
Kreger, Richard H. <sup>3</sup>	650,821	165,160	485,661	2.80%
Longview Fund, LP	781,250	781,250	-	0.00%
Midtown Partners & Co., LLC <sup>4</sup>	203,402	73,309	130,093	1.23%
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	2.25%
<b>TOTALS</b>	<b>30,339,589</b>	<b>13,176,132</b>	<b>17,163,457</b>	

(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.

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

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## PLAN OF DISTRIBUTION

The Shares covered by this Prospectus are being registered by us for the account of the Selling Stockholders.

The Shares offered by this Prospectus may be sold from time to time directly by or on behalf of the Selling Stockholders in one or more transactions on the OTC Bulletin Board or on any stock exchange on which the Common Stock may be listed at the time of sale, in privately negotiated transactions, or through a combination of these methods. The Selling Stockholders may sell Shares through one or more agents, brokers or dealers or directly to purchasers. These brokers or dealers may receive compensation in the form of commissions, discounts or concessions from the Selling Stockholders and/or purchasers of the Shares, or both. Compensation as to a particular broker or dealer may be in excess of customary commissions. The Selling Stockholders will act independently of us in making decisions with respect to the timing, manner and size of each sale or non-sale related transfer. If a Selling Stockholder is an employee, officer or director of the Company, he or she will be subject to our policies concerning trading and other transactions in the Company's securities.

Each Selling Stockholder of the Shares and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their Shares 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 the 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. There is no assurance that the Selling Stockholders will sell all or a portion of the stock being offered hereby.

In connection with the sale of Shares, 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 Shares in the course of hedging the positions they assume. The Selling Stockholders may also sell the Shares short and deliver these Shares to close out short positions, or loan or pledge the Shares to broker-dealers or other financial institutions that in turn may sell these Shares. The Selling Stockholders may also enter into option or other transactions with broker-dealers or other financial institutions that require the delivery to the broker-dealer or other financial institution of the Shares, which the

broker-dealer or other financial institution may resell pursuant to this Prospectus, or enter into transactions in which a broker-dealer makes purchases as a principal for resale for its own account or through other types of transactions.

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In connection with the sales, a Selling Stockholder and any participating broker or dealer may be deemed to be “underwriters” within the meaning of the Securities Act, and any commissions they receive and the proceeds of any sale of Shares may be deemed to be underwriting discounts or commissions under the Securities Act. A Selling Stockholder who is deemed to be an “underwriter” within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act. The Selling Stockholders and any other person participating in such distribution will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including, without limitation, Regulation M. Regulation M may limit the timing of purchases and sales of shares of our Common Stock by the Selling Stockholders and any other person. Furthermore, Regulation M may restrict, for a period of up to five business days prior to the commencement of the distribution, the ability of any person engaged in a distribution of shares of our Common Stock to engage in market-making activities with respect to these shares. All of the foregoing may affect the marketability of shares of our Common Stock and the ability of any person or entity to engage in market-making activities with respect to shares of our Common Stock.

To the extent required, the Shares to be sold, the names of the persons selling the Shares, the respective purchase prices and public offering prices, the names of any agent, dealer or underwriter and any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement of which this Prospectus is a part.

We are bearing all of the fees and expenses relating to the registration of the Shares. Any underwriting discounts, commissions or other fees payable to broker-dealers or agents in connection with any sale of the Shares will be borne by the Selling Stockholders. In order to comply with certain states’ securities laws, if applicable, the Shares may be sold in such jurisdictions only through registered or licensed brokers or dealers. In certain states, the Shares may not be sold unless the Shares have been registered or qualified for sale in such state, or unless an exemption from registration or qualification is available and is obtained and complied with. Sales of the Shares must also be made by the Selling Stockholders in compliance with all other applicable state securities laws and regulations.

The Selling Stockholders may agree to indemnify any broker-dealer or agent that participates in transactions involving sales of the Shares against certain liabilities in connection with the offering of the Shares arising under the Securities Act.

We have notified the Selling Stockholders of the need to deliver a copy of this Prospectus in connection with any sale of the Shares.

## **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, PROMOTERS AND CONTROL PERSONS**

### **Directors and Executive Officers**

**Lawrence A. Siebert** (50), 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. Mr. Larkin holds a BBA in Accounting from Dowling College and is a member of the American Institute of Certified Public Accountants.

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**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 bioMérieux Inc. 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** (55), 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** (44), 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 (68), 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.

**SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

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 March 31, 2007.

<b>Name and Address of Beneficial Owner</b>	<b>Number of Shares Beneficially Owned</b>	<b>Percent of Class</b>
Lawrence Siebert <sup>(2)</sup> 3661 Horseblock Road Medford, NY 11763	2,141,919	17.68%
Javan Esfandiari <sup>(3)</sup> 3661 Horseblock Road Medford, NY 11763	229,580	1.92%
Richard J. Larkin <sup>(4)</sup> 3661 Horseblock Road Medford, NY 11763	145,261	1.22%
Alan Carus <sup>(5)</sup> 3661 Horseblock Road Medford, NY 11763	90,000	0.76%
Les Stutzman <sup>(1)</sup> 3661 Horseblock Road Medford, NY 11763	25,000	0.21%
Gary Meller <sup>(6)</sup> 3661 Horseblock Road	87,000	0.73%

Medford, NY 11763		
<b>All officers and directors as a group<sup>(7)</sup></b>	<b>2,718,760</b>	<b>21.49%</b>
Mark Baum <sup>(8)</sup> 580 Second Street, Suite 102 Encinitas, CA 92024	1,408,597	11.18%
Avi Pelosof <sup>(9)</sup> 3661 Horseblock Road Medford, NY 11763	650,113	5.41%

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

The beneficial ownership percent in the table is calculated with respect to the number of outstanding shares (11,754,015) of our common stock outstanding as of March 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 11,754,015 shares of common stock outstanding, our 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 our 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 our 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. 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 they can be exercised only upon 61 days prior notice and therefore are not exercisable within 60 days.
- (3) 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
- (4) 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 they can be exercised only upon 61 days prior notice and therefore are not exercisable within 60 days.
- (5) 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.
- (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 footnotes (1)-(6)
- (8) 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 they can be exercised only upon 61 days prior notice and therefore are not exercisable within 60 days.
- (9) Includes 300,000 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 they can be exercised only upon 61 days prior notice and therefore are not exercisable within 60 days. Mr. Pelosof voluntarily resigned from the Company on January 31, 2007.

## 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.

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## 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.

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.

## 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.

*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 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.

### **INTEREST OF NAMED EXPERTS AND COUNSEL**

The validity of the common stock covered by this Registration Statement has been passed upon for the Company 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.

### **DISCLOSURE OF COMMISSION POSITION ON 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.

### **CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

Mark L. Baum, our former president prior to the merger and a former director of the company, entered into a nine-month employment agreement with the Company, 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 the Company 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 2004 as payment of dividends on the series A preferred he received 4,333 shares of common stock. Prior to the merger, Mr. Baum was the sole director and officer of the Company. On March 18, 2005, as compensation for Mr. Baum's service on the board of directors of the Company, 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 December 31, 2006, \$65,287.39 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 one share of series B preferred stock convertible into 81,967 shares of common stock and a warrant to purchase 77,868 shares of common stock.

Mr. Siebert also invested \$18,700 in Chembio Diagnostic Systems Inc. pursuant to a private placement of convertible notes on March 22, 2004. Mr. Siebert converted the entire principal amount of the note that he received, together with accrued interest thereon, into .942 shares of 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 \$0.45 per share. These shares were gifted by Mr. Siebert to a third party. In May of 2005 as payment of dividends on the series A preferred he received 72,234 shares of common stock. In July of 2005 as payment of dividends on the series B preferred he received .03871 shares of series B preferred stock. In November of 2005 as payment of dividends on the series A preferred he received 77,488 shares of common stock. In January of 2006 as payment of dividends on the series B preferred he received .04674 shares of series B preferred 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 he 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 totaled \$182,181 and was repaid in the fourth quarter of 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 our 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 he received 1007 shares of common stock. In June of 2006 as payment of dividends on the series A preferred Mr. Larkin received 265 shares of common stock. In November of 2006 as payment of dividends on the series A preferred he received 726 shares of common stock.

Avi Pelossof, vice president of sales and marketing of the Company from May 5, 2004 to January 31, 2007, invested \$4,000 in the Company pursuant to the March 22, 2004 private placement of convertible notes. Mr. Pelossof 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 of 2006 as payment of dividends on the series A preferred he received 403 shares of common stock. In June of 2006 as payment of dividends on the series A preferred Mr. Pelossof received 106 shares of common stock. In November of 2006 as payment of dividends on the series A preferred he received 290 shares of common stock.

In addition, Mr. Pelosof exercised 100,000 options in December 2006 at \$.60 per share, and another 50,000 options in January 2007 at \$.75 per share.

