

CHEMBIO DIAGNOSTICS, INC.  
Form 424B3  
April 02, 2008

---

Filed Pursuant to Rule 424(b)(3)  
Registration Statement on Form S-1 No. 333-138266

**PROSPECTUS**

**CHEMBIO DIAGNOSTICS, INC.**

**20,008,319 SHARES OF COMMON STOCK**

This prospectus relates to 20,008,319 shares of our common stock which may be offered for sale from time to time by the Selling Stockholders identified in this Prospectus, consisting of 1,952,813 outstanding restricted shares, up to an aggregate of 4,124,940 shares of common stock issuable pursuant to the exercise of warrants, and additional shares of common stock which Selling Stockholders may receive at a later date pursuant to the anti-dilution provisions of certain warrants. We anticipate that the Selling Stockholders will offer the Shares for sale at prevailing market prices on the OTC Bulletin Board on the date of such sale. We will not receive any proceeds from these sales. We are paying the expenses incurred in registering the Shares, but all selling and other expenses incurred by each of the Selling Stockholders will be borne by each Selling Stockholder.

Our common stock is quoted on the OTC Bulletin Board under the symbol "CEMI." On March 27, 2008 the closing bid and ask prices for one share of our common stock were \$.14 and \$.16, respectively, as reported by the OTC Bulletin Board website. These over-the-counter quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

-----

**These securities are speculative and involve a high degree of risk. You should consider carefully the "Risk Factors" beginning on Page 2 of this prospectus before making a decision to purchase our stock.**

-----

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

-----

The date of this prospectus is April 2, 2008

---

**TABLE OF CONTENTS**

	Page
PROSPECTUS SUMMARY	1
RISK FACTORS	2
USE OF PROCEEDS	8
DETERMINATION OF OFFERING PRICE	8
DILUTION	8
SELLING SECURITY HOLDERS	8
PLAN OF DISTRIBUTION	10
LEGAL PROCEEDINGS	11
DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS, CONTROL PERSONS	11
SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT	13
DESCRIPTION OF SECURITIES	15
INTEREST OF NAMED EXPERTS AND COUNSEL	15
DISCLOSURE OF COMMISSION POSITION OF INDEMNIFICATION FOR SECURITIES ACT LIABILITIES	16
ORGANIZATION WITHIN LAST FIVE YEARS	16
DESCRIPTION OF BUSINESS	19
MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	32
DESCRIPTION OF PROPERTY	42
CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS	42
LEGAL MATTERS	42
MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS	43
EXECUTIVE COMPENSATION	44
FINANCIAL STATEMENTS	47
CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	47
ADDITIONAL INFORMATION	47

## 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.*

This Prospectus relates to 20,008,319 shares of our common stock which may be offered for sale from time to time by the Selling Stockholders identified in this Prospectus, consisting of 1,952,813 outstanding restricted shares, up to an aggregate of 4,124,940 shares of common stock issuable pursuant to the exercise of warrants, and additional shares of common stock which Selling Stockholders may receive at a later date pursuant to the anti-dilution provisions of certain warrants. We anticipate that the Selling Stockholders will offer the Shares for sale at prevailing market prices on the OTC Bulletin Board on the date of such sale. We will not receive any proceeds from these sales. We are paying the expenses incurred in registering the Shares, but all selling and other expenses incurred by each of the Selling Stockholders will be borne by each Selling Stockholder.

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

### **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 a 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 for certain tests has been received.

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.

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.

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.

### Summary Financial Data

The following table presents summary historical financial information for the fiscal years ended December 31, 2007 and 2006. 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.

	Year Ended December 31, 2007	Year Ended December 31, 2006
Revenue	\$ 9,230,948	\$ 6,502,480
Operating Expenses	6,738,467	6,596,761
Net Loss	(2,626,892)	(4,995,020)
Current Assets	5,471,307	6,953,668
<b>Total Assets</b>	<b>6,584,997</b>	<b>7,906,577</b>
Current Liabilities	2,242,583	1,840,435
<b>Total Liabilities</b>	<b>2,322,171</b>	<b>2,297,193</b>
<b>Convertible Redeemable Preferred</b>	n/a	6,549,191
<b>Stockholders' Equity (Deficit)</b>	<b>4,262,826</b>	<b>(939,807)</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.

2

---

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. While we have recently received ISO 13.485 certification, there are no assurances that we will be able to maintain this certification, in addition we are in the process of implementing quality and documentary procedures in order to obtain CE registration, and we are not aware of any material reason why such approval will not be granted. However, if for any reason a CE 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.

3

---



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.

On March 13, 2007, our Dual Path Platform Immunassay Device patent application issued as United States patent no. 7,189,522. Additional protection for this intellectual property is pending worldwide. 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. 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. However there can be 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.

4

---

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

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

**The success of our business depends, in addition to the market success of our products, 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 2007, 2006 and 2005. At December 31, 2007, we had a stockholders' equity of \$4.2 million and a working capital surplus of \$3.2 million. 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 2008, there are no assurances that we will be successful in raising sufficient capital.

On December 19, 2007, we received \$1.1 million pursuant to the exercise of certain warrants. In spite of this capital raise, there is no guarantee that the Company will be successful in raising additional capital if needed.

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

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

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

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

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

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

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

5

---

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.

**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 Senior 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 March 2010. We have obtained a key man insurance policy for Mr. Esfandiari.

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

We believe it to be in our best 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, 2007, we have incurred net losses. As of December 31, 2007, we have an accumulated deficit of \$35 million. We incurred net losses of \$2.6 million and \$5 million in 2007 and 2006, 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.

6

---

**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***

**Until recently, our Common Stock was classified as penny stock, and it continues to be extremely illiquid, so investors may not be able to sell as much stock as they want at prevailing market prices.**

Until recently, our Common Stock was 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 securities that are classified as penny stocks. 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 penny stock issuers 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.

At the present time, transactions in our Common Stock are not subject to the “penny stock” rules because our average revenue for 2005, 2006 and 2007 exceeded \$6 million per year. However, there can be no assurance that transactions in our Common Stock will not be subject to the “penny stock” rules in the future.

The average daily trading volume of our Common Stock on the over-the-counter market was less than 100,000 shares per day over the three months ended April 2, 2008. 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.

**Sales of a substantial number of shares of our Common Stock into the public market by the selling stockholders, as well as the exercise of our outstanding warrants on a cash or a cashless basis, 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 that this post-effective amendment to the registration statement is declared effective by the SEC, a significant number of shares of our Common Stock will be eligible to be immediately sold in the market. In addition, pursuant to the December 2007 plan (the “Plan”) to simplify our capital structure, certain holders of warrants and options (collectively, the “Non-Employee Warrants”) not including options or warrants issued to employees or directors in their capacity as such may exercise their warrants on a cashless basis. Certain Non-Employee Warrant holders are now permitted to exercise 9,323,855 warrants on a cashless basis at an exercise price of \$0.45 per share at any time on or before June 30, 2008.

The Plan’s cashless exercise provision permits Non-Employee Warrant holders to use any excess of the market price of the Company’s Common Stock over the exercise price of a Non-Employee Warrant as part of the exercise price for another warrant by submitting both warrants at the time of exercise. Pursuant to the Plan, certain Non-Employee Warrant holders are permitted on or before June 30, 2008 to use the greater of (i) \$0.53 or (ii) the VWAP for the

ten-trading day period that ends on the second trading day before the exercise date as the value of the Common Stock, so that each Non-Employee Warrant used as part of the exercise price payment will represent the difference between the greater of these two values and the applicable exercise price.

As of March 27, 2008, our Common Stock was trading at \$0.16 cents per share. If a large number of Non-Employee Warrant holders exercise their warrants on a cashless basis on or before June 30, 2008, our stock price could drop. Even a perception by the market that selling stockholders may sell in large amounts after the post-effective amendment to the registration statement is declared effective could place significant downward pressure on our stock price.



**You will experience substantial dilution upon the exercise warrants underlying common stock that we are currently registering.**

There are 4,124,940 shares of common stock underlying warrants registered in this registration statement, and 13,098,674 shares of common stock underlying warrants and options registered in another registration statement. These securities were issued by the Company in connection with the Company's previously completed private placements, and as adjusted in connection with the Company's December 2007 plan to simplify its capital structure. As of April 2, 2008, we have approximately 22 million warrants and options outstanding. As a result, the exercise of the outstanding warrants and options will result in substantial dilution to the holders of our Common Stock.

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

As of April 2, 2008, our named executive officers, directors and 5% stockholders beneficially owned approximately 65% 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.

#### **DETERMINATION OF OFFERING PRICE**

We are not selling any common stock in this offering. We anticipate that the Selling Stockholders will offer the Shares for sale at prevailing market prices on the OTC Bulletin Board on the date of such sale. We will not receive any proceeds from these sales.

#### **DILUTION**

We currently file reports with the SEC, and we are not selling any common stock in this offering. The selling security holders are the current stockholders of the Company.

#### **SELLING SECURITY HOLDERS**

The securities are being offered by the named selling security holders below. The selling security holders hold one or more of the following securities which are described in section "Description of Securities": common stock and warrants to purchase common stock exercisable at prices ranging from \$0.40 per share to \$1.00 per share. However, the table below assumes 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 terms of these agreements, and the specific 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 1,952,813 shares of our common stock now owned by them, up to an aggregate of 4,124,940 shares of common stock issuable pursuant to the exercise of warrants, and additional shares of common stock which Selling Stockholders may receive at a later date pursuant to the anti-dilution provisions of certain warrants. The selling security holders may, from time to time, offer and sell any or all of the shares that are registered under this prospectus, although they are not obligated to do so.

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

- the number of shares of common stock beneficially owned as of April 2, 2008 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 the Company's total outstanding shares of common stock beneficially owned by each selling security holder after the offering contemplated hereby; and
- in notes to the table, additional information concerning the selling security holders including any NASD affiliations and any relationships, excluding non-executive employee and other non-material relationships, that a selling security holder had during the past three years with the registrant or any of its predecessors or affiliates.

Selling security holders (C)	Number of Shares of Common Stock Owned Before Offering (A)	Number of Shares to be Offered (B)	Number of Shares Owned After Offering	Percentage of Shares of Common Stock Owned After Offering
ACM SPV, LLC	63,873	63,873	-	0.00%
Alpha Capital AG 1	1,894,024	548,112	1,345,912	2.20%
BCMF Trustees, LLC	318,060	318,060	-	0.00%
Bio-Business Science & Development LTDA	327,721	327,721	-	0.00%
Bristol Investment Fund, Ltd.	219,740	219,740	-	0.00%
Bushido Capital Master Fund, LP	1,891,144	195,638	1,695,506	2.77%
C.E. Unterberg, Towbin Capital Partners I, L.P. 5	1,020,610	229,375	791,235	1.31%
CFRR Holdings, LLC	4,843	4,843	-	0.00%
Cranshire Capital, LP	616,376	78,125	538,251	0.89%
Crestview Capital Master, LLC 2	24,145,310	2,000,000	22,145,310	35.77%
Ferrari, Braden	4,688	4,688	-	0.00%
Frankenthal, Stuart J.	369,826	46,875	322,951	0.53%
Imas, Ariel	6,250	6,250	-	0.00%
Inverness Medical Innovations, Inc.	5,367,840	625,000	4,742,840	7.83%
Iroquois Master Fund, Ltd.	54,935	54,935	-	0.00%
Kreger, Richard H. 3	1,090,404	188,230	902,174	1.49%
Longview Fund, LP	1,467,128	390,625	1,076,503	1.77%
Marti A. Meyerson EDS Trust	1,991,019	232,031	1,758,988	2.91%
Midtown Partners & Co., LLC 4	261,122	40,522	220,600	0.36%
Morton H. Meyerson	2,031,244	236,719	1,794,525	2.96%
Pierce Diversified Strategy Master Fund, LLC - Series BUS	760,481	195,313	565,168	0.93%
Ralph Rabman	3,524	3,524	-	0.00%
RHK Midtown Partners LLC	20,833	20,833	-	0.00%
Rohan, J. Rory 3	548,994	46,721	502,273	0.83%
<b>TOTALS</b>	<b>44,479,989</b>	<b>6,077,753</b>	<b>38,402,236</b>	

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

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

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

understanding to distribute the securities.