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 our 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 a registration statement that the Company filed in January 2007, Crestview agreed to reduce the number of its shares of common stock covered by the January 2007 registration statement to 2,000,000. Crestview also agreed to waive any penalties that we would otherwise owe Crestview because of the failure to register all of Crestview's shares in that registration statement. In return, we agreed that, upon request by Crestview, we 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 us.

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 to approve the funding, the motion was approved unanimously, with the exception of Gerald Eppner<sup>1</sup> who abstained. Mr. Eppner stated that he understood the benefits of the economics of the transaction and our need to proceed 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 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.

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<sup>1</sup> Mr. Eppner resigned from the board of directors on January 30, 2007.

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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 Dr. 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 of directors. 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 a registration statement that was to be filed shortly thereafter.

### **Director Independence**

Our common stock trades on the OTC Bulletin Board. As such, we are not currently subject to corporate governance standards of listed companies, which require, among other things, that the majority of the board of directors be independent.

Since we are not currently subject to corporate governance standards relating to the independence of our directors, we choose to define an "independent" director in accordance with the NASDAQ Global Market's requirements for independent directors (NASDAQ Marketplace Rule 4200). We do not currently have an independent director under the above definition. We do not list that definition on our Internet website.

## **DESCRIPTION OF BUSINESS**

### **General**

Chembio Diagnostics, Inc. (the "Company", "We", "Our", or "Us") and our subsidiaries develop, manufacture and market rapid diagnostic tests that detect infectious diseases. Our main products presently commercially available are three rapid tests for the detection of HIV antibodies in whole blood, serum and plasma samples, two of which were approved by the FDA last year. These products employ single path lateral flow technology which we have licensed from Inverness Medical Innovations, Inc. ("Inverness"), who is also our exclusive marketing partner for those two products in the United States under its Clearview® brand. Inverness launched its marketing of these products in the United States in February 2007. Chembio's two HIV STAT-PAK® rapid HIV tests are marketed outside the United States through different partners and channels under license from Inverness. We also have a rapid test for Chagas disease (a parasitic disease endemic in Latin America) as well as a line of rapid tests for tuberculosis, including tests for tuberculosis in animals for which USDA approval is pending.

On March 13, 2007, we were issued United States patent #7,189,522 for our Dual Path Platform (DPP™) rapid test system. We believe that as a result of the patent protection we now have with DPP™, we have a significant opportunity to develop and license many new rapid tests in a number of fields including but not limited to infectious diseases. We have already completed initial development on some products in this new platform. We believe the DPP™ provides significant advantages over standard single path lateral flow assays, and are developing most of our new products using this platform.

Our products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments. Our products are sold either under

our STAT-PAK® or SURE CHECK® registered trademarks and/or the private labels of our marketing partners, such as is the case with the Inverness Clearview® label.

### **Rapid HIV Tests**

A major component of our revenue growth in 2006 was 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 that 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 testing, as the stigma associated with the disease is lessened and the ability to resume normal activities is substantially improved.

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All three of our rapid HIV tests are qualitative “yes/no” tests for the detection of antibodies to HIV 1 & 2 with results available within approximately 15 minutes. The tests differ only in the method of sample collection and test procedure, flexibility with different sample types, and cost of manufacture. Our rapid HIV tests have been marketed under our SURE CHECK® and STAT-PAK® trademarks. Pursuant to our agreement with Inverness Medical Innovations, Inc., the SURE CHECK® product is now being marketed globally (with limited exceptions) by Inverness as Clearview® Complete HIV 1/2 and the cassette format of our STAT-PAK (we also have a third product known as HIV 1/2 STAT-PAK dipstick) is now being marketed by Inverness in the United States as Clearview HIV 1/2 STAT-PAK®. We continue to market our STAT-PAK® cassette and dipstick outside the United States through other marketing channels.

### **Regulatory Status:**

#### **Rapid HIV Tests**

The FDA approved our Pre-Market Applications for our SURE CHECK HIV 1/2 (now Inverness’ Clearview® Complete HIV 1-2 and HIV 1/2 STAT-PAK (now Inverness’ Clearview HIV 1/2 STAT-PAK) products on May 25, 2006. A Clinical Laboratory Improvement Act (“CLIA”) waiver was granted by the FDA for the HIV 1/2 STAT-PAK on November 20, 2006. Labeling changes to the Inverness Clearview® brands for both products were approved during the first quarter of 2007. CLIA waiver is still pending for the Clearview Complete HIV 1-2; accordingly this product is presently only available as a non-waived product. CLIA waiver is required in order to market the products in public health clinics and physicians’ offices where the level of training is traditionally less than the training at clinical laboratories and hospitals. Public health clinics and physicians’ offices now constitute the largest portion of the available market for our products. We were advised by the FDA in February 2007 that additional user studies will be required in order to obtain CLIA waiver for the Clearview Complete HIV 1/2, and this work is in progress. We believe that we will be able to receive a CLIA waiver for this product during 2007.

Our third rapid HIV test, HIV 1/2 STAT-PAK *Dipstick*, though not FDA approved, qualifies under FDA export regulations to sell, subject to any required approval by the importing country, to customers outside the United States. The dipstick product is our most competitively priced version of our three rapid HIV tests, and was designed primarily for resource-constrained, donor-funded markets that have large test volume needs.

Although we have received approval from a number of potential importing countries for all three of our HIV tests, Brazil, Mexico, Nigeria and Uganda are the only countries in which we have realized significant sales. As a result of favorable evaluations of our HIV 1/2 STAT-PAK and HIV 1/2 STAT-PAK Dipstick products by the World Health Organization (the “WHO”), these products are qualified 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:**

On September 29, 2006 we executed marketing and license agreements with Inverness. These agreements not only provide for the marketing of our rapid HIV tests in the United States, but also grant us a license to Inverness’ single path lateral flow patents that may be applicable to our other products, including those that we had under development at the time of the grant. As part of these agreements we settled litigation that had been ongoing with another company, StatSure Diagnostics, Inc., relating to the barrel device that is incorporated into our Sure Check® (now Inverness Clearview Complete) HIV 1/2 product.

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



In September 2005 we were designated as the confirmatory test in Uganda's national rapid testing protocol, and through the offices we have established in East Africa and Nigeria, 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. We have identified and/or appointed distributors in several countries in Africa (Kenya, Mozambique, South Africa, and others) so that we will be positioned to service those markets if we are selected in their national testing protocols. Our focus is on those African countries that are receiving funding from PEPFAR and other large relief programs.

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

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In November 2006, we received an order for 990,000 units of our Sure Check product from our distributor in Mexico, a division of Bio-Rad Laboratories, Inc. This distribution agreement is the one exception to our otherwise global exclusive agreement with Inverness as it relates to this product. Approximately half of this order was shipped during the fourth quarter of 2006 and the balance has been shipped during the first quarter of 2007. Absent other arrangements, this exception to Inverness' global exclusivity will be eliminated on September 29, 2007.

We are establishing distributors in a number of other markets where we believe there is or will be a significant market opportunity for our products.

### **CHAGAS RAPID TEST**

We have 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. Although the Chagas disease is endemic only in regions of Latin America there are an estimated 16-18 million existing Chagas disease cases, resulting in approximately 20,000 deaths annually, and an estimated 300,000 new cases each year. Chagas disease is transmitted by a parasitic bug which lives in cracks and crevices of poor-quality houses usually in rural areas, through blood transfusions or congenitally from infected mother to fetus. There is an effective therapy available to treat the early chronic phase, but this therapy only eliminates the infection if it is administered to children that are diagnosed with the disease. Our Chagas STAT-PAK product is the only rapid test for Chagas disease which has performed well in multi-center studies in endemic regions of Latin America.

In January 2006, we received a \$1.2 million order from the Pan American Health Organization to supply our Chagas disease rapid tests for a screening program in Bolivia. These tests were delivered in the first three quarters of 2006. The Pan American Health Organization, headquartered in Washington D.C., is affiliated with the World Health Organization, and that procurement was used to implement a nationwide Chagas screening program for all children under the age of 10 in endemic regions of Bolivia. We are 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 United States, Europe, Canada and Central America. However, as a result of pricing pressures, regulatory changes and potential patent litigation in this field, and in order to focus our efforts on rapid HIV tests we sold substantially all of the business related to our private label pregnancy tests. 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 revenues. We also have other commercially available products, such as rapid tests for Lyme disease and other products, whose aggregate revenues are currently not material to us. We also are involved in the development of new products, as described below under "Research and Development".

### **Lateral Flow Technology**

All our current products employ single path 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, whether single or dual path, allows the development of accurate, 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 micro liters 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. 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. The sensitivity and specificity of our rapid HIV tests during our clinical trials undertaken in connection with our FDA Pre-Marketing Applications were 99.7% and 99.9%, respectively.