- [1] Konrad Ackerman has ultimate control over Alpha Capital AG and the shares held by Alpha Capital AG.
- [2] 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.
- [3] Affiliated with Midtown Partners & Co., LLC, investment banking services.
- [4] NASD member, assisted the Company in fundraising.
- [5] Assisted the Company in December 2007 equity simplification plan.

## 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.

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 that is adverse to our interest.

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

### **Directors and Executive Officers**

**Lawrence A. Siebert (51)**, President, Chief Executive Officer and Director. Mr. Siebert was appointed Chief Executive Officer of Chembio Diagnostics, Inc. and Chairman of our board of directors upon consummation of the merger of the Company and Chembio Diagnostic Systems, Inc. in 2004. Mr. Siebert has been Chairman of Chembio Diagnostic Systems Inc. for approximately 16 years and its President since May 2002. Prior to his involvement with Chembio Diagnostic Systems, Inc., in 1992 Mr. Siebert was involved 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 (51)**, 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.



**Javan Esfandiari (41)**, Executive VP 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 (53)**, Vice President, Operations. Mr. Bruce was hired in April 2000 as Director of Operations. He is responsible for manufacturing, maintenance, inventory, shipping, receiving, and warehouse operations. Prior to joining Chembio Diagnostic Systems Inc., he held director level positions at Wyeth Laboratories from 1984 to 1993. From 1993 to 1998, he held various management positions in the Operations department at biomerieux, Inc. (formerly Organon Teknika Corp.). 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 (56)**, VP of Sales & Marketing – Vet TB. 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 (45)**, 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 to 2005, Director level positions in Quality Assurance, Quality Control, Process Development and Regulatory Affairs at United Biomedical, Inc. from 1987 to 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.

**Cathy Dudnanski (48)**, VP of Marketing, Ms. Dudnanski joined Chembio in 2005 as Marketing Director for human diagnostic products including HIV 1/ 2 and Chagas disease. She was promoted to Vice President in 2007. Ms. Dudnanski brings over 20 years of domestic and international marketing and sales experience in medical devices and diagnostics to the Company. Between 2003 to 2005, Ms. Dudnanski was the Global Marketing Manager for Suction and Oxygen Care for GE Healthcare. From 2000 to 2003, Ms. Dudnanski was the Director of Sales & Marketing for ZeptoMetrix Corporation (former Division of Hemagen Diagnostics, Inc.) where her responsibilities included sales and marketing of research products to biotechnology firms and academia. From 1992 to 1999, Ms. Dudnanski was the Director of Sales & Marketing for Hemagen Diagnostics, Inc. where she was responsible for the infectious disease and autoimmune disease product lines. She received a B.S. in Medical Technology from Roanoke College and an MBA from Loyola. Ms. Dudnanski is MT (ASCP) certified and a member of the American Society of Microbiology.

**Robert L. Aromando, Jr. (52)**, Executive VP of Commercial Operations. Mr. Aromando joined the Company in May 2007. Prior to this position, between 2001 and 2007, Mr. Aromando was Vice President of Marketing for Bracco Diagnostics Inc., a Princeton, New Jersey-based pharmaceutical company and part of the Bracco Group. Most of his

focus at Bracco was on managing the efforts of a marketing department, launching new products, business development and life cycle management. Prior to joining Bracco Mr. Aromando completed a one-year contract as interim President and Chief Executive Officer for American Bio Medica Corporation, a publicly-traded diagnostic healthcare company. Prior to American Bio Medica Corporation, Mr. Aromando was Director of Global Marketing for Covance, a leading pharmaceutical development organization headquartered in Princeton, New Jersey where he had responsibility for managing the strategic direction of the clinical development marketing department. He also spent eight years at Roche Diagnostic Systems (member of the Roche Group) as Director of Global Marketing responsible for the drugs of abuse business unit. His focus at Roche was allocated to government affairs as well as providing solutions for substance abuse programs in the workplace, criminal justice, drug treatment and school sectors. Mr. Aromando's career in healthcare also included stints at American Home Products and Litton Bionetics Laboratory Products.

**Alan Carus, CPA (69)**, Director, Audit Committee chair. Mr. Carus was elected to Chembio's Board of Directors on April 15, 2005, and currently serves on the Company's Audit, Compensation, and Nominating and Corporate Governance Committees, including as Chairman of the Audit Committee. 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 Shipholding 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 (57)**, Director. Dr. Meller was elected to our Board of Directors on March 15, 2005, and currently serves on the Company's Audit, Compensation and Nominating and Corporate Governance Committees, including as Chairman of the Compensation Committee. 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 is our largest stockholder. Dr. Meller is a graduate of the University of New Mexico School of Medicine and has an MBA from the Harvard Business School.

**Kathy Davis (51)**, Director. Ms. Davis was elected to the Company's Board of Directors in May 2007, and currently serves on the Company's Audit, Compensation and Nominating and Corporate Governance Committees, including as Chairman of the Nominating and Corporate Governance Committee. Ms. Davis is presently the owner of Davis Design Group LLC, a company that provides analytical and visual tools for public policy design. Previously she served as the Chief Executive Officer of Global Access Point, a start up company with products for data transport, data processing, and data storage network and hub facilities. From October 2003 to January 2005 Ms. Davis was Lieutenant Governor of the State of Indiana, and from January 2000 to October 2003 was Controller of the City of Indianapolis. From 1989 to 2003 Ms. Davis held leadership positions with agencies and programs in the State of Indiana including State Budget Director, Secretary of Family & Social Services Administration, and Deputy Commissioner of Transportation. From 1982 to 1989 Ms. Davis held increasingly senior positions with Cummins Engine, where she managed purchasing, product cost, manufacturing, engineering, and assembly of certain engine product lines. Ms. Davis also led the startup of and initial investments by a \$50 million Indiana state technology fund, serves on the not-for-profit boards of Noble of Indiana, Indiana Museum of African American History, University of Evansville Institute of Global Enterprise, and Purdue College of Science Dean's Leadership Council. She has a Masters of Business Administration from Harvard Business School and a Bachelor of Science in Mechanical Engineering from the Massachusetts Institute of Technology.

**James Merselis(54)**, Director. Mr. Merselis was elected to the Company's Board of Directors in March 2008. From 2002 to 2007, Mr. Merselis served as the President, Chief Executive Officer, and Director of Hemosense, Inc. (AMEX: HEM), a company that develops, manufactures, and sells handheld blood coagulation monitoring systems. From 1998 to 2002, Mr. Merselis served as President, Chief Executive Officer, and Director of Micronics, Inc., a Redmond, WA, based company that develops in vitro diagnostic products for disease diagnosis, prognosis, and treatment monitoring. From 1976 to 1998, Mr. Merselis held multiple positions at Boehringer Mannheim, including serving as Managing Director of the British affiliate of Boehringer Mannheim. Mr. Merselis holds an Advanced Management Program Certificate from the Harvard Business School, and a Bachelor of Science degree in Biology (Pre-Med) from Nebraska Wesleyan University.

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

The following table sets forth certain information regarding the beneficial ownership of our common stock by each person or entity known by us to be the beneficial owner of more than 5% of the outstanding shares of common stock, and by each of our directors, each of our “named executive officers”, and all of our directors and executive officers as a group as of April 2, 2008.

13

---

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Owner	Percent of Class
Siebert, Lawrence <sup>(1)</sup> 3661 Horseblock Road Medford, NY 11763	7,465,605	11.85%
Esfandiari, Javan <sup>(2)</sup> 3661 Horseblock Road Medford, NY 11763	714,580	1.17%
Larkin, Richard <sup>(3)</sup> 3661 Horseblock Road Medford, NY 11763	290,967	0.48%
Ippolito, Tom <sup>(4)</sup> 3661 Horseblock Road Medford, NY 11763	65,000	0.11%
Bruce, Richard <sup>(5)</sup> 3661 Horseblock Road Medford, NY 11763	140,000	0.23%
Carus, Al <sup>(6)</sup> 3661 Horseblock Road Medford, NY 11763	138,000	0.23%
Meller, Gary <sup>(7)</sup> 3661 Horseblock Road Medford, NY 11763	223,000	0.37%
Davis, Katherine L. <sup>(8)</sup> 3661 Horseblock Road Medford, NY 11763	36,000	0.06%
James D. Merselis <sup>(9)</sup> 3661 Horseblock Road Medford, NY 11763	9,000	0.01%
<b>Officers and Directors as a group</b> <sup>(10)</sup>	<b>9,082,227</b>	<b>14.14%</b>
Vicis Capital Master Fund 126 East 56th Street, Tower 56, Suite 700 New York, NY 10022	4,608,707	7.61%
Millenium 3 Opportunity Fund, LLC <sup>(11)</sup> 4 Becker Farm Road Roseland, NJ 07068	4,006,610	6.45%
Inverness Medical Innovations, Inc. 51 Sawyer Road, Suite 200 Waltham, MA 02453	5,367,840	8.87%
Crestview Capital Master, LLC <sup>(12)</sup> 95 Revere Drive, Suite A Northbrook, IL 60062	24,145,310	36.20%

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 (60,537,534) of the Company's common stock as of April 2, 2008, and 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.

14

---

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 2007, 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 2007.

- (1) Includes 245,000 shares issuable upon exercise of options exercisable within 60 days and 2,205,731 warrants.
- (2) Includes 492,500 shares issuable upon exercise of options exercisable within 60 days and 2,007 shares issuable upon exercise of warrants. Does not include 100,000 shares issuable upon exercise of options that are not exercisable within the next 60 days
- (3) Includes 212,500 shares issuable upon exercise of options exercisable within 60 days and 27,436 shares issuable upon exercise of warrants.
- (4) Includes 65,000 shares issuable upon exercise of options exercisable within 60 days.
- (5) Includes 140,000 shares issuable upon exercise of options exercisable within 60 days.
- (6) Includes 123,000 shares issuable upon exercise of options exercisable within 60 days. Does not include 144,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
- (7) Includes 123,000 shares issuable upon exercise of options exercisable within 60 days. Does not include 144,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
- (8) Includes 36,000 shares issuable upon exercise of options exercisable within 60 days. Does not include 144,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
- (9) Includes 9,000 shares issuable upon exercise of options exercisable within 60 days.
- (10) Includes footnotes (1)-(9)
- (11) Includes 1,557,376 shares issuable upon exercise of warrants.
- (12) Includes 6,169,056 shares issuable upon exercise of warrants.

## 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.

### 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.

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.

**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 225,419 shares of common stock and warrants to purchase 69,930 shares of our common stock.