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We can develop and produce lateral flow tests that are qualitative (reactive/non-reactive), as in the case of our HIV tests, and we can develop semi-quantitative tests, reflecting different concentrations of the target marker(s) using different colored latex test lines for each concentration. We can also develop tests for multiple conditions, using different colored lines. We have developed proprietary techniques that enable us to achieve high levels of sensitivity and specificity [see definition above] 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 rapid HIV test which 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.

On March 13, 2007, we were issued United States patent number #7,189,522 describing a Dual Path Immunoassay system which we believe provides several advantages over standard single path lateral flow test systems (See “Intellectual Property”). We believe that this system, which we refer to as DPP™ (for Dual Path Platform), provides us with significant new product development and licensing opportunities.

## **Target Market**

### **Rapid HIV 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. We are presently one of only two United States-based manufacturers of rapid HIV tests; and we believe that we are the only one with products that 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 over the next three years in order to insure that treatment targets are achieved<sup>1</sup>. In addition, a confirmatory test is needed in the case of a positive result. This is a result of the continuing growth in the epidemic and 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>2</sup> and the United States Presidential Emergency Plan for AIDS Relief (“PEPFAR”). PEPFAR alone has a goal to provide treatment to two million people in order to identify these two million people; rapid testing is being implemented on a very large scale. The United States is the largest donor, by far, to these programs. Each of these programs recognizes that a massive scale-up in the use of rapid HIV tests is the only way their treatment goals can hope to be achieved.

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. According to the UNAIDS 2006 Update Report, as of the end of 2006, there were an estimated nearly 40 million people infected with HIV/AIDS worldwide, of which an estimated 6 million were in need of antiretroviral therapy. There were nearly 4.3 million new infections and 2.9 million AIDS-related deaths in 2006. The number of people in need of treatment will continue to grow as expected infection rates increase significantly worldwide, and there is little expectation for an effective vaccine anytime soon. 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>1</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>2</sup> [www.theglobalfund.org/en](http://www.theglobalfund.org/en)

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The marketing of our FDA-approved rapid HIV tests in the United States was just launched by Inverness during the first quarter of 2007. In the United States the need for rapid HIV tests 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 United States Centers for Disease Control (“CDC”) in September 2006, we expect the United States 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 the CDC recommendations were published, the United States rapid HIV test market was estimated to become at least a \$50 million market during the next few years. The market may grow much faster and larger however as a result of these two developments.

The non-exclusive licenses we received from Inverness to their lateral flow patents to market our two HIV 1/2 STAT-PAK products outside the United States enable us to further expand our international marketing efforts beyond developing countries. In addition to our efforts in Africa, we have distribution initiatives underway in new markets in Latin America, Europe, and Asia. Registration and regulatory requirements for these markets vary widely.

### **Chagas Rapid Test**

We had developed a Chagas rapid test several years ago, but the market for the product was not meaningful, as most prevention efforts, were minimal and were made using laboratory tests used for blood bank screening of blood. However, there is now a greater interest in our Chagas 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 better than those with latent and recurring infections afflicting those beyond early ages.

### **Other Products Under Development**

We are 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 test for TB as there is for HIV. If successful, our TB product development efforts will leverage the marketing and distribution capability which we have been using for our HIV products. We had our 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 our 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 with different and/or additional patented antigens that we have identified and that we would license in order to produce higher sensitivity levels, particularly in HIV-TB co-infected patients. Given the variations both in TB strains and latency presented in different geographic regions, there are questions as to what the performance standards should be and whether certain tests may in fact be appropriate for use only in certain regions.

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

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 prohibitions, have recently occurred in Minnesota, Texas, New Mexico and Michigan. TB control of meat at slaughterhouses is dependent upon visual inspection. We believe that a more accurate and rapid test could conceivably complement or supplant these visual inspections.

We have already completed development of a rapid lateral-flow test for the detection of TB in Non-Human Primates (PrimaTB STAT-PAK™), and we have 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 room temperature (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.

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We amended the product license application to the USDA for approval of our 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. Clinical trials to validate reproducibility were successfully completed in December of 2006. At the same time, we have been working toward the establishment license with the USDA, which is required along with the first product license requiring an inspection by USDA officials. The inspection of our facility and quality system was completed on February 27, 2007. We anticipate approval of the Prima TB STAT-PAK during the second quarter of 2007.

The next USDA submissions will be for ElephantTB STAT-PAK and CervidTB STAT-PAK.

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

Our marketing strategy is to:

- Support, review and assess the marketing and distribution efforts of our rapid HIV tests by Inverness Medical Innovations, Inc. Inverness and Chembio's marketing and regulatory teams have been working together since October 2006 after we signed the agreements and we are very encouraged by the commitment they are making to maximize the success of these products in the United States market. We believe that their highly professional cadre of technical field support staff together with the strong distribution partners they support in the hospital, public health and physician office markets will combine to provide a marketing organization that will be a key asset.
- Expand our international sales effort and strategic partnerships in the developed and 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 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 several other markets. These efforts will most likely include obtaining CE Marks for our rapid HIV tests. In order to achieve this we will need to become ISO 13.485 certified, which we expect to complete during the second quarter of 2007.
- Pursue potential over-the-counter marketing opportunities in the United States and internationally for our HIV tests. We will analyze whether to focus our efforts for this market on an oral fluid HIV test product, which we are currently developing with our DPP™ technology.
- Launch our initial veterinary TB product, PrimaTB 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 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 our business strategy.

**Inverness Medical Innovations, Inc.** - As described in more detail below in Management's Discussion and Analysis, on September 29, 2006, we executed several agreements by and among the Company, Inverness Medical Innovations, Inc. and StatSure Diagnostic Systems, Inc. Pursuant to these agreements, Inverness became our marketing partner for our two FDA approved rapid HIV tests in the United States and for one of the products in the non-United States markets. We are the exclusive manufacturer of the products. The marketing of the products in the US was begun by Inverness in February 2007. The agreements contain margin sharing formulae that are designed to provide Inverness and Chembio with reasonable profit margins after deduction for certain costs of the products.



**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 United States-based manufacturer) to be recommended by CHAI for sales of rapid HIV tests. While CHAI is not a procurer of the tests per se, it is a major factor in influencing which tests are to be procured. CHAI also has major agreements with generic HIV ARV manufacturers and manufacturers of viral load and CD-4 monitoring diagnostic tests, and those agreements have been very successful models.

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**Brazilian Ministry of Health** - We are committed to securing alliances and technology-transfer agreements with government agencies and commercial entities. For example, we 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 the initial three-year period which has just now been completed, we were to transfer our proprietary technology related to HIV 1/2 STAT-PAK to Bio-Manguinhos in exchange for commitments to purchase at least one million rapid tests. The purchase commitment has been met, though we expect additional procurements prior to the completion of the technology transfer agreement, currently anticipated to occur in 2007. Thereafter, Bio-Manguinhos will have the right to produce its own rapid tests and we 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 has been instrumental in our obtaining the collaborations we have and that we continue to pursue. Our patent protection that we now have with our Dual Path Platform™ should enhance our ability to develop collaborative relationships and to license out the technology.

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 a rapid test for 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. 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 now have our Dual Path Platform (DPP™) patent. This access should continue to improve as we grow our revenues, obtain additional regulatory approvals, and as new development and licensing opportunities ensue for DPP™ (See Management's Discussion and Analysis of Financial Condition and Results Of Operations - Overview).

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 compete effectively for the same individuals to the extent that a competitor uses its substantial resources to attract any such individuals.

We have been able to obtain patent protection by entering into licensing arrangements for reagents and lateral flow technologies. The very recent issuance, in March 2007, by the United States Patent & Trademark Office of our Dual Path Platform patent gives us our first patent protection on a rapid test platform, which we believe enhances our competitive position.

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Competitive factors specifically related to our HIV tests are product quality, price and ease of use as well as distribution. Product quality for a rapid HIV 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 distribution model positions us to compete effectively and win a meaningful share of this expanding market.

The leading products in the international rapid HIV test market are UniGold®, produced by Trinity Biotech in Ireland, and Determine®, produced by Inverness in Tokyo. Until June 2005, the Determine business was owned by Abbot Diagnostics (Abbott) before it was sold to Inverness. In connection with this transaction, Abbott retained the distribution rights to the Determine product for 32 months. The Determine and UniGold products are the market leaders 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 three other 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 United States, our competitors are Orasure Technologies with OraQuick®, and Trinity with its UniGold® 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 one of those submissions are made, (or in any case if Inverness markets a competitive product in the United States), we have the right to terminate our agreement with Inverness or make Inverness' 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 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 successfully building its brand and market share in the United States market. Its non-United States sales of its 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 United States. Its main advantage is the fact that its test can be used with oral fluid samples, though its FDA approved sensitivity is 99.3% with these samples. OraQuick is not approved for use with serum samples which may limit its marketability in certain settings.

The shelf life of our HIV products' 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 products are extremely convenient and easier to use than OraQuick on finger-stick whole blood samples.

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 has actually done a technology transfer such as what we have done in Brazil 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 we are 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). All of our new product development activities involve employment of our Dual Path Platform technology for which we were recently awarded a patent. We believe that this platform enables us to pursue many new product development and licensing opportunities, and we are currently developing a strategy for doing this. Several studies that we have completed in-house in 2007 further confirm that this platform can provide improved features that include higher sensitivity, earlier detection, use of multiple sample types including oral fluid, and improved ability to detect multiple analytes in one test device. Our studies thus far have primarily been based upon serological, antibody detection tests for infectious diseases. We are beginning to now conduct studies to establish whether these same or other advantages can be realized in the detection of antigens.

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## **HIV**

We have completed initial design of an oral fluid HIV antibody detection test on our Dual Path Platform in accordance with our agreement with Inverness, and Inverness has notified us that it would like to enter into negotiations concerning marketing rights to this product as provided in our agreement. In February we commenced the ninety day negotiation period for this marketing opportunity as provided in our agreement. We are considering developing other specialty products for HIV that would incorporate DPP™ and that would be developed in collaboration with contract partners, such as an HIV confirmatory test.

## **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 serology 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 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, PrimaTB STAT-PAK, for detecting active pulmonary tuberculosis in non-human primates (monkeys). 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.

## **Syphilis**

In November 2006, we entered into a Cooperative Research & Development agreement with the CDC pursuant to which we hope to complete development of a multi-analyte test on our Dual Path Platform that could be used as a screen and confirmatory test within the same device. The CDC is providing access to its own patented reagents, sera samples and expertise as part of this agreement.

During 2006 and 2005, \$1,401,473 and \$1,364,898, respectively, was spent on research and development activities. A significant portion of these expenditures have been on our HIV and human and non-human primate tuberculosis product development and related regulatory approval efforts.

## **Employees**

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

## **Governmental Regulation**

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

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

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

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

The Clinical Laboratory Improvement Act of 1988 ("CLIA") prohibits laboratories from performing in vitro tests for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of, the health of human beings unless there is in effect for such laboratories a certificate issued by the United States Department of Health and Human Services (via the FDA) applicable to the category of examination or procedure performed. Although a certificate is not required for the Company, we consider the applicability of the requirements of CLIA in the design and development of our 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 our products and this is in fact critical to the marketability of a product into the point of care diagnostics market.

In addition, the FDA regulates the export of medical devices that have not been approved for marketing in the United States. The Federal Food, Drug and Cosmetic Act contains general requirements for any medical device that may not be sold in the United States and is intended for export. Specifically, a medical device intended for export is not deemed to be adulterated or misbranded if the product: (1) complies with the specifications of the foreign purchaser; (2) is not in conflict with the laws of the country to which it is intended for export; (3) is prominently labeled on the outside of the shipping package that it is intended for export; and (4) is not sold or offered for sale in the United States. Some medical devices face additional statutory requirements before they can be exported. If an unapproved device does not comply with an applicable performance standard or pre-market approval requirement, is exempt from either such requirement because it is an investigational device, or is a banned device, the device may be deemed to be



adulterated or misbranded unless the FDA has determined that exportation of the device is not contrary to the public health and safety and has the approval of the country to which it is intended for export. However, the Federal Food, Drug and Cosmetic Act does permit the export of devices to any country in the world, if the device complies with the laws of the importing country and has valid marketing authorization in one of several “listed” countries under the theory that these listed countries have sophisticated mechanisms for the review of medical devices for safety and effectiveness.

We are 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 United States 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 the Company that might arise from future legislative or administrative action cannot be predicted.

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Prior to receiving FDA approval, our rapid HIV 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. We completed clinical trials for the SURE CHECK HIV (now also known as Inverness/Clearview Complete HIV 1/2) and HIV 1/2 STAT-PAK (now marketed in the United States as Clearview 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. Our pre-market application was approved by the FDA on May 25, 2006, and we filed our CLIA waivers in July, 2006. A CLIA waiver was granted by the FDA for HIV 1/2 STAT-PAK on November 20, 2006. We also have our first veterinary tuberculosis rapid test under review by the USDA, and had our facility inspected by this agency on February 27, 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 to: (1) build our owned intellectual property portfolio around our Dual Path Platform technology; (2) pursue licenses, trade secrets and know-how within the area of lateral flow technology; and (3) 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. We possess know-how to develop tests for multiple conditions using colored latex which is proprietary. Our buffer formulations enable extremely long shelf lives of our rapid HIV tests and we believe that this provides us with an important competitive advantage.

### *Lateral Flow Technology and Reagent Licenses*

Prior to the issuance of our United States patent covering our Dual Path Platform (DPP™), we owned no issued patents covering lateral flow technology. Therefore we obtained non-exclusive licenses from Inverness Medical Innovations, Inc. and Abbott Laboratories with respect to their portfolios of single path lateral flow patents. Although we believe our DPP™ is outside of the scope of other lateral flow patents that we are aware of, we consult with patent counsel, and seek licenses and/or redesigns of products that we believe to be in our best interests and those of our stockholders. Because of the costs and other negative consequences of time-consuming patent litigation, we often attempt to obtain a license on reasonable terms. Nevertheless there is no assurance that Abbott's and/or Inverness' lateral flow patents will not be challenged or that other patents containing claims relevant to our 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 the applicable product such that a license would not be necessary. However, this alternative could delay or limit our ability to sell these products in the United States and/or other markets, which would adversely affect our results of operations, cash flows and business.

The DPP™ technology provides improved sensitivity as compared with conventional platforms in a number of

preliminary studies using well characterized HIV, Tuberculosis and other samples. We anticipate signing new development projects based upon these new technologies in the near future that will provide new product applications and marketing opportunities. We have also filed patent applications relating to our veterinary tuberculosis rapid tests and improvements to the sample collection method in our "barrel" (SURE CHECK) device which is one of the formats which Inverness is marketing. On March 20, 2007 we were issued United States Patent #7,192,721 which covers the method and use of a specific combination of antigens on a lateral flow test for the detection of antibodies to tuberculosis in multiple non-primate animal species.

The peptides used in our rapid HIV 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 to reduce the royalty rate. 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 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 beginning in 1995, for a number of diseases and for pregnancy.

## The Merger

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

## Glossary

AIDS	Acquired Immunodeficiency Syndrome. AIDS is caused by the Human Immunodeficiency Virus, HIV.
ANTIBODY	A protein which is a natural part of the human immune system produced by specialized cells to neutralize antigens, including viruses and bacteria that invade the body. Each antibody producing cell manufactures a unique antibody that is directed against, binds to and eliminates one, and only one, specific type of antigen.
ANTIGEN	Any substance which, upon entering the body, stimulates the immune system leading to the formation of antibodies. Among the more common antigens are bacteria, pollens, toxins, and viruses.
ARVs	Anti-Retroviral Treatments for AIDS
CD-4	The CD4+ T-lymphocyte is the primary target for HIV infection because of the affinity of the virus for the CD4 surface marker. Measures of CD4+ T-lymphocytes are used to guide clinical and therapeutic management of HIV-infected persons.
CDC	United States 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	United States Food and Drug Administration
FDIC	Federal Deposit Insurance Corporation
HIV	Human Immunodeficiency Virus. HIV (also called HIV-1), a retrovirus, causes AIDS. A similar retrovirus, HIV-2, causes a variant disease, sometimes referred to as West African AIDS. HIV infection leads to the destruction of the immune system.
IgG	IgG or Immunoglobulin are proteins found in human blood. This protein is called an “antibody” and is an important part of the body’s defense against disease. When the body is attacked by harmful bacteria or viruses, antibodies help fight these invaders.
MOH	Ministry of Health
MOU	Memoranda of Understanding
NGO	Non-Governmental Organization
OTC	Over-the-Counter
PEPFAR	The President’s Emergency Plan for AIDS Relief
PMA	Pre-Marketing Approval
PROTOCOL	A procedure pursuant to which an immunodiagnostic test is performed on a particular specimen in order to obtain the desired reaction.
REAGENT	A chemical added to a sample under investigation in order to cause a chemical or biological reaction which will enable measurement or identification of a target substance.
RETROVIRUS	A type of virus which contains the enzyme Reverse Transcriptase and is capable of transforming infected cells to produce diseases in the host such as AIDS.
Ryan White CARE Act	The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act is Federal legislation that addresses the unmet health needs of persons living with HIV disease by funding primary health care and support services. The CARE Act was named after Ryan White, an Indiana teenager whose courageous struggle with HIV/AIDS and against AIDS-related discrimination helped educate the nation.
SAB	Staff Accounting Bulletin
SENSITIVITY	Refers to the ability of an assay to detect and measure small quantities of a substance of interest. The greater the sensitivity, the smaller the quantity of the substance of interest the assay can detect. Also refers to the likelihood of detecting the antigen when present.
SFAS	Statement of Financial Accounting Standards
SPECIFICITY	The ability of an assay to distinguish between similar materials. The greater the specificity, the better an assay is at identifying a substance in the presence of substances of similar makeup.
SPUTUM	Expectorated matter; saliva mixed with discharges from the respiratory passages
TB	Tuberculosis (TB) is a disease caused by bacteria called Mycobacterium tuberculosis. The bacteria usually attack the lungs. But, TB bacteria can attack any part of the body such as the kidney, spine, and brain. If not treated properly, TB disease can be fatal. TB is spread through the air from one person to another. The bacteria are

put into the air when a person with active TB disease of the lungs or throat coughs or sneezes. People nearby may breathe in these bacteria and become infected.