15

---



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

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

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

## **ORGANIZATION WITHIN LAST FIVE YEARS**

Lawrence A. Siebert, the president, chief executive officer and chairman of the board of directors of Chembio Diagnostics, Inc. (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. On May 5, 2004, 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 \$0.90 per share, pursuant to the Company's private placement of its Series A Preferred Stock on May 5, 2004. Pursuant to the terms of the original Series A Preferred Stock, the shares of Series A Preferred Stock held by Mr. Siebert were convertible into 1,547,100 shares of the Company's common stock at \$0.60 per share. The remaining debt of \$234,062 held by Mr. Siebert was exchanged on May 5, 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 \$0.90 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 was also due to Mr. Siebert, but was not accruing interest. As of December 31, 2007, the accrued interest had been repaid. Mr. Siebert also invested \$50,000 in the Company's Series B Preferred Stock private placement pursuant to which he received 1 share of Series B Preferred Stock, which was originally convertible into 81,967 shares of common stock at \$0.61 per share, together with a warrant to purchase 77,868 shares of common stock at an exercise price of \$0.61 per share.

Mr. Siebert 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 \$0.90 per share, pursuant to the Company's private placement of its Series A Preferred Stock on May 5, 2004.

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 for a total of \$182,181. This amount was repaid in the fourth quarter of 2006. In addition as of December 31, 2007, all of the accrued interest on the debt due to Mr. Siebert had

been paid.

On February 15, 2008, the Compensation Committee approved the reduction of the exercise price to \$0.48 per share of each employee stock option award issued under the 1999 Equity Incentive Plan for which the exercise price was greater than \$0.48 per share. As a result of this price reduction, the following number of employee stock options awarded to the Company's officers and directors under the 1999 Equity Incentive Plan qualified for this price reduction: (i) Mr. Siebert: 170,000 options; (ii) Mr. Larkin: 87,500 options; (iii) Mr. Esfandiari: 532,500 options; (iv) Mr. Aromando: 100,000 options; (v) Mr. Ippolito: 15,000 options; (vi) Mr. Bruce: 90,000 options; (vii) Mr. Carus: 252,000 options; (viii) Dr. Meller: 252,000 options; and (ix) Ms. Davis: 180,000 options.

In addition, on February 15, 2008 the Compensation Committee granted to certain of the Company's employees options to purchase the Company's common stock under the 1999 Equity Incentive Plan. Included in these employee option grants were the following option grants to officers: (i) Mr. Siebert received 75,000 options; (ii) Mr. Larkin received 75,000 options; (iii) Mr. Esfandiari received 60,000 options; (iv) Mr. Bruce received 50,000 options; (v) Mr. Ippolito received 50,000 options; and (vi) Mr. Aromando received 25,000 options. The exercise price for each of these options is \$0.22 per share, which was the closing market price for the Company's common stock on February 15, 2008, which was the date of the grant. The options vest on the date of the grant, and each option granted will expire and terminate, if not exercised sooner, upon the earlier to occur of (a) 30 days after termination of the employee's employment with the Company or (b) the fifth anniversary of the date of grant.

16

---

Avi Pelossof, the Company's Vice President of Sales and Marketing from May 5, 2004 to January 31, 2007, exercised 100,000 options in December 2006 at \$0.60 per share, and another 50,000 options in January 2007 at \$0.75 per share.

Robert Aromando, the Company's Executive Vice President of Commercial Operations was hired in May of 2007. In June 2007 in connection with his joining the Company, he was granted options to purchase 100,000 shares of common stock at an exercise price of \$0.62 per share. These options will become exercisable one year from the date of grant. As discussed above, on February 15, 2008, the exercise price for these options was reduced to \$0.48.

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 Stock private placement in March 2006. Crestview also invested \$2 million in our Series C Preferred Stock private placement in September 2006. Details of these transactions are set forth below. Crestview currently is the largest stockholder of the Company.

As referred to above, in January 2005, for a purchase price of \$3 million, Crestview acquired 60 shares of our Series B Preferred Stock, together with warrants to purchase 4,672,130 shares of our common stock at a warrant exercise price of \$0.61 per share.

In March 2006, for a purchase price of \$1 million, Crestview acquired 20 shares of Series B Preferred Stock together with warrants to purchase 1,557,377 shares of common stock at a warrant exercise price of \$0.61 per share. These shares were issued in connection with the Company's January 2005 private placement as described herein. In September 2006, for a purchase price of \$2 million, we issued 40 shares of Series C Preferred Stock to Crestview together with warrants to purchase 625,000 shares of common stock at an exercise price of \$1.00 per share.

In January 2007, because of comments from the staff of the SEC concerning the Company's registration statement No. 333-138266 (the "Prospectus"), Crestview agreed to reduce the number of its shares of common stock covered by the Prospectus to 2,000,000. Crestview also agreed to waive any penalties that the Company would otherwise owe Crestview because of the failure to register all of Crestview's shares in the Prospectus. In consideration for this waiver, the Company agreed that, upon request by Crestview, the Company will file one or more registration statements with the SEC in order to register the resale of other shares beneficially owned by Crestview. The cost of any such registration statements shall be borne by the Company.

In addition to Crestview's \$2,000,000 investment in the Company's September 2006 private placement of Series C Preferred Stock, the Company also received an investment of \$2,000,000 on that date from Inverness Medical Innovations, Inc. ("Inverness"). At that time, a Certificate of Designation for the Series C Preferred Stock was filed with the Secretary of State of Nevada reflecting the agreed upon conversion price of \$0.85 per share of common stock. This private placement of Series C Preferred Stock was completed on October 5, 2006, and it raised an aggregate of \$8,150,000 (including the \$2,000,000 invested by each of Crestview and Inverness). During the period between September 29, 2006 and October 5, 2006, we requested the assistance of Crestview and others in identifying prospective investors for us. On October 3, 2006, a Crestview representative informed Mr. Siebert of a conversation he had earlier that day with a fund manager who indicated that his fund would be interested in investing a substantial amount in the offering, but only at a conversion price of no more than \$0.80.

At a board of directors meeting on October 4, 2006, Mr. Siebert expressed his recommendation that the board approve lowering the conversion price to \$0.80 in order to be able to obtain the additional funds. The board discussed the \$1,300,000 promissory note bridge financing which had been completed in June 2006, the noteholders who expected to convert their notes into Series C Preferred Stock, and the restrictions on future equity sales by the Company 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 who abstained. Mr. Eppner stated that he understood the benefits of the economics of the transaction and the Company's

need to proceed so quickly, but that he did not wish to vote in favor.

17

---

At a board meeting held on October 11, 2006, the board members discussed the Series C Preferred Stock private placement. Mr. Eppner indicated that in his view it would be desirable to review the sequence of events in this transaction to assure proper guidelines for corporate governance and to determine if disclosure or other issues needed to be considered. At a board meeting held on October 26, 2006, it was discussed that a subcommittee of the audit committee, whose members would be Mr. Eppner and Alan Carus, would review certain issues related to the Series C Preferred Stock private placement.

The first meeting of the audit committee to review the Series C Preferred Stock offering was held on October 27, 2006. The audit committee decided it would review the role of Crestview in the Series C Preferred Stock offering, Crestview's status as a possible control person, the role of 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. 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 \$0.85 to \$0.80, (iii) although he agreed with Mr. Carus that the \$0.80 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.

On January 30, 2007, Gerald Eppner resigned from his position as a director of the Company, effective immediately. At the time of his resignation, as additional consideration of his time and efforts as a member of the board of directors, the Company granted Mr. Eppner \$20,000, and caused his outstanding unvested stock options to become vested immediately. In his resignation letter, Mr. Eppner stated that he did not resign due to any disagreement with the Company, or because of any matter relating to the Company's operations, policies or practices.

On December 19, 2007 (the "Closing Date"), amendments to the governing documents for the Company's Series A, Series B and Series C Convertible Preferred Stock (collectively, the "Preferred Stock") and for certain warrants and options (collectively, the "Non-Employee Warrants"), not including options or warrants issued to employees or directors in their capacity as such (these actions collectively, the "Plan"), were approved by the Company and the requisite percentages of the holders of the Preferred Stock and of the Non-Employee Warrants (See - Note 1 to the condensed consolidated financial statements). Subsequent to these amendments, all shares of Preferred Stock were converted to common stock and certain of the Non-Employee Warrants were exercised, including the following: (i) Mr. Siebert's 38.74442 shares of Series A Preferred Stock were converted into 2,421,526 shares of common stock at \$0.48 per share, his 1.08545 shares of Series B Preferred Stock were converted into 113,067 shares of common stock at \$0.48 per share, and Mr. Siebert purchased 337,500 shares of common stock through the exercise of warrants at an exercise price of \$0.40 per share, for a total of \$135,000 in cash; and (ii) Crestview's 82.32274 shares of Series B Preferred Stock were converted into 10,290,342 shares of the Company's common stock at \$0.40 per share, Crestview's 40 shares of Series C Preferred Stock were converted into 4,166,666 shares of common stock at \$0.48 per share, Crestview exercised a portion of its Series B Warrants to purchase a total of 60,451 shares of common stock for an aggregate purchase price of \$24,180.40, and Crestview exercised all of its Series C Warrants to purchase a total of 625,000 shares of common stock for an aggregate purchase price of \$250,000.

### **Director Independence**

Our common stock trades on the OTC Bulletin Board. As a result, 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.

We also are not currently subject to corporate governance standards defining the independence of our directors. We have chosen to define an “independent” director in accordance with the NASDAQ Global Market's requirements for independent directors (NASDAQ Marketplace Rule 4200). Under this definition, we have determined that Katherine L. Davis and Al Carus currently qualify as independent directors. We do not list the “independent” definition we use on our Internet website.

## DESCRIPTION OF BUSINESS

### FORWARD-LOOKING STATEMENTS

*This report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, and Section 27A of the Securities Act of 1933. Any statements contained in this report that are not statements of historical fact may be forward-looking statements. When we use the words “intends,” “estimates,” “predicts,” “potential,” “continues,” “anticipates,” “plans,” “expects,” “believes,” “should,” “could,” “may,” “will” or the negative of these terms or other comparable terminology, we are identifying forward-looking statements. Forward-looking statements involve risks and uncertainties, which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. These factors include our; research and development activities, distributor channel; compliance with regulatory impositions; and our capital needs. 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.*

*Except as may be required by applicable law, we do not undertake or intend to update or revise our forward-looking statements, and we assume no obligation to update any forward-looking statements contained in this report as a result of new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. You should carefully review and consider the various disclosures we make in this report and our other reports filed with the Securities and Exchange Commission that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.*

For further information about these and other risks, uncertainties and factors, please review the disclosure included in the “Risk Factors” section beginning on page 2.

### General

Chembio Diagnostics, Inc. (the “Company”) and its subsidiaries develop, manufacture and market rapid diagnostic tests that detect infectious diseases. The Company’s 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. These products employ single path lateral flow technology which we have licensed from Inverness Medical Innovations, Inc. (“Inverness”), which 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) and two rapid tests for detecting tuberculosis antibodies in animals for which we have received USDA approval.