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

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

In addition, certain statements made in this report may constitute "forward-looking statements". These forward-looking statements involve known or unknown risks, uncertainties and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Specifically, 1) our ability to obtain necessary regulatory approvals for our products; and 2) our ability to increase revenues and operating income, is dependent upon our ability to develop and sell our products, general economic conditions, and other factors. You can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "intends," "plans," "anticipates," "believes," "estimate," "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 rapid diagnostic tests that detect infectious diseases. Our main products presently commercially available are three rapid tests for the detection of HIV antibodies in whole blood, serum and plasma samples, two of which were approved by the FDA in 2006; the third is sold for export only. These products all employ single path lateral flow technology. We also have a rapid test for Chagas disease (a parasitic disease endemic in Latin America) as well as a line of rapid tests for tuberculosis, including tests for tuberculosis in animals for which USDA approval is pending. Our products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments. Our products are sold either under our STAT PAK® or SURE CHECK ® registered trademarks or the private labels of our marketing partners, such as is the case with the Clearview® label owned by Inverness Medical Innovations, Inc., which is our exclusive marketing partner for our rapid HIV test products in the United States.

### Recent Events

On March 30, 2006, we 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, we received approval of our Pre-Market Applications ("PMAs") from the FDA for our SURE CHECK(R) HIV 1/2 and HIV 1/2 STAT-PAK(TM) rapid tests. The approved PMAs allow us to market our rapid HIV tests to clinical laboratories and hospitals in the United States. FDA approval also allows us to further expand our

international marketing efforts into countries that require regulatory approval in the manufacturer's country of domicile. New labeling for these products to be sold under the Inverness Clearview labels were submitted and approved by the FDA during the first quarter of 2007, thereby allowing Inverness to begin marketing these products in the United States, which has also occurred during the first quarter of 2007.



On June 29, 2006, we borrowed \$1,300,000 from a group of four institutional investors as a bridge financing arrangement. The loan was repaid in part on September 29, 2006 and the balance converted on October 5, 2006 into Series C Preferred Stock. The loan was secured by a lien on our assets.

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

## **RESULTS OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2006 AS COMPARED WITH THE YEAR ENDED DECEMBER 31, 2005**

### **Revenues:**

Revenues are comprised of \$6.294 million in net product sales and \$.208 million in grants and development income for the year ended December 31, 2006 as compared with \$3.360 million in net product sales, \$.250 million in license revenue and \$.331 million in grants and development income for the year ended December 31, 2005. The increase in net product sales is attributable to increased sales of our HIV product of \$2.034 million and of our Chagas product of \$1.147 million which were partially offset by decreased sales of our pregnancy test kit of \$.116 million and decreases in other product sales aggregating \$.131 million. The decrease in license revenue of \$.250 million was due to a technology transfer agreement that occurred in 2005 and was not recurring. The decrease in grant and development income of \$.123 million was due to grants received in 2005 that weren't continued or awarded in 2006. We are expecting new grants for 2007 that will maintain 2006 levels.

Net product sales for 2006 increased 87% compared to 2005. HIV net product sales increased 85% in 2006 compared to 2005. We believe that sales of our HIV products will continue to increase in 2007 both as a result of the international marketing strategies that were implemented in 2006 and from the sales through our marketing partner Inverness Medical to the United States market as a result of approval from the United States Food and Drug Administration (FDA). We also received our first significant order for our Chagas test (Chagas is a disease which is primarily found in Latin America), in the amount of \$1.2 million which it shipped in 2006, a \$1.1 million dollar increase over 2005. These sales are not expected to continue at this level in 2007.

Net product sales for the three months ended December 31, 2006 increased 93% to \$2.624 million compared to the same period in 2005. HIV product sales increased 101% to \$2.464 million for the three months ended December 31, 2006 compared to the same period in 2005.

### **Gross Margin:**

Gross margin on net product sales for the year ended December 31, 2006 was 28.7%, as compared to 22.3% for the year ended December 31, 2005. 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.

The gross margin on net product sales for the three months ended December 31, 2006 declined to 32.2% from 38.1% in the comparable 2005 period. This was due in part to the incremental costs of producing a large 990,000 unit order for the HIV barrel product for Mexico, more than half of which was shipped during the fourth quarter of 2006. Incremental costs included increased labor costs due to a second shift and overtime, increased overhead costs for factory supervision, and increased material costs related to acceptance of test components manufactured in-house as well as those purchased from third parties. In addition, product mix also contributed to the decline in gross margin percentage for the fourth quarter of 2006 as compared with the fourth quarter of 2005.

### **Research and Development:**

Research and development expenses for the year ended December 31, 2006 were \$1,402,000 compared with \$1,365,000 for the year ended December 31, 2005. This category includes costs incurred for regulatory approvals, product evaluations and registrations. Expenses for Clinical & Regulatory Affairs, totaled \$323,000 for the year ended December 31, 2006, a decrease of \$88,000 compared to the year ended December 31, 2005. This category also

includes costs for clinical studies which decreased by \$78,000 and a reduction in outside regulatory consultants of \$28,000 in 2006 compared to 2005, which were partially offset by an increase in salaries of \$14,000. The costs related to the clinical trials and consulting in 2005 were related to the evaluation of our HIV tests in preparation and follow up of our FDA Pre-Marketing Approval (“PMA”) application submitted in February of 2005. Expenses other than Clinical & Regulatory increased \$124,000 in 2006 compared to 2005 and were related to increased salaries and wage-related costs of \$107,000 for new hires and bonuses in the R&D group, and for increases in employee benefits (including stock option expenses per SFAS No. 123R “Share-Based Payment” (“SFAS 123R”)) 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) of \$40,000, increase in temporary labor of \$34,000 offset by a decrease in travel and entertainment of \$14,000, and decreased grant payments to a university of \$54,000.

Subject to cash availability, we currently plan to increase our spending on research and development in 2007 because we believe such spending will result in the development of new and innovative products that are based on the DPP™ technology.

We have 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**

We have filed an application with the United States Department of Agriculture (USDA) to license our rapid assay, PrimaTB STAT-PAK™. A final set of clinical reproducibility trials was successfully completed during the fourth quarter of 2006 and the facility inspection, which is the final step to USDA licensure, has been completed. Subject to a satisfactory outcome of the facility inspection, we anticipate that commercialization will begin in the second quarter of 2007, though there is no assurance that this commercialization will successfully occur.

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

We have completed development and are 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™. We anticipate 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 this commercialization will be successful.

**Dual Path Platform (DPP™)**

During the fourth quarter of 2006 and 2007 year-to-date, significant additional progress was made in developing prototypes of the Dual Path Platform, including a new HIV test in this format and incorporating an oral fluid collection system that would be used with this DPP HIV product. Generally, we have already seen a great amount of interest in this platform as a result of our initial business development efforts for collaborative and licensing opportunities for this technology; this interest existed prior to the issuance of the DPP™ patent because it represents a way to participate in the lateral flow rapid test market that may not have been otherwise available to certain companies and because of its performance features, which we are increasingly able to demonstrate. Now that the patent has been issued, we intend to more vigorously pursue discussions with several parties and also develop a strategic plan for the long term development of this technology. We believe we can extend this technology to many applications not only within the infectious disease field, but to many other fields as well.

**Selling, General and Administrative Expense:**

Selling, general and administrative expense increased \$1,930,000 to \$5,195,000 in the year ended December 31, 2006 compared with 2005. This increase was attributable to increased staff and bonuses in the accounting, administration and sales and marketing departments of \$505,000, increase in employee stock option expenses (per SFAS 123R) of \$132,000 and a decrease relating to recruiting expenses of \$104,000. Increased sales resulted in an increase in royalties, advertising and related materials of \$48,000 and commissions of \$159,000 as well as increased consulting costs of \$109,000. In addition there was an increase of \$355,000 in costs regarding investor relations, and \$114,000 increased expenses related to our board of directors (includes option costs per 123R), increases in travel, entertainment and show expenses of \$126,000, increased depreciation expense (related to ERP system and leasehold improvements) of \$89,000, increase in other expenses of \$40,000 and increased legal and accounting expenses of \$363,000 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 of \$20,000 related to Sarbanes-Oxley compliance.

As our sales of rapid HIV test products increase, we expect 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. In September 2006, we entered into agreements with Inverness, which provide a license to the Company to market our lateral flow devices for which we pay a royalty of either 5% or 8.5% of our net sales of the applicable product, depending on the market to which the sales are made.

**Other Income and Expense:**

Interest expense increased by \$371,000 for the year ended December 31, 2006 compared with the year ended December 31, 2005. This was primarily attributable to the valuation of the bridge warrants (we borrowed \$1.3 million in June of 2006 at a rate of 2% for 90 days plus warrants exercisable at \$.70). Some of this debt was converted into the Series C Offering which allowed for a discount of 12.5%, this resulted in a loss on the extinguishment of \$87,000. Interest income for the year ended December 31, 2006 decreased \$10,000. In addition, during 2006, we received a marketing grant from New York State of \$25,000.

**LIQUIDITY AND CAPITAL RESOURCES**

We had a working capital surplus of \$5,113,000 at December 31, 2006 and a working capital surplus of \$650,000 at December 31, 2005. On September 29, 2006 and October 5, 2006, we completed the Series C Preferred Stock Offering for \$8,150,000. On June 29, 2006, we borrowed \$1,300,000 which was partially repaid in cash (approximately \$700,000) from the Series C Preferred Stock Offering proceeds, and the remainder (approximately \$600,000) was repaid through conversion to the Series C Preferred Stock offering, as described in the Recent Events section above and more fully in Note 1 of the consolidated financial statements. On March 30, 2006, we completed a transaction related to the Series B Preferred Stock Offering under which we 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 sales and marketing, research and development, intellectual property, and also for working capital, investor relations and capital expenditures.

We believe our resources are sufficient to fund our needs through the end of 2007 and into early 2008. Our 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) our 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 additional capital.

The following table lists the future payments required on our debt and any other contractual obligations as of December 31, 2006:

OBLIGATIONS	Total	Less than 1			Greater than 5
		Year	1-3 Years	4-5 Years	
Long Term Debt(1)	\$ 93,160	\$ 93,160	\$ -	\$ -	\$ -
Capital Leases (2)	51,498	44,417	7,081	-	-
Operating Leases	38,683	38,683	-	-	-
Other Long Term Obligations(3)	707,500	442,500	177,500	25,000	62,500
<b>Total Obligations</b>	<b>\$ 890,841</b>	<b>\$ 618,760</b>	<b>\$ 184,581</b>	<b>\$ 25,000</b>	<b>\$ 62,500</b>

(1) This includes the balance of accrued interest.

(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 Recent Events above.

On September 29, 2006, we executed several agreements by and among the Company, Inverness Medical Innovations, Inc. (“Inverness”) and StatSure Diagnostic Systems, Inc. (“StatSure”). Pursuant to these agreements, Inverness is marketing our FDA approved rapid HIV tests, we have a nonexclusive license to Inverness’ lateral flow patents, and the Company and StatSure settled their patent litigation. The distribution agreements contain gross margin sharing formulae among Inverness, the Company and StatSure. In addition, we have the exclusive right and duty to manufacture the products marketed by Inverness under all the agreements, and we have the right to subcontract manufacturing, but not sublicense or subcontract our rights or obligations.

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First, we executed an HIV Barrel License, Marketing and Distribution Agreement among the Company, Inverness and StatSure. This agreement covers our 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 each of the Company and StatSure may keep in place for up to one year];
- Inverness will exclusively market SURE CHECK as well as any new HIV products in the “barrel field” that are developed, and may not compete with any products in the “barrel field” as defined in the agreement worldwide ;
- The Company and StatSure have each granted Inverness exclusive rights to their intellectual property in the HIV barrel field;
- Inverness has a first right to negotiate agreements to market and distribute any of our new HIV antibody detection tests, including products that may incorporate our patent-pending Dual Path Platform (DPP(TM)); and
- As described above, the SURE CHECK HIV 1/2 product has been re-labeled Clearview Complete HIV 1/2 and Inverness has commenced marketing of this product. CLIA waiver for this product is still pending.

In addition, we executed an HIV Cassette License, Marketing and Distribution Agreement with Inverness. This agreement covers our FDA-approved HIV 1/2 STAT-PAK(TM) 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 United States market only, and we have a non-exclusive license under the Inverness lateral flow patents to continue to market the product under our brand in the rest of the world;
- Inverness may bring a competitive HIV cassette product to the United States market, but in that event we can expand our lateral flow license for this product to the United States and have other options under the agreement;
- We received a non-exclusive license under the Inverness lateral flow patents for our HIV 1/2 STAT-PAK cassette for marketing outside the United States; and
  - As described above, the HIV 1/2 STAT-PAK product has been re-labeled Clearview HIV 1/2 STAT-PAK and Inverness has commenced marketing of this product. CLIA waiver for this product has been granted.

The Company and Inverness also executed a Non-Exclusive License, Marketing and Distribution Agreement, which covers our other lateral flow rapid tests, including but not limited to our HIV 1/2 STAT-PAK(TM) Dipstick. Some of the terms of this agreement are:

- We received a non-exclusive license under the Inverness lateral flow patents for our HIV 1/2 STAT-PAK Dipstick for marketing outside the United States;
  - We received a worldwide non-exclusive license to manufacture and market a number of other Company-branded products under the Inverness lateral flow patents, including all of our rapid tests for human and veterinary and tuberculosis, Chagas disease, and tests for other defined emerging and neglected diseases;
- 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; and





- 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 HIV barrel products after reimbursement to the Company of our 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 our 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 HIV barrel products after these deductions.

In July 2006, we submitted to the FDA CLIA ("Clinical Laboratory Improvement Act") waiver applications for our 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 (now Clearview HIV 1/2 STAT-PAK) in November of 2006. The CLIA waiver application concerning the HIV barrel product formerly submitted to the FDA as SURE CHECK HIV 1/2 and now approved as Clearview Complete HIV 1/2 is still pending at the FDA.

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 United States consumers. All of these developments bode well for the expansion of the United States 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, we established offices in Nigeria and Tanzania, and we believe these offices will be significant in our continuing efforts to become part of the national testing protocols in many countries in Africa. Our 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. We have made some progress towards having our HIV products designated in other countries where we have focused our efforts, though this progress is more uncertain and slower than we anticipated it would be. We have registered our products and have arrangements with distribution partners in certain of these countries and we are in negotiations for similar arrangements in other countries. We believe that our strategy of establishing offices in these challenging markets is a very effective way to obtain sustainable and supportable business.

In 2006, we were 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, we have agreed to offer our HIV STAT-PAK Dipstick, our lowest cost rapid HIV test product, at a reduced price in the expectation that we will receive significant order volume not otherwise obtainable. If these order volumes are not realized, we have the right to terminate the agreement or renegotiate pricing. We are the only United States-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, we are now actively engaged with CHAI in developing sales opportunities in many of these countries. Although in some of these countries we have already made substantive sales efforts, there are many more where this is not the case. To date we have not derived any tangible results from our being selected by the Clinton HIV/AIDS Initiative, though these efforts continue. There is no commitment or assurance that either our direct efforts to establish additional distributors and/or local assembly, or our

activities through CHAI will materialize into meaningful sales.

Our technology transfer and supply agreement in Brazil is moving forward. We shipped \$1,515,000 of rapid HIV test components to this customer in the year ended December 31, 2006, a 28% increase over the same period in 2005.

In November 2006, we received an order for 990,000 units of our Sure Check product from our distributor in Mexico, a division of Bio-Rad Laboratories, Inc. This distribution agreement is the one exception to our otherwise global exclusive agreement with Inverness as it relates to this product. Approximately half of this order was shipped during the fourth quarter of 2006, and the balance was shipped during the first quarter of 2007. Absent other arrangements, this exception to Inverness' global exclusivity will be eliminated on September 29, 2007.

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

We have hired a senior diagnostics marketing executive to focus on our Tuberculosis products, both for veterinary and human TB. Our non-human primate Tuberculosis product is currently under review by the United States Department of Agriculture (USDA), and we hope to receive USDA approval during the second quarter of 2007 for our first product, PrimaTB STAT-PAK™ subject only now to a satisfactory facility inspection by the USDA which has been scheduled. We plan to submit additional veterinary Tuberculosis products to the USDA, including a cattle Tuberculosis test, subject to having the necessary performance data.

### **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.

We believe that there are several accounting policies that are critical to understanding our 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 -*

We sell our products directly through our sales force and through distributors. Revenue from direct sales of our product is recognized upon shipment to the customer. Income from research grants are recognized when earned. Sales are recorded net of discounts, rebates and returns.

#### *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. Our 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. For example, each additional 1% of obsolete inventory would reduce such inventory by approximately \$11,000.