On March 13, 2007, we were issued United States patent #7,189,522 for our Dual Path Platform (DPP™) rapid test system. Additional patent protection for DPP™ is pending worldwide. DPP™ enables Chembio to participate in the growing point of care diagnostics market with a patent-protected point-of-care platform technology. The independent sample strip on our DPP™ devices enables the development of products whose performance we believe exceeds that of comparable tests developed on a single path lateral flow platform. We therefore believe that as a result of the patent protection we now have with DPP™, we have a significant opportunity to develop and/or license many new rapid tests in a number of fields including but not limited to infectious diseases. During both 2007 and 2008 year to date we have made significant progress in establishing commercial opportunities for this new platform that are now in development (see Research and Development”). We have completed initial development of an oral fluid HIV test on this new platform and are currently conducting pre-clinical studies on this product. We believe the DPP™ provides significant advantages over standard single path lateral flow assays particularly where challenging sample matrices, such as oral fluid, are involved, or where multiplexing is desired. We are developing all of our new products using this

platform. Our strategy for the development of this platform technology is also dual; we are entering into exclusive collaborations with large marketing partners for whom we will develop and manufacture products on the DPP™ and we are developing our own products that we may choose to market through selected distribution partners either under a Chembio or other brand.

Our products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, and medical professionals. 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 for our rapid HIV tests in the United States.



## **Rapid HIV Tests**

The major component of our revenue growth in 2007 was increased sales of our rapid HIV tests, and most of that increase was a result of our entry into the US rapid HIV test market as a result of the launch of our tests by Inverness. 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. 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 principally 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 worldwide) and HIV 1/2 STAT-PAK (now Inverness' Clearview® HIV 1/2 STAT-PAK in the United States only) 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 for the Clearview® Complete HIV 1-2 was granted on October 22, 2007. 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. 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. In 2006 we made certain improvements to this product so that it could be run flat on an adhesive backing card as an alternative to being dipped in a vial containing the sample and buffer solution. This change made the product procedure similar to a cassette format with less cost than those associated with producing the cassette format.

Although we have received approval from a number of potential importing countries for all three of our HIV tests, Brazil, Mexico, Nigeria, Ethiopia 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 (“PEPFAR”).

## **Partners Involved in the Products:**

On September 29, 2006 we executed marketing and license agreements with Inverness. These agreements provide for the marketing of our rapid HIV tests in the United States; the agreements 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 September 2005 we were designated as the confirmatory test in Uganda's national rapid testing protocol. 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. In February 2008, Nigeria changed from a parallel algorithm to a serial algorithm, and this designation was changed to that of a confirmatory test. In October, 2007 our HIV 1/2 STAT-PAK® was designated by the Ethiopian Ministry of Health as the confirmatory test in that country's national rapid testing algorithm. We have identified and/or appointed distributors in these and other countries in Africa so that we are positioned to service those new 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 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 one-half of this order was shipped during the fourth quarter of 2006 and the balance was shipped during the first quarter of 2007. Additional orders were received and shipped during the first and second quarters of 2007 in the amount of approximately \$600,000. Absent other arrangements, which are under discussion this exception to Inverness' global exclusivity will be eliminated on September 29, 2008.

20

---

We have established or 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 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. In January 2006, the Company received a \$1.2 million order from the Pan American Health Organization to supply its 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 (the "PAHO"), headquartered in Washington D.C., is affiliated with the WHO, and this procurement was used to implement a nationwide Chagas screening program for all children under the age of 10 in endemic regions of Bolivia. Although the Company is actively looking at developing additional business opportunities for this product in those regions of Latin America that are impacted by this disease, these opportunities must be funded by donors such as the PAHO. The private commercial market for this disease is very limited. We do anticipate completing the requirements for obtaining a CE mark (Community European) for this product, and registration in Mexico, which may provide additional sales opportunities. This certification is necessary to obtain CE Markings for our products which are required in order to sell in most European countries, as well as many other countries in the world.

### **Other Products**

In 2007 our facility was licensed by the USDA to manufacture and market two products for veterinary tuberculosis. Revenues from these products have not been material and the market opportunity for the products approved thus far is limited due to certain restrictions placed on sales by the USDA pending further discussions. The USDA manufacturing facility approval is however very material to our being able to pursue collaborations to develop and manufacture other veterinary products on our DPP™ platform that would be marketed by companies that are engaged in these markets, and we are actively pursuing such collaborations. We also are involved in the development of several new products, for our own account and for others pursuant to existing and pending agreements as described below under "Research and Development".

### **Lateral Flow Technology**

All of our commercially available 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.

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 the Company with significant new product development and licensing opportunities.

During 2007 we entered a collaborative agreement with Alverix, which was formerly a business unit of Avago Technologies. Alverix has developed cost-effective reflectance and fluorescent readers that can objectively measure, quantify, record and report test results. The readers have been customized and private labeled for us to use with our DPP™ cassette. We believe that combining DPP™ with this reader feature will help to broaden the potential market applications of DPP™.

## **Target Market**

### **Rapid HIV Tests**

We believe that the September 2006 recommendations by the United States Centers for Disease Control (“CDC”) that called for testing for HIV as part of routine medical care in the United States and that reversed a long standing policy of informed consent will drive the demand for testing in the United States. Similarly, because HIV medicines have become much less expensive and more widely available, unprecedented multi-billion dollar financial commitments have been made for prevention, treatment and care. For example, the largest commitment ever to funding the fight against the epidemic in Africa and other countries was authorized by President Bush in 2003. This was a five-year, fifteen billion dollar program known as the President’s Emergency Plan for AIDS Relief, or PEPFAR. PEPFAR is now expected to be re-authorized for another five years beginning in fiscal 2009. In January 2008, President Bush stated in his State of the Union Address that PEPFAR “II” should be doubled to \$30 billion. On February 27, 2008, the Foreign Affairs Committee of the United States House of Representatives approved the reauthorization of PEPFAR in the amount of \$50 billion. Approval by the U.S. House of Representatives, the Senate, and President is pending. The other large funding source for HIV testing, care and treatment is the Global Fund for AIDS, Tuberculosis and Malaria. This fund is primarily supported by the United States (21.9% of which is appropriated from PEPFAR), the European community, Japan and certain other countries.

According to UNAIDS, as of the end of 2007, there were an estimated 33.2 million people living with HIV/AIDS worldwide. There were nearly 2.5 million new infections in 2007 and 2.1 million AIDS-related deaths in 2007. In order for more infected individuals to gain access to life-saving treatments, treatments that are made increasingly available by PEPFAR and other large bilateral and multilateral donor funded programs, testing and early detection will need to increase. Therefore, based upon the treatment goals of PEPFAR and other large programs, we believe that there will be a funded increasing global demand for several hundred million rapid HIV tests for the foreseeable future.

The marketing of our FDA-approved rapid HIV tests in the United States was 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, and also in the physicians' office laboratories. There are approximately 20-25 million HIV tests performed in clinical settings in the United States. Rapid HIV tests account for approximately 20-25% of this market, or approximately 5-6 million tests. We believe that the total number of HIV tests will continue to grow, and that the share available to rapid HIV tests will also grow.

## **Chagas Rapid Test**

Chagas disease is endemic only in regions of Latin America where 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.

## **Other Products**

### **Veterinary Tuberculosis Tests**

Tuberculosis in animal species can become a significant problem either because of potential transmission to humans, costs in lost agricultural productivity or because of 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. In 2007 we received approval from the USDA to manufacture and market our single path lateral-flow test for the detection of TB in Non-Human Primates (PrimaTB STAT-PAK™). The test can use serum, plasma, or whole blood, is simple and easy to use, has up to a 12-month shelf life at room temperature (RT) storage, and provides results within 20 minutes. This compares to the only currently available technology, the eye-lid tuberculin test, which is inconvenient, subjective, and unreliable.

## **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, which is a leading marketer of point of care diagnostic products, has significantly expanded its distribution footprint since we signed our agreement with them, and we believe that this will enhance opportunities for them to market our rapid HIV tests. In particular, Inverness has been very active in acquiring point of care product lines serving hospital emergency rooms and physicians' offices.
- Leverage our DPP™ intellectual property and regulated product development and manufacturing experience to create new collaborations where Chembio can be the exclusive development and manufacturing partner with world class marketing partners. Beginning with our Cooperative Research Development Agreement entered into in November 2006 with the United States Centers for Disease Control, we have entered several new collaborations related to DPP™ that are described below (see "Research & Development").
- Develop a small number of Chembio brand DPP™ products that capitalize on the advantages of this newly patented point of care technology and select distribution partners for such products.

## **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);
  - The ability to manufacture products cost-effectively;
    - 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 tests for detection of antibodies to infectious diseases such as HIV and Chagas disease, 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. The patent protection that we now have with our Dual Path Platform™ should enhance our ability to develop more profitable collaborative relationships and to license out the technology.

We believe our regulatory achievements are a strong asset for developing new products collaborations. There are only three companies that have approved PMA's for lateral flow rapid tests, all HIV tests: Trinity Biotech (Ireland), Orasure Technologies, Inc. (PA) and Chembio. We believe that this is a significant competitive advantage when considering new products and collaborations. During 2006 and 2007 we obtained two CLIA waivers for each of our FDA PMA approved HIV tests. These products therefore represent two of the four CLIA waived rapid HIV tests. Also, during 2007 we received facility and product licenses from the USDA, and became certified under ISO 13.485. This combination of regulatory credentials is unique.

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 if we continue our trend of improved sales and operating results. Establishment of collaborations for our DPP™ with large companies should provide us with additional credibility in the investment community and may also facilitate our access to strategic capital. The simplification of our capital structure that was completed in December 2007 should also improve our access to capital (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 March 2007 issuance 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. Additional protection of this intellectual property is pending worldwide.

Competitive factors specifically related to our HIV tests are product quality, delivery, sensitivity, specificity, ease-of-use, shelf life and price. Other factors can be sample size required, the presence of a true IgG control, and time to result. During the last few years, the competitive features of certain products produced by some international competitors have improved. In addition, these companies typically have substantially lower costs of labor, regulatory approval and compliance, and intellectual property (if any) as compared with Chembio. Price has therefore become an increasingly important factor, especially for products based upon the conventional single path lateral flow platform which are currently marketed HIV and other tests are based upon.

The leading competitors in the international rapid HIV test market are Trinity Biotech (Ireland), Inverness (U.S.) and Standard Diagnostics (Korea). Uni-Gold HIV®, marketed by Trinity Biotech of Ireland and Determine®, formerly a Japanese division of Abbott Diagnostics that is now owned by Inverness, are the market leaders in the developing world, particularly sub-Saharan Africa which is where most of the funding for rapid HIV tests is being allocated from donor funded programs such as PEPFAR. Neither of these products is FDA-approved although Trinity does manufacture in Ireland an FDA-approved rapid HIV test, Uni-Gold Recombigen, for marketing in the United States. Inverness' Organics subsidiary in Israel also has a rapid HIV test, Double Check Gold as does its subsidiary in China, ABON; neither of these products is FDA-approved. As such, while Inverness is our exclusive marketing

partner in the United States, it is also the principal competitor to our rapid HIV tests outside the United States. Furthermore, in 2007 Trinity Biotech settled litigation with Inverness, and as part of that settlement it has contracted with ABON, an Inverness subsidiary, to manufacture the Uni-Gold® HIV products for marketing outside the United States. Standard Diagnostics of Korea also has a low-cost product that has been increasingly competitive against each of the other competitors in the developing world. There are a number of additional competitors, including several based in China and India, that produce competitive rapid HIV tests, though they are not FDA approved. Nevertheless, all of these products are eligible for procurement under the current PEPFAR USAID waiver program due to the fact that there were no FDA-approved products when PEPFAR was originally authorized several years ago. In order to realize sales in the markets where the donor funds are allocated, the product must additionally be selected by a country's ministry of health or their designees to be part of a national testing protocol or "algorithm". The algorithms typically use multiple rapid tests in sequence or in parallel to screen and confirm patients at the point of care and are increasingly allowing for multiple tests to be qualified in these algorithms. Chembio's sales in Africa and certain other markets are therefore based on the fact that its test has been one of those selected. The selection process in each of these countries is very challenging based upon a number of factors, including but not limited to product performance and price.

24

---

In the developed world, particularly the United States and Europe, the competitive landscape is quite different. There are only two companies that have products that are FDA PMA approved and are CLIA-waived: Orasure Technologies (Bethlehem, PA) with OraQuick®, and Trinity Biotech Ltd. with its UniGold® Recombigen product (manufactured by Trinity at its facility in Ireland). The requirements for the PMA and CLIA waiver are difficult, costly, time-consuming, and represent a competitive advantage. We do not anticipate that Inverness has any plan to submit any of its products produced outside the U.S. to the FDA. Further, our agreements with Inverness provide that in the event one of those submissions is made (or 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 would retain a license under the Inverness lateral flow patents to market the products under a Chembio brand and/or through third party distribution partners.

The comparative competitive features of Chembio's products (marketed under Inverness' Clearview® brand in the U.S.) in comparison to the other FDA PMA approved and CLIA-waived products are shown below.

	<i>Chembio</i>	<i>Orasure</i>	<i>Trinity</i>
<b>No. of Rapid Test Formats FDA PMA approved and CLIA waived</b>	<b>2</b>	<b>1</b>	<b>1</b>
<b>Sensitivity</b>	<b>99.7%</b>	<b>99.6%*</b>	<b>100.0%</b>
<b>Specificity</b>	<b>99.9%</b>	<b>99.9%</b>	<b>99.7%</b>
<b>Analyte(s)</b>	<b>HIV 1&amp;2</b>	<b>HIV 1&amp;2</b>	<b>HIV1</b>
<b>Format(s)</b>	<b>Standard SPLF Cassette &amp; Proprietary Unitized Barrel Format</b>	<b>Oral fluid Swab connected to Standard SPLF Cassette</b>	<b>Standard SPLF Cassette</b>
<b>Sample Types</b>	<b>Plasma, Serum, Venous Whole Blood, Fingerstick Whole Blood</b>	<b>Plasma, Oral Fluid, Serum, Venous Whole Blood, Fingerstick Whole Blood</b>	<b>Plasma, Serum, Venous Whole Blood, Fingerstick Whole Blood</b>
<b>Sample Size</b>	<b>~5 microliters</b>	<b>~5 microliters</b>	<b>~50 microliters</b>
<b>U.S. Pricing</b>	<b>\$7-\$13</b>	<b>\$11.50-\$20</b>	<b>\$7.50-\$20</b>
<b>Estimated US Market Share</b>	<b>&lt;5%</b>	<b>75%</b>	<b>15%</b>
<b>US Marketing Partner</b>	<b>Inverness</b>	<b>Abbott &amp; Direct</b>	<b>Direct</b>
<b>True IgG Control</b>	<b>Yes</b>	<b>Yes</b>	<b>No</b>
<b>Shelf Life</b>	<b>24 mos.</b>	<b>6 mos.</b>	<b>12 mos.</b>
<b>* Orasure sensitivity on oral fluid are lower</b>			

Orasure has a dominant market share in the United States market. Orasure's main advantage is that its test was first to market and that, for certain market segments (primarily public health), the fact that it can be performed with oral fluid samples is an attractive feature. Orasure's Oraquick product's main disadvantages are its price, limited shelf life, that it is more difficult to use with whole blood samples, and that it is not approved for use with serum samples. Also, Orasure's claimed sensitivity with oral fluid samples is lower, and there have been some reports of performance problems on oral fluid samples. Orasure markets its products directly through its own sales organization to the public health market, has made a significant investment in that market, and has nearly 100% of this market with its oral fluid test. Orasure has an exclusive marketing arrangement with Abbott Diagnostics for its sales effort to the hospital market.



The Uni-Gold product that is marketed by Trinity accounts for an estimated 15% of the market. This product does not detect HIV-2. Though HIV-2 is a rare strain of HIV, there have been more cases identified of late. Trinity's product also requires a much larger sample size, and does not have a true IgG control. This means that a control line, which is intended to confirm that the test procedure has been performed correctly, will appear on their product so long as any liquid material is applied to its sampling area; Chembio's (and Orasure's) control line will appear only if a biological sample is applied. Trinity also relies on its own sales force to market its product, and does not have any other rapid tests to sell to distributors.

We believe Chembio, through its marketing agreement with Inverness, is well positioned to compete for market share against these two US market competitors, at least in the hospital and physicians' office market. Inverness has made a significant investment in its launch of our products and we believe this is a very important product for Inverness in the United States market. The shelf life of our HIV products' is 24 months, which is double that of Uni-Gold 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.

### **Chembio's HIV Tests**

One of our two product formats, the "barrel" format now marketed by Inverness as Clearview® Complete HIV 1-2, is a unique product format and is a unitized product (meaning that all components necessary to perform a single test are contained in a single pouch). The "barrel" has a proprietary method of collecting finger-stick whole blood samples that eliminates the need for a transfer loop or other device to transfer the sample from the fingertip to the sample well. Also, the buffer solution is in a unitized vial that is pierced by the barrel tip to initiate the sample migration up the test strip contained inside the "barrel", and thereby creates a closed system that helps to minimize possible exposure to potentially infectious samples. The "barrel" product did not receive the CLIA waiver until October 22, 2007 so sales of this product were nominal in 2007. We anticipate that sales of this format will increase in 2008.

Our other FDA PMA approved rapid HIV test, marketed by Inverness as Clearview® HIV 1-2 STAT PAK®, is a standard lateral flow plastic cassette format wherein the sample is transferred to the sample port in the cassette by means of a transfer loop. Though this step is not required in the barrel format, the cassette is less costly to manufacture, is more familiar to customers that have performed other lateral flow tests, and is a more flexible format that utilizes the same procedure for all approved sample matrices (venous whole blood, finger-stick whole blood, serum and plasma). To date this format has accounted for almost all of the sales we have had through Inverness.

We are currently pursuing certain improvements and amendments to the cassette and barrel formats which, if successfully completed, could enhance their marketability. These items include lowering of the lower age limits (currently the lower age limit is 18) of individuals that the tests are approved for. We anticipate completing the testing requirements for this amendment during the first quarter, and approval of the amendment by the FDA before the end of the second quarter.

### **Research and Development**

During 2007 and 2006, \$1.9 million and \$1.4 million, respectively, was spent on research and development activities. Substantially all of our new product development activities involve employment of our Dual Path Platform (DPP™) technology for which we were awarded a U.S patent in 2007. We believe that this platform enables us to pursue many new product development and licensing opportunities, and we have developed a dual path strategy for doing this. The DPP™ can provide improved features on certain tests developed with it that include higher sensitivity, earlier detection, use of multiple sample types including oral fluid, and improved ability to detect multiple analytes (multi-plexing) in one test device. We have completed several studies that confirm this and we are currently conducting a pre-clinical trial on our DPP™ HIV test for use with oral fluid. We also believe tests developed on our DPP™ platform, such as our oral fluid HIV test, will be simple for untrained users to perform, thereby enabling CLIA

waiver for such a product.

**We currently have the following products in development on the DPP:**

**Technology Transfer and Supply Agreements with Bio-Manguinhos**

On January 29, 2008 we signed three new technology transfer, supply and license agreements with the Bio-Manguinhos unit of the Oswaldo Cruz Foundation of Brazil for products being developed by Chembio with its patented DPP™ technology. Previously, in 2004, Bio Manguinhos and Chembio entered into a similar agreement concerning one of Chembio's HIV rapid tests.

26

---

Two of the products being developed will be used in screening programs funded by Brazil's Ministry of Health for the control and eradication of Leishmaniasis and Leptospirosis, respectively, which are both blood-borne infectious diseases that are endemic to Brazil. A third test being developed is for the confirmation of HIV-1 in patients who have tested positive with a screening test. Bio-Manguinhos, also known as the Immunobiological Technology Institute, is the largest producer of vaccines and kits for diagnosis of infectious and parasitic diseases in Latin America. Chembio's DPP™ test platform was selected for the screening programs because of its high sensitivity and specificity of prototypes evaluated by Bio-Manguinhos and because of the unique multiplexing capabilities of DPP™ for the confirmatory assay. The DPP™ point-of-care screening tests will complement the current Bio-Manguinhos national program, which currently only uses laboratory-based technologies. The HIV confirmatory test will allow for the simultaneous binding and uniform delivery of samples to multiple HIV antigens printed in the detection zone, providing results equivalent to Western blot in a simple point-of-care format that provides results within 20 minutes. Under the new agreements, once the products meet mutually agreed-upon performance specifications and are approved for sale in Brazil, Chembio will receive a minimum purchase order for at least one million tests within a one-year period. Thereafter, the agreement allows for production of the products to be transferred to Brazil, subject to certain royalty payments.

Based upon the initial prototypes we have developed for each of these products, we anticipate that these products will be successfully developed in accordance with the agreed-upon specifications. Also, based upon our experience with Bio-Manguinhos through the earlier agreement, we anticipate that the other aspects of our agreement will be successful, though there can be no assurance that this will in fact occur.

### **Cooperative Research & Development Agreement with the CDC for Syphilis Test**

In November 2006 we signed a Cooperative Research and Development Agreement (CRADA) with the United States Centers for Disease Control and Prevention to develop a rapid combination test for syphilis, capable of detecting treponemal and non-treponemal antibodies in the same device, utilizing Chembio's Dual Path Platform (DPP™) technology and the CDC's patented Syphilis antigens. This test could serve both as a screening and confirmatory test in a point-of-care setting.

Syphilis is a sexually transmitted disease (STD) caused by the bacterium *Treponema pallidum*. Infection rates have been on the increase lately; worldwide, 12 million individuals are diagnosed with syphilis each year and are at increased risk of becoming infected with and transmitting HIV. In addition, syphilis can be transmitted from an infected woman to her unborn child during pregnancy. Early and appropriate diagnosis and treatment prevents infection of the child and development of severe complications.

The difficulty in following up with patients who have undergone syphilis testing in a variety of settings and testing for syphilis in many prenatal settings are major obstacles to effective syphilis control. The development of a rapid, point-of-care test, that combines the sensitivity of a screening test with the specificity of a confirmatory test is important in aiding clinicians to provide appropriate treatment at an initial clinic visit.

While development work continues with good progress, there can be no assurance that a product will be successfully developed and/or successfully commercialized.

We have several other DPP™ research and development projects in various stages, including products that we are or may be developing under contract for third party marketing partners. There can be no assurance that any of these projects will result in completed products or that such products, if successfully completed, will be successfully commercialized.

### **Employees**

At December 31, 2007, we employed 109 people, including 97 full-time employees. Effective May 2006, we entered into an employment agreement with Lawrence Siebert, President and Chairman. Effective March 2007, we entered into an employment agreement with Javan Esfandiari, Executive Vice-President of Research and Development.

### **Governmental Regulation**

The manufacturing and marketing of the Company's 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. These regulations govern almost all aspects of development, production and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing and record keeping. The Company's FDA and USDA regulated products require some form of action by each agency before they can be marketed in the United States, and, after approval or clearance, the Company must continue to comply with other FDA requirements applicable to marketed products, e.g. CLIA regulations (for medical devices). Failure to comply with the FDA's requirements can lead to significant penalties, both before and after approval or clearance.

27

---



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

If the medical device does not qualify for the 510(k) procedure (either because it is not substantially equivalent to a legally marketed device or because it is required by statute and the FDA's implementing regulations to have an approved application), the FDA must approve a pre-market approval (PMA) application before marketing can begin. Pre-market approvals must demonstrate, among other matters, that the medical device provides a reasonable assurance of safety and effectiveness. A pre-market approval is typically a complex submission, including the results of preclinical and clinical studies. Preparing a pre-market approval is a much more expensive, detailed and time-consuming process as compared with a 510(K) pre-market notification. 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 be, and often is, much longer, often requiring one year or more, and may include requests for additional data. The Company has approved PMAs for the two rapid HIV tests now marketed by Inverness Medical as Clearview® Complete HIV 1-2 and Clearview® HIV 1-2 STAT PAK®.

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, it considers the applicability of the requirements of CLIA in the design and development of its products. The statutory definition of "laboratory" is very broad, and many of our customers are considered labs. A CLIA waiver will remove certain quality control and other requirements that must be met for certain customers to use the Company's products and this is in fact critical to the marketability of a product into the point of care diagnostics market. The Company has received a CLIA waiver for each of the two rapid HIV tests now marketed by Inverness Medical as Clearview® Complete HIV 1-2 and Clearview® HIV 1-2 STAT PAK®. The CLIA waiver was granted by the FDA for HIV 1-2 STAT-PAK on November 20, 2006 and for the Clearview® Complete HIV 1-2 on October 22, 2007.

In addition, the FDA regulates the export of medical devices that have not been approved for marketing in the United States. The Federal Food, Drug and Cosmetic Act contains general requirements for any medical device that may not be sold in the United States and is intended for export. Specifically, a medical device intended for export is not deemed to be adulterated or misbranded if the product: (1) complies with the specifications of the foreign purchaser;

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

The Company is also subject to regulations in foreign countries governing products, human clinical trials and marketing, and may need to obtain approval or evaluations by international public health agencies, such as the World Health Organization, in order to sell diagnostic products in certain countries. Approval processes vary from country to country, and the length of time required for approval or to obtain other clearances may in some cases be longer than that required for 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 Chembio that might arise from future legislative or administrative action cannot be predicted.

One or more of the Company's rapid HIV tests are also approved for marketing in several foreign jurisdictions, including but not limited to Brazil, Mexico, India and a number of other nations in the developing world.

In 2007 Chembio received certification under ISO 13485:2003. ISO (International Organization for Standardization) is the world's largest developer and publisher of International Standards. It is comprised of a network of the national standards institutes of 155 countries, one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system. ISO 13485:2003, in particular, specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services. The primary objective of ISO 13485:2003 is to facilitate harmonized medical device regulatory requirements for quality management systems. ISO 13485:2003 is the quality system that is most recognized globally, including throughout the European Community for products seeking a CE mark. Chembio has engaged a European Notified Body and Authorized Representative in connection with its plans to obtain a CE mark for its products.

## **Environmental Laws**

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

## **Intellectual Property**

### *Intellectual Property Strategy*

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 DPP™; 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. The Company possesses proprietary know-how to develop tests for multiple conditions using colored latex. 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 single path lateral flow patents, we consult with patent counsel, and seek licenses

and/or redesigns of products that we believe to be in the best interests of the Company and our stockholders. Because of the costs and other negative consequences of time-consuming 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 the Company's products will be not be granted and that licenses to such patents if any will be available on reasonable terms, if any.

In the event that it is determined that a license is required and it is not possible to negotiate a license agreement under a necessary patent, we may be able to modify 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, and/or increase penalties all of 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. The Company anticipates signing new development projects based upon these new technologies in the near future that will provide new product applications and marketing opportunities. We have also filed two patents 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.

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. In prior years we concluded license agreements related to intellectual property rights associated with HIV- 1, and during the first quarter of 2008 we entered into a license agreement for HIV-2.

### **Corporate History**

On May 5, 2004, we completed a merger with Chembio Diagnostic Systems Inc. through which Chembio Diagnostics Systems Inc. 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. In 2003, we had sold our prior business, and as a result, we had no specific business immediately prior to the merger.

Since the formation of Chembio Diagnostic Systems Inc. in 1985, it has been involved in developing, manufacturing, selling and distributing in-vitro diagnostic tests, including rapid tests beginning in 1995, for a number of conditions in humans and animals.

On March 12, 2004, we implemented a 1-for-17 reverse split of our common stock. All references to shares of our common stock in this Post Effective Amendment No. 5 to the Registration Statement have been adjusted to reflect this reverse split.

**Glossary**

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

<b>Ryan White CARE Act</b>	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.
<b>SAB</b>	Staff Accounting Bulletin
<b>SENSITIVITY</b>	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.
<b>SFAS</b>	Statement of Financial Accounting Standards
<b>SPECIFICITY</b>	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.
<b>SPUTUM</b>	Expectorated matter; saliva mixed with discharges from the respiratory passages
<b>TB</b>	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.
<b>UNAIDS</b>	Joint United Nations Program on HIV/AIDS
<b>USAID</b>	United States Agency for International Development
<b>USDA</b>	U.S Department of Agriculture
<b>WHO</b>	World Health Organization

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

**Overview**

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

In addition, certain statements made in this report may constitute "forward-looking statements". These forward-looking statements involve known or unknown risks, uncertainties and other factors that may cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Specifically, 1) our ability to obtain necessary regulatory approvals for our products; and 2) our ability to increase revenues and operating income, is dependent upon our ability to develop and sell our products, general economic conditions, and other factors. You can identify forward-looking statements by terminology such as "may," "could", "will," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continues" or the negative of these terms or other comparative 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.

Except as may be required by applicable law, we do not undertake or intend to update or revise our forward-looking statements, and we assume no obligation to update any forward-looking statements contained in this report as a result of new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. You should carefully review and consider the various disclosures we make in this report and our other reports filed with the Securities and Exchange Commission that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

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. The Company's 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. The Company also has 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 which is USDA approved. The Company's products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments. Chembio's products are sold either under the Company's STAT-PAK® or SURE CHECK® registered trademarks or under the private labels of its marketing partners, such as is the case with the Clearview® label owned by Inverness Medical Innovations, Inc., which is the Company's exclusive marketing partner for its rapid HIV test products in the United States.



## **Recent Events**

On December 19, 2007 (the “Closing Date”) amendments to the governing documents for the Company’s Series A, Series B and Series C Convertible Preferred Stock (collectively, the “Preferred Stock”) and for certain warrants and options (collectively, the “Non-Employee Warrants”) not including options or warrants issued to employees or directors in their capacity as such (these actions collectively, the “Plan”) were approved by the Company and the requisite percentages of the holders of the Preferred Stock and of the Non-Employee Warrants. Subsequent to these amendments, among other matters, all the Preferred Stock and certain of the Non-Employee Warrants were converted to shares of the Company’s common stock. A description of the terms of the Plan is included in Note 1 to the consolidated financial statements.

On February 1, 2008, we entered into a sublicense agreement with Bio-Rad Laboratories, Inc. and Bio-Rad Pasteur (collectively, "Bio-Rad"). Bio-Rad is the exclusive licensee of Institute Pasteur of Paris, France, under the HIV-2 patents. Pursuant to the terms of the Agreement, Bio-Rad sublicensed to the Company patents related to the use of HIV2. The Company will also pay Bio-Rad a royalty on net sales in the United States and Canada of rapid test immunoassay tests sold under the Company's name (a) for simultaneously detecting "HIV type 1 + HIV type 2" antibodies and/or antigens; (b) being operated with the Company's Point of Care Rapid Test Platform; and (c) allowing visual and automated signal reading and interpretation through a single test unit format. The Company will be manufacturing products under the sublicense agreement immediately, but it does not currently have any sales that are subject to the royalty. The Agreement will continue until the expiration of the last-to-expire of the sublicensed patents, unless otherwise terminated at an earlier date by the Company or Bio-Rad.

## RESULTS OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2007 AS COMPARED WITH THE YEAR ENDED DECEMBER 31, 2006

### Revenues

Selected Product Categories:	For the years ended			
	December 31, 2007	December 31, 2006	\$ Change	% Change
HIV	\$ 7,927,676	\$ 4,434,432	\$ 3,493,244	78.78%
Chagas	67,888	1,216,794	(1,148,906)	-94.42%
Other	769,313	642,786	126,527	19.68%
<b>Net Sales</b>	<b>8,764,877</b>	<b>6,294,012</b>	<b>2,470,865</b>	<b>39.26%</b>
Research grant income	466,071	208,468	257,603	123.57%
<b>Total Revenues</b>	<b>\$ 9,230,948</b>	<b>\$ 6,502,480</b>	<b>\$ 2,728,468</b>	<b>41.96%</b>

Revenues for our HIV tests during the year ended December 31, 2007 increased by \$3.5 million over the same period in 2006. This was primarily attributable to increased sales in Africa and sales to our distributor in the United States, offset by the reduction of sales to Brazil in 2006 that were not repeated in 2007. Sales of our Chagas product declined because a \$1.2 million order received in 2006 was not repeated. The increase in grant and development income was due to revenue generated from grant and feasibility studies for our DPP™ platform of which \$509,000 was received and \$466,000 was earned in 2007. The \$43,000 balance is reflected in deferred revenues. Sales to Africa (see Note 3 of the financial statements) were primarily from Nigeria of approximately \$2.7 million. We have been advised recently that our designation in Nigeria as one of the screening tests has changed to that of the confirmatory test as this country moves from a parallel to a serial testing algorithm, which we expect to significantly reduce our sales to Nigeria in 2008.

### Gross Margin:

Gross Margin related to	For the years ended			
	December 31, 2007	December 31, 2006	\$ Change	% Change
<b>Net Product Sales:</b>				
<b>Gross Margin per Statement of Operations</b>	\$ 3,862,303	\$ 2,016,568	\$ 1,845,735	91.53%
<b>Less: Research grant income</b>	466,071	208,468	257,603	123.57%
	<b>\$ 3,396,232</b>	<b>\$ 1,808,100</b>	<b>\$ 1,588,132</b>	<b>87.83%</b>

**Gross Margin from  
Net Product Sales**

<b>Gross Margin %</b>	<b>38.75%</b>	<b>28.73%</b>
-----------------------	---------------	---------------

The increase in our gross margin resulted primarily from increased quantities of our product sales and increased average unit prices on product sales to our U.S. distributor.

33

---

**Research and Development:**

This category includes costs incurred for regulatory approvals, product evaluations and registrations.

Selected expense lines:	For the years ended		\$ Change	% Change
	December 31, 2007	December 31, 2006		
<b><u>Clinical &amp; Regulatory Affairs:</u></b>				
Wages and related costs	\$ 186,428	\$ 174,489	\$ 11,939	6.84%
Consulting	40,813	78,249	(37,436)	-47.84%
Clinical Trials	29,664	61,427	(31,763)	-51.71%
Other	12,657	8,942	3,715	41.55%
<b>Total Regulatory</b>	<b>\$ 269,562</b>	<b>\$ 323,107</b>	<b>\$ (53,545)</b>	<b>-16.57%</b>
<b><u>R&amp;D Other than Regulatory:</u></b>				
Wages and related costs	\$ 952,557	\$ 756,902	195,655	25.85%
Consulting	70,237	12,605	57,632	457.22%
Share-based compensation	189,843	60,547	129,296	213.55%
Materials and supplies	300,604	135,576	165,028	121.72%
Other	123,850	112,735	11,115	9.86%
<b>Total other than Regulatory</b>	<b>\$ 1,637,091</b>	<b>\$ 1,078,365</b>	<b>\$ 558,726</b>	<b>51.81%</b>
<b>Total Research and Development</b>	<b>\$ 1,906,653</b>	<b>\$ 1,401,472</b>	<b>\$ 505,181</b>	<b>36.05%</b>

Expenses for Clinical & Regulatory Affairs for the year ended December 31, 2007 decreased by \$53,500 as compared to the same period in 2006. This was primarily due to a reduction in consulting and clinical trial expenses related to CLIA waiver for our HIV products, which were performed on both FDA approved HIV products in 2006 and repeated for only one of these products in 2007.

Expenses other than Clinical & Regulatory Affairs increased by \$558,700 in the year ended December 31, 2007 as compared with the same period in 2006 and were primarily related to an increase in the work related to feasibility studies of our DPP™ platform and grant income resulting in an increase in our personnel and material costs. In addition the cost of share-based compensation related to the value of common stock and employee stock options issued to an employee pursuant to a contract also contributed to the increase.

Subject to cash availability, the Company currently plans to continue to increase its spending on research and development in 2008 because it believes such spending will result in the deployment of new and innovative products that are based on the newly patented DPP™ technology.

The Company entered into five externally funded research agreements during 2007 that accounted for total financial commitments of \$600,000, of which \$439,000 was received by the Company during 2007 (approximately \$396,000 of which was earned in 2007 on a percentage of completion basis) with clinical diagnostics, life science, companion animal, academic, and government-affiliated public health entities. These agreements all related to potential applications for point of care tests that would employ our DPP™ technology. The Company has several Research & Development and Regulatory projects underway. Some highlights include:



### **Research & Development - Dual Path Platform (DPP™)**

During 2007 we made significant progress in implementing our strategy for the deployment of our Dual Path Platform technology. We have further confirmed that this platform technology has potential application to a broad range of point-of-care/point-of-use products and markets. We believe that our DPP™ intellectual property, product development and regulated manufacturing know-how and experience are core strengths, but that significant additional resources would be required for the associated product development and marketing needed to adequately address such a wide range of opportunities. A key aspect of our strategy is therefore to leverage our strengths in developing collaborations with premier organizations that have significant sales, marketing and distribution capabilities. We have received a substantial amount of interest in these kinds of collaborations. If successful, in each case we would be an exclusive development and long-term manufacturing partner to these companies, and the companies would also acquire an exclusive license to our DPP™ intellectual property with respect to marketing the product in the field of interest. We have several projects in discussion and in negotiation, and we anticipate that we will consummate agreements during 2008 relative to these activities. There can be no assurance however that these discussions will be successfully concluded or, even if they are, that products will be developed and successfully commercialized as a result of such agreements.

On January 29<sup>th</sup> 2008 we signed three new technology transfer, supply and license agreements with the Bio-Manguinhos (B-M) unit of the Oswaldo Cruz Foundation of Brazil for products being developed by Chembio with its patented Dual Path Platform (DPP™) technology. Previously, in 2004, B-M and Chembio entered into a similar agreement concerning one of Chembio's HIV rapid tests.

Two of the products being developed will be used in screening programs funded by Brazil's Ministry of Health for the control and eradication of Leishmaniasis and Leptospirosis, respectively, which are both blood-borne infectious diseases that are endemic in Brazil. A third test being developed is for the confirmation of HIV-1 in patients who have tested positive with a screening test. Bio-Manguinhos, also known as the Immunobiological Technology Institute, is the largest producer of vaccines and kits for diagnosis of infectious and parasitic diseases in Latin America. Chembio's DPP™ test platform was selected for the screening programs because of its high sensitivity and specificity of prototypes evaluated by Bio-Manguinhos and because of the unique multiplexing capabilities of DPP™ for the confirmatory assay. The DPP™ point-of-care screening tests will complement the current Bio-Manguinhos national program, which currently only uses laboratory-based technologies. The HIV confirmatory test will allow for the simultaneous binding and uniform delivery of samples to multiple HIV antigens printed in the detection zone, providing results equivalent to Western blot in a simple point-of-care format that provides results within 20 minutes. Under the new agreements, once the products meet mutually agreed-upon performance specifications and are approved for sale in Brazil, Chembio will receive a minimum purchase order for at least one million tests within a one-year period. Thereafter, the agreement allows for production of the products to be transferred to Brazil, subject to certain royalty payments. This is similar to Chembio's 2004 agreement with B-M for one of the Company's rapid HIV tests.

Based upon the initial prototypes we have developed for each of these products, we anticipate that these products will be successfully developed in accordance with the agreed-upon specifications. Also, based upon our experience with Bio-Manguinhos through the earlier agreement, we anticipate that the other aspects of our agreement will be successful, though there can be no assurance that this will in fact occur.

We have several other DPP™ research and development projects in various stages, including products that we are or may be developing under contract for third-party marketing partners. There can be no assurance that any of these projects will result in completed products or that such products, if successfully completed, will be successfully commercialized.

We are also pursuing under Chembio brands the development of products on the DPP™ platform that we believe will address market opportunities in point-of-care testing. We anticipate that we will select such products during the first

quarter of 2008. We are attempting to identify products that could generate attractive revenues and margins, address significant market opportunities and that would feature the unique advantages of DPP™, such as its improved sensitivity, sample management and/or multiplexing features. There can be no assurance that these efforts will be successful in developing a Chembio-branded product or products, and that if developed such product or products will be successfully commercialized.

### **Regulatory Activities**

In July 2007, we submitted to the FDA the results of our untrained user studies in connection with our pending CLIA waiver application for the HIV barrel product marketed by Inverness under the name Clearview® Complete™ HIV 1/2. In October 2007, we announced that the FDA granted a CLIA waiver for this product. We believe that CLIA waiver for this product will create additional sales opportunities for Inverness with this product that were not available previously without the CLIA waiver.

In August 2007, we received ISO 13.485 certification. ISO 13.485 is a directive of the International Standards Organization (ISO) that is specifically related to manufacturers of in-vitro diagnostic products. This certification is necessary to obtain CE (Community European) Markings for our products which are required in order to sell in most European countries, as well as many other countries in the world. We have made progress in pursuing CE Markings for all of our rapid HIV tests, which we anticipate receiving during 2008. We have also made progress in pursuing CE Marking for our Chagas rapid test, which we anticipate receiving during 2008.

35

---

During the fourth quarter we were granted an Investigational Device Exemption (IDE) by the FDA in connection with a study for which we have agreed upon a protocol with FDA. If this program is successfully completed, it would enable us and therefore Inverness to expand the age range of our two FDA-approved rapid HIV tests beyond the current 18-64 year old range down to individuals 13 years of age and above. We believe that this study and associated submission, which will be a supplement to our Pre-Marketing Approval (PMA), will be completed during the first quarter of 2008. However there is no assurance that this study will be completed successfully or that the FDA will approve these additional claims based upon our submission.

The Company received its first USDA approval during the second quarter of 2007 for manufacturing and marketing its Prima-TB STAT PAK™ test, a rapid test for the detection of active pulmonary tuberculosis in non-human primate whole blood samples. There is no assurance that commercialization of these products will be successful.

**Selling, General and Administrative Expense:**

Selected expense lines:	For the years ended		\$ Change	% Change
	December 31, 2007	December 31, 2006		
<b>Wages and related costs</b>	\$ 1,517,728	\$ 1,502,747	\$ 14,981	1.00%
<b>Consulting</b>	229,322	318,536	(89,214)	-28.01%
<b>Commissions, License and Royalties</b>	1,098,356	900,431	197,925	21.98%
<b>Options (per SFAS 123R)</b>	152,319	182,674	(30,355)	-16.62%
<b>Marketing Materials</b>	75,570	55,734	19,836	35.59%
<b>Investor Relations</b>	224,843	574,557	(349,714)	-60.87%
<b>Legal, Accounting and 404</b>	613,603	792,460	(178,857)	-22.57%
<b>Travel, Entertainment and shows</b>	121,433	186,551	(65,118)	-34.91%
<b>Bad Debt Allowance</b>	(11,210)	22,479	(33,689)	-149.87%
<b>Other</b>	809,850	659,120	150,730	22.87%
<b>Total S, G &amp; A</b>	<b>\$ 4,831,814</b>	<b>\$ 5,195,289</b>	<b>\$ (363,475)</b>	<b>-7.00%</b>

Selling, general and administrative expense for the year ended December 31, 2007 decreased by 7 percent as compared with the same period in 2006. Reduction in spending on investor relations and decreased professional fees were partially offset by increases in commission, license and royalty expenses. The decreased cost of professional fees (legal, accounting and section 404 of Sarbanes-Oxley) were related to the reduction of legal fees related a patent lawsuit that was settled in late 2006, which was partially offset by the added cost of section 404 related expenses. The increase in commission, license and royalty expenses were due to added royalty burden due to our agreements with Inverness Medical Systems, Inc. as well as the settlement with Bio-Rad Laboratories for past royalties on HIV-2 offset by reduced commissions on sales to Brazil which occurred in 2006 but were not repeated in 2007. Our periodic review of our allowance for doubtful accounts resulted in a reduction of the allowance in the year ended December 31, 2007.

As the Company's sales of its rapid test products increase, it will incur increased costs for commissions and royalties on intellectual property licenses.



**Other Income and Expense:**

Other Income and Expense	For the years ended			
	December 31, 2007	December 31, 2006	\$ Change	% Change
<b>Other income (expense)</b>	\$ 120,862	\$ 30,000	\$ 90,862	302.87%
<b>Interest income</b>	145,289	29,532	115,757	391.97%
<b>Interest expense</b>	(16,879)	(87,464)	70,585	-80.70%
<b>Loss on extinguishment of debt</b>	-	(386,895)	-	0.00%
<b>Total Other Income and Expense</b>	<b>\$ 249,272</b>	<b>\$ (414,827)</b>	<b>\$ 664,099</b>	<b>-160.09%</b>

Interest income for the year ended December 31, 2007 increased due to the additional availability of funds to invest. In addition the Company received \$133,000 in 2007, net of expenses, from New York State related to a program for qualified emerging technology companies, which was partially offset by the retirement of a fixed asset in 2007 of \$12,000, resulting in the increase in other income. The conversion of a bridge loan in 2006 related to the loss on extinguishment of debt. The lack of interest expense related to the bridge loan in 2006 and the effect of several of our operating leases approaching the end of their terms, resulted in the decrease in interest expense in 2007 over 2006.

**SELECTED FOURTH QUARTER INFORMATION FOR THE THREE MONTHS ENDED DECEMBER 31, 2007 AND 2006.**

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**SELECTED OPERATION INFORMATION**  
**FOR THE THREE MONTHS ENDED**  
**UNAUDITED**

	December 31, 2007	December 31, 2006
<b>REVENUES:</b>		
Net sales	\$ 2,160,901	\$ 2,610,413
Research grant income	215,416	(1,026)
<b>TOTAL REVENUES</b>	<b>2,376,317</b>	<b>2,609,387</b>
Cost of sales	1,150,742	1,780,163
<b>GROSS PROFIT</b>	<b>1,225,575</b>	<b>829,224</b>
<b>OVERHEAD COSTS:</b>		
Research and development expenses	521,580	339,153
Selling, general and administrative expenses	1,341,715	1,454,524
	<b>1,863,295</b>	<b>1,793,677</b>
<b>LOSS FROM OPERATIONS</b>	<b>(637,720)</b>	<b>(964,453)</b>



**Revenues:**

Selected Product Categories:	For the three months ended			
	December 31, 2007	December 31, 2006	\$ Change	% Change
HIV	\$ 2,001,279	\$ 2,464,192	\$ (462,913)	-18.79%
Chagas	6,808	15,887	(9,079)	-57.15%
Other	152,814	130,334	22,480	17.25%
<b>Net Sales</b>	<b>2,160,901</b>	<b>2,610,413</b>	<b>(449,512)</b>	<b>-17.22%</b>
<b>Research grant income</b>	215,416	(1,026)	216,442	21095.71%
<b>Total Revenues</b>	<b>\$ 2,376,317</b>	<b>\$ 2,609,387</b>	<b>\$ (233,070)</b>	<b>-8.93%</b>

Revenues for our HIV tests during the three months ended December 31, 2007 decreased by \$463,000 over the same period in 2006. This was primarily due to \$1.1 million of revenues realized during the three months ended December 31, 2006 received from a division of Bio-Rad Laboratories in Mexico that did not recur in 2007 as well as sales to Brazil of \$845,000 in 2006 that did not recur in 2007 offset by increased rapid HIV test sales to Africa of \$740,000 and to our distributor in the United States of \$875,000, including an adjustment of \$94,000 for sales prior to the fourth quarter of 2007.

**Gross Margin:**

Gross Margin related to	For the three months ended			
	December 31, 2007	December 31, 2006	\$ Change	% Change
Net Product Sales:				
<b>Gross Margin per Statement of Operations</b>	\$ 1,225,575	\$ 829,224	\$ 396,351	47.80%
<b>Less: Research grant income</b>	215,416	(1,026)	216,442	21095.71%
<b>Gross Margin from Net Product Sales</b>	<b>\$ 1,010,159</b>	<b>\$ 830,250</b>	<b>\$ 179,909</b>	<b>21.67%</b>
<b>Gross Margin %</b>	<b>46.75%</b>	<b>31.81%</b>		

Our gross margins increased for the three months ended December 31, 2007 as compared to the same period in 2006. This increase was due to several factors some of which included: a) improved average selling prices due to sales in the United States, and b) the timing of certain additional payments under our U.S. rapid HIV test marketing agreements, and c) a change in the overhead allocated to inventories based on actual results for the year.

**Research and Development:**

This category includes costs incurred for regulatory approvals, product evaluations and registrations. Clinical & Regulatory Affairs totaled \$14,000 for the three months ended December 31, 2007 as compared to \$73,600 for the same period in 2006. Research & Development costs other than Regulatory totaled \$507,600 for the three months ended December 31, 2007 as compared to \$265,600 for the same period in 2006.

Expenses for Clinical & Regulatory Affairs for the three months ended December 31, 2007 decreased by \$59,600 as compared to the same period in 2006. This was primarily due to credit for certain regulatory expenses we incurred during 2007 that we billed to our U.S. marketing partner in the fourth quarter of 2007 under our agreements.

Expenses other than Clinical & Regulatory Affairs increased in the three months ended December 31, 2007 as compared with the same period in 2006 and were primarily related to an increase in the work related to feasibility studies of our DPP™ platform and to research grants that resulted in an increase in personnel, consulting and material costs. In addition the cost of share-based compensation related to the value of common stock and employee stock options issued to an employee pursuant to a contract also contributed to the increase.

38

---

**Selling, General and Administrative Expense:**

Selling, general and administrative expense for the three months ended December 31, 2007 decreased by 7.8 percent as compared with the same period in 2006. Reduction in spending on investor relations and decreased professional fees were offset partially by increases in commission, license and royalty expenses. The decreased cost of professional fees (legal, accounting and section 404 -Sarbanes-Oxley) were related to the reduction of legal fees related to the Plan (see Note 1) of \$250,000 which were charged to paid in capital (some of this amount was charged to legal expenses in the third quarter of 2007) offset by the added cost of section 404 related expenses. The increase in commission, license and royalty expenses were due to added royalty burden due to the settlement with Bio-Rad Laboratories for past royalties on HIV-2.

**Operating Loss**

The operating loss shown was impacted by the number of adjustments described above that were made during the fourth quarter of 2007, please see our analysis of the full year results for a more complete understanding of our financial results for 2007.

**LIQUIDITY AND CAPITAL RESOURCES**

	For the years ended			
	December	December		%
	31, 2007	31, 2006	\$ Change	Change
<b>Net cash used in operating activities</b>	\$ (1,345,796)	\$ (4,202,923)	\$ 2,857,127	-67.98%
<b>Net cash used in investing activities</b>	(410,425)	(374,513)	(35,912)	9.59%
<b>Net cash provided by financing activities</b>	293,204	8,635,674	(8,342,470)	-96.60%
<b>NET (DECREASE) INCREASE IN CASH</b>	<b>\$ (1,463,017)</b>	<b>\$ 4,058,238</b>	<b>\$ (5,521,255)</b>	<b>-136.05%</b>

The Company had a decrease in cash for the year ended December 31, 2007 as compared to an increase in cash for the same period in 2006. The decrease during the 2007 period is primarily attributable to the cash used in operations. The increase during the 2006 year was primarily due to cash from the sale of additional Series B Preferred of \$1,000,000, proceeds from a bridge loan of \$1,300,000 and net proceeds from the sales of Series C Preferred of \$7,440,000, all received in 2006.

The Company had a working capital surplus of \$3,229,000 at December 31, 2007 and a working capital surplus of \$5,113,000 at December 31, 2006. Its liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenue growth; (2) the extent, if any, to which that revenue growth improves operating cash flows; (3) the Company's expenditures for research and development, facilities, marketing, regulatory approvals, and other expenditures it may determine to make; and (4) the Company's 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 2008, there are no assurances that we will be successful in raising sufficient capital.

The following table lists the future payments required on the Company's debt and certain other contractual obligations as of December 31, 2007:

<b>OBLIGATIONS</b>	<b>Total</b>	<b>Less than 1 Year</b>	<b>1-3 Years</b>	<b>4-5 Years</b>	<b>Greater than 5 Years</b>
--------------------	--------------	-------------------------	------------------	------------------	-----------------------------

<b>Capital Leases (1)</b>	\$	136,752	\$	35,832	\$	85,716	\$	15,204	\$	-
<b>Operating Leases</b>		170,880		128,160		42,720		-		-
<b>Other Long Term Obligations(2)</b>		1,775,666		897,666		810,500		27,000		40,500
<b>Total Obligations</b>	\$	<b>2,083,298</b>	\$	<b>1,061,658</b>	\$	<b>938,936</b>	\$	<b>42,204</b>	\$	<b>40,500</b>

(1) This represents capital leases used to purchase capital equipment. (Obligations inclusive of interest).

(2) 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, the Company executed several agreements by and among the Company, Inverness Medical Innovations, Inc. ("Inverness") and StatSure Diagnostic Systems, Inc. ("StatSure"). Pursuant to these agreements, Inverness markets the Company's FDA-approved rapid HIV tests under Inverness' Clearview® brand, Chembio received a nonexclusive license to Inverness' lateral flow patents, and the Company and StatSure settled their patent litigation related to the HIV barrel format product, marketed exclusively now by Inverness (except in Mexico) as Clearview Complete HIV 1/2HIV 1/2. Inverness markets Chembio's cassette format rapid HIV test under the Clearview and Chembio's HIV 1/2 STAT-PAK® brand, i.e., as Clearview HIV 1/2 STAT-PAK. This enables Chembio to have brand identity for its cassette product which Chembio markets directly, not through Inverness, outside the United States. The distribution agreements with Inverness contain gross margin sharing formulae among Inverness, the Company and, in the case of the HIV barrel product, StatSure. The specific terms of these agreements are available for review in the Company's Current Report on Form 8-K filed with the Commission on October 5, 2006 (SEC Accession No. 000085), which is incorporated by reference herein.

Inverness launched marketing of our two FDA approved rapid HIV tests in the United States during the first quarter of 2007. Though both products are now CLIA waived, we only received the CLIA waiver for the HIV barrel product in October of 2007. We believe that Inverness' distribution network in the point of care markets for HIV tests, namely hospital emergency departments, public health clinics, and physicians' offices, is outstanding and superior to the networks of the two other CLIA-waived competitive products. However, Inverness, in the development of the market for our products, is competing against a well established product manufactured by the principal competitor in the US market, Orasure Technologies. Furthermore Orasure's product has certain product features and specifications not currently available in our products being marketed by Inverness. These features and specifications include the inability to currently use our product with oral fluid samples and the current limitation of the regulatory approval of our product that is only approved for use in testing individuals that are over 18 years of age. We are currently completing steps to address these issues. There can be no assurance that we will successfully complete these steps or that, assuming we do, that Inverness will take all steps reasonably necessary to exploit the improved market opportunity in that case. We do believe however that there are other features and specifications, such as test performance (sensitivity and specificity), shelf life, ease of use, and price that we believe should help to offset those disadvantages in the interim. We therefore believe that Inverness will be successful in increasing its share of the growing United States rapid HIV test market, although there are risks and uncertainties associated with this.

During 2007 we signed a contract with the Partnership for Supply Chain Management ("PSCM") based in Washington D.C. PSCM is the organization now charged with centralizing procurement, distribution, logistics and forecasting under the United States President's Emergency Plan for AIDS Relief ("PEPFAR") and other donor-funded relief programs in the developing world. Our sales to the PEPFAR program are increasingly through this organization. However, sales into PEPFAR countries still largely depend upon being selected in national testing protocols. Currently our STAT-PAK test is designated as the confirmatory test in all of the national rapid HIV testing protocols in the Republic of Uganda, and in four of the eight parallel testing algorithms (two tests are used on each patient) adopted by the Nigerian Ministry of Health. We have been advised recently that our designation in Nigeria as one of the screening tests has changed to that of the confirmatory test as this country moves from a parallel to a serial testing algorithm. Sales to Nigeria for 2007 approximated \$2.7 million and a substantial amount is not expected to recur in 2008. In October 2007, we were also selected as the confirmatory test to be used in Ethiopia, and initial orders have been shipped to this market. Progress in being selected in additional countries is unpredictable and very price competitive.

Numerous other distribution opportunities are being pursued directly by Chembio for its HIV 1/2 STAT-PAK cassette and dipstick tests outside the United States, and progress is being made. However there can be no assurance that these

efforts will result in successful distribution arrangements.

During 2007 we sold our HIV barrel product under our SURE CHECK® brand to our distributor in Mexico, a division of Bio-Rad Laboratories, Inc. We shipped approximately \$1.4 million of this product to this customer during 2007. Our agreement with Inverness provides that this distribution arrangement, which is currently the only exception to our otherwise global exclusive agreement with Inverness