#### *Allowance for doubtful accounts -*

Our policy is to review our accounts receivable on a periodic basis, no less than monthly. On a quarterly basis an analysis is made of the adequacy of our allowance for doubtful accounts, and adjustments are made accordingly. The current allowance is approximately 3.09% of accounts receivable. For example, each additional 1% of accounts receivable that becomes uncollectible would reduce such balance of accounts receivable by approximately \$13,500.

#### *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 we do not become profitable, we may be unable to utilize our deferred tax asset, which approximates \$7,183,000 and \$6,128,000 at December 31, 2006 and 2005, respectively.

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, we determined that it was appropriate to establish a valuation allowance for the full amount of our deferred tax assets.

The above listing is not intended to be a comprehensive list of all of our 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 our 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 15,600 square feet of industrial space for \$9,671 per month. The space is utilized for R&D (approximately 1,000 square feet), offices (approximately 5,100 square feet) and production (approximately 9,500 square feet). The lease term expires on April 30, 2007, and we have an option 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

Please refer to the "Certain Relationships and Transactions and Corporate Governance" section beginning on page 23 for a discussion of the Company's relationships and related transactions.

### LEGAL MATTERS

The validity of the shares of our common stock offered by the Selling Stockholders has been passed upon by the law firm of Patton Boggs, LLP.

### 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 table below sets forth the high and low bid prices per share of our common stock. These prices represent inter-dealer quotations without retail markup, markdown, or commission and may not necessarily represent actual transactions. We completed a 1 for 17 reverse stock split on March 12, 2004, and all of the prices in this table have been adjusted to reflect this split.

<b>Fiscal Year</b>	<b>High Bid</b>	<b>Low Bid</b>
<b>2006</b>		
<b>First Quarter</b>	\$0.75	\$0.33
	\$1.15	\$0.65

Second Quarter		
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

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

### **Holders**

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

### **Dividends**

We have never paid cash dividends on our common stock and we have 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 each of our series A, series B and series C preferred stock generally prohibit us from making any distribution with respect to any equity securities that by their terms do not rank senior to the applicable series A, series B or series C preferred stock.

## Equity Compensation Plan Information

## Equity Compensation Plan Information as of March 31, 2007

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	1,515,750	\$0.698	1,319,250
Equity compensation plans not approved by security holders	--	--	--
<b>Total</b>	<b>1,515,750</b>	<b>\$0.698</b>	<b>1,319,250</b>

## EXECUTIVE COMPENSATION

The following table summarizes all compensation recorded by the Company in the latest completed fiscal year 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.

Name and Principal Position	Year	Salary (\$) <sup>1</sup>	Bonus (\$) <sup>2</sup>	Option Awards (\$) <sup>3</sup>	All Other Compensation	Total (\$)
Lawrence A. Siebert, CEO and Director <sup>4</sup>	2006	\$ 207,115	\$ 20,000	\$ 21,017	\$ 7,200	\$ 255,332
Richard J. Larkin, CFO	2006	\$ 140,385	\$ 15,000	\$ 27,300	\$ -	\$ 182,685
Avi Pelossof, Vice President of Sales and Marketing <sup>5</sup>	2006	\$ 156,538	\$ 12,000	\$ 51,081	\$ 6,120	\$ 225,739
Javan Esfandiari, Director of Research and Development	2006	\$ 150,385	\$ 12,000	\$ 41,390	\$ 4,800	\$ 208,575
Les Stutzman - Vice President of Marketing	2006	\$ 116,539	\$ 11,500	\$ 12,009	\$ 20,075 <sup>6</sup>	\$ 160,123



<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 valuations of these options reflect the compensation costs of each option award over the requisite service period in accordance with FAS123R.

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

<sup>6</sup> This amount represents the rental payments the Company makes for the apartment Mr. Stutzman rents when he visits the Company.

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## 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 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 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, 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
<b>Lawrence A. Siebert</b>	50,000 <sup>2</sup>		0.75	11/19/2007	4/17/2006
	10,000 <sup>2</sup>		0.75	12/31/2008	4/17/2006
	10,000 <sup>2</sup>		0.75	5/4/2011	4/17/2006
	50,000 <sup>2</sup>		0.75	5/28/2011	4/17/2006
		50,000 <sup>2</sup>	0.75	5/28/2011	1/1/2007
	50,000 <sup>3</sup>		0.75	5/4/2011	5/5/2004
<b>Richard J. Larkin</b>	25,000 <sup>2</sup>		0.75	5/17/2010	4/17/2006
		25,000 <sup>2</sup>	0.75	5/17/2010	4/17/2006
	18,750 <sup>1</sup>		0.62	3/24/2011	3/24/2006
		18,750 <sup>1</sup>	0.62	3/24/2011	1/1/2007
	50,000 <sup>3</sup>		0.45	9/15/2010	5/5/2004
<b>Avi Pelossof</b>	40,000 <sup>2</sup>		0.75	11/19/2007	4/17/2006
	10,000 <sup>2</sup>		0.75	12/31/2008	4/17/2006
	25,000 <sup>2</sup>		0.75	5/17/2010	4/17/2006
		25,000 <sup>2</sup>	0.75	5/17/2010	1/1/2007
	25,000 <sup>1</sup>		0.62	3/24/2011	3/24/2006
		25,000 <sup>1</sup>	0.62	3/24/2011	1/1/2007
	10,000 <sup>2</sup>		0.75	5/4/2011	4/17/2006
	27,500 <sup>2</sup>		0.75	5/27/2011	4/17/2006
		50,000 <sup>2</sup>	0.75	5/27/2011	1/1/2007
		22,500 <sup>2</sup>	0.75	5/27/2011	1/1/2007
	40,000 <sup>3</sup>		0.75	5/4/2011	5/5/2004
<b>Javan Esfandiari</b>	30,000 <sup>2</sup>		0.75	3/31/2008	4/17/2006
	5,000 <sup>2</sup>		0.75	12/31/2008	4/17/2006
	25,000 <sup>2</sup>		0.75	5/17/2010	4/17/2006
		25,000 <sup>2</sup>	0.75	5/17/2010	1/1/2007
	18,750 <sup>1</sup>		0.62	3/24/2011	3/24/2006
		18,750 <sup>1</sup>	0.62	3/24/2011	1/1/2007
	5,000 <sup>2</sup>		0.75	5/4/2011	4/17/2006
	25,000 <sup>2</sup>		0.75	5/28/2011	4/17/2006
	25,000 <sup>2</sup>		0.75	5/28/2011	4/17/2006
		25,000 <sup>2</sup>	0.75	5/28/2011	5/28/2007
	30,000 <sup>3</sup>		0.75	5/4/2011	5/5/2004
<b>Les Stutzman</b>	15,000 <sup>1</sup>		0.62	3/24/2011	3/24/2006
	10,000 <sup>3</sup>		0.57	9/19/2010	9/19/2006
		10,000 <sup>3</sup>	0.57	9/19/2010	9/19/2007

<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.

<sup>2</sup> 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.

**DIRECTOR COMPENSATION**

<b>Name</b>	<b>Fees Earned or Paid in Cash (\$)<sup>1</sup></b>	<b>Stock Awards (\$)<sup>2</sup></b>	<b>Option Awards (\$)<sup>3</sup></b>	<b>Total (\$)</b>
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

<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 received an \$18,000 annual fee as a member of the board of directors, 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.

<sup>2</sup> 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.

<sup>3</sup> Each outside member of the board of directors is issued options granting the holder 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 the director's 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. The fair value of options at the date of grant was estimated using the Black-Scholes option pricing model.

<sup>4</sup> Mr. Eppner resigned from our Board of Directors on January 30, 2007.

**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 our 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."

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

Not applicable.

**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.

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>.

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**

**Index to Consolidated Financial Statements**

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**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 sheets of Chembio Diagnostics, Inc. and Subsidiaries (the "Company") as of December 31, 2006 and 2005 and the consolidated statements of operations, stockholders' equity (deficit) and cash flows for the two years in the period ended December 31, 2006. 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, 2006 and 2005, and the consolidated results of its operations and its cash flows for the two years in the period ended December 31, 2006 in conformity with accounting principles generally accepted in the United States of America.

**LAZAR LEVINE & FELIX LLP**

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

New York, New York  
March 28, 2007

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

- ASSETS -

	2006		2005
<b>CURRENT ASSETS:</b>			
Cash	\$ 4,290,386	\$	232,148
Accounts receivable, net of allowance for doubtful accounts of \$42,967 and \$20,488 for 2006 and 2005, respectively	1,350,240		1,255,073
Inventories	1,108,950		687,983
Prepaid expenses and other current assets	204,092		292,989
<b>TOTAL CURRENT ASSETS</b>	<b>6,953,668</b>		<b>2,468,193</b>
<b>FIXED ASSETS, net of accumulated depreciation</b>	<b>603,603</b>		<b>438,632</b>
<b>OTHER ASSETS</b>	<b>349,306</b>		<b>109,581</b>
	\$ 7,906,577	\$	3,016,406

- LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT) -

<b>CURRENT LIABILITIES:</b>			
Accounts payable and accrued liabilities	\$ 1,709,939	\$	1,477,925
Current portion of accrued interest payable	93,160		120,000
Current portion of obligations under capital leases	37,336		38,368
Payable to related party	-		182,181
<b>TOTAL CURRENT LIABILITIES</b>	<b>1,840,435</b>		<b>1,818,474</b>
<b>OTHER LIABILITIES:</b>			
Obligations under capital leases, net of current portion	7,081		44,417
Accrued interest, net of current portion	-		100,812
Series C redemption put	449,677		-
<b>TOTAL LIABILITIES</b>	<b>2,297,193</b>		<b>1,963,703</b>
<b>COMMITMENTS AND CONTINGENCIES</b>			
<b>PREFERRED STOCK</b>			
Series C 7% Convertible - \$.01 par value: 165 shares issued and outstanding. Liquidation preference-\$8,397,583	6,549,191		-

**STOCKHOLDERS' EQUITY (DEFICIT)**

Preferred Stock - 10,000,000 shares authorized:

Series A 8% Convertible - \$.01 par value: 149,921,119 and 158,680,999 shares issued and outstanding for 2006 and 2005, respectively. Liquidation preference \$4,557,604 and \$4,822,957 for 2006 and 2005, respectively.	<b>2,504,313</b>	2,628,879
Series B 9% Convertible - \$.01 par value: 113,935,911 and 102,197,600 shares issued and outstanding for 2006 and 2005, respectively. Liquidation preference-\$5,958,848 and \$5,341,896 for 2006 and 2005, respectively	<b>3,555,786</b>	3,173,239
Common stock - \$.01 par value; 100,000,000 shares authorized 11,296,961 and 8,491,429 shares issued and outstanding for 2006 and 2005, respectively.	<b>112,970</b>	84,914
Additional paid-in capital	<b>19,960,618</b>	14,034,099
Accumulated deficit	<b>(27,073,494)</b>	(18,868,428)
<b>TOTAL STOCKHOLDERS' EQUITY (DEFICIT)</b>	<b>(939,807)</b>	1,052,703
	<b>\$ 7,906,577</b>	<b>\$ 3,016,406</b>

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

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

	FOR THE YEARS ENDED	
	December 31, 2006	December 31, 2005
<b>REVENUES:</b>		
Net sales	\$ 6,294,012	\$ 3,359,532
License revenue	-	250,000
Research grants and development income	208,468	331,198
<b>TOTAL REVENUES</b>	<b>6,502,480</b>	<b>3,940,730</b>
Cost of sales	4,485,912	2,608,584
<b>GROSS PROFIT</b>	<b>2,016,568</b>	<b>1,332,146</b>
<b>OVERHEAD COSTS:</b>		
Selling, general and administrative expenses	5,195,289	3,265,235
Research and development expenses	1,401,472	1,364,898
	<b>6,596,761</b>	<b>4,630,133</b>
<b>LOSS FROM OPERATIONS</b>	<b>(4,580,193)</b>	<b>(3,297,987)</b>
<b>OTHER INCOME (EXPENSES):</b>		
Settlement of accounts payable	-	21,867
Other income	25,000	-
Interest income	29,532	39,803
Interest expense	(386,895)	(15,683)
Loss on extinguishment of debt	(87,464)	-
Gain on disposal of fixed assets	5,000	-
<b>LOSS BEFORE INCOME TAXES</b>	<b>(4,995,020)</b>	<b>(3,252,000)</b>
Income taxes	-	-
<b>NET LOSS</b>	<b>(4,995,020)</b>	<b>(3,252,000)</b>
Dividends payable in stock to preferred stockholders	1,022,897	818,321
Dividend accreted to preferred stock for associated costs and a beneficial conversion feature	2,187,149	2,698,701
<b>NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS</b>	<b>\$ (8,205,066)</b>	<b>\$ (6,769,022)</b>
<b>Basic and diluted loss per share</b>	<b>\$ (0.80)</b>	<b>\$ (0.88)</b>

<i>Weighted number of shares outstanding, basic and diluted</i>	<b>10,293,168</b>	7,705,782
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The accompanying notes are an integral part of these consolidated financial statements.

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

	Series A Preferred Stock		Series B Preferred Stock		Common Stock		Additional paid in capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Amount	Amount	Amount
<b>Balance at December 31, 2004</b>	-	\$ -	-	\$ -	6,907,143	\$ 69,071	\$ 9,079,341	\$ (12,099,406)	\$ (2,950,994)
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	-	-	4.06988	435,509	-	-	-	(435,509)	-
Accretion of beneficial conversion	-	261,666	-	2,437,035	-	-	-	(2,698,701)	-
<b>Common Stock Issued:</b>									
Upon conversion of Preferred Series A Preferred	(3.02476)	(52,631)	(8.20228)	(228,877)	823,654	8,237	273,271	-	-
Dividend		4,414			630,632	6,306	372,092	(382,812)	-

For services	-	-	-	-	95,000	950	52,300	-	53,250
<b>Warrants and options:</b>									
Issued for services	-	-	-	-	-	-	90,288	-	90,288
Exercised	-	-	-	-	35,000	350	24,850	-	25,200
Cancelled	-	-	-	-	-	-	(65,932)	-	(65,932)
<b>Net loss for 2005</b>	-	-	-	-	-	-	-	(3,252,000)	(3,252,000)

**Balance at December 31, 2005**      158.68099   \$2,628,879   102.19760   \$ 3,173,239   8,491,429   \$ 84,914   \$14,034,099   \$ (18,868,428)   \$ 1,052,703

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

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)**  
**FOR THE YEAR ENDED DECEMBER 31, 2006**

	Series A Preferred Stock		Series B Preferred Stock		Common Stock		Additional paid in capital Amount	Accumulated Deficit Amount	Total Amount
	Shares	Amount	Shares	Amount	Shares	Amount			
<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>\$ 1,052,7</b>
<b>Preferred Stock issued:</b>									
cash	-	-	20.0000	1,000,000	-	-	(112,750)	-	887,2
fees	-	-	2.0000	100,000	-	-	(100,000)	-	
dividends	-	-	1.79797	89,899	-	-	(89,899)	-	
location of fair value to warrants	-	-	-	(481,470)	-	-	1,880,185	-	1,398,7
location of value beneficial conversion	-	-	-	(463,434)	-	-	2,187,149	-	1,723,7
creation of preferred dividend	-	366,563	-	508,751	-	-	-	(1,022,897)	(147,5
creation of beneficial conversion	-	-	-	463,434	-	-	-	(2,187,149)	(1,723,7
payment of dividends	-	(369,123)	-	(473,982)	959,608	9,596	633,284	-	(200,2
<b>Common Stock issued:</b>									
common converted from preferred	(8.75980)	(122,006)	(12.05966)	(360,651)	1,426,483	14,265	468,392	-	
services	-	-	-	-	178,750	1,788	137,890	-	139,6
<b>Warrants and Options:</b>									
consultants/Advisory board	-	-	-	-	-	-	137,022	-	137,0
for CEO warrant	-	-	-	-	-	-	34,000	-	34,0
exercised	-	-	-	-	240,691	2,407	143,914	-	146,3
issued for bridge	-	-	-	-	-	-	328,341	-	328,3
option valuation per R	-	-	-	-	-	-	278,991	-	278,9
<b>Loss for 2006</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>(4,995,020)</b>	<b>(4,995,0</b>
<b>Balance at December 31, 2006</b>	<b>149.92119</b>	<b>\$2,504,313</b>	<b>113.93591</b>	<b>\$3,555,786</b>	<b>11,296,961</b>	<b>\$ 112,970</b>	<b>\$19,960,618</b>	<b>\$ (27,073,494)</b>	<b>\$ (939,8</b>

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



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

**FOR THE YEARS ENDED:**

	<b>December 31, 2006</b>	<b>December 31, 2005</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (4,995,020)	\$ (3,252,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	209,541	98,508
Provision for doubtful accounts	22,479	4,120
Expenses related to shares, options and warrants issued for services	565,668	77,606
Expenses related to warrants issued with bridge financing	328,341	-
Expenses related to conversion of bridge into Series C Preferred Stock	99,469	-
Changes in:		
Accounts receivable	(117,645)	(1,094,137)
Restricted cash	-	250,000
Inventory	(420,967)	(149,336)
Accounts payable and accrued expenses	256,039	212,939
Other	(150,828)	(153,060)
<b>Net cash used in operating activities</b>	<b>(4,202,923)</b>	<b>(4,005,360)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Acquisition of fixed assets	(374,513)	(348,741)
<b>Net cash used in investing activities</b>	<b>(374,513)</b>	<b>(348,741)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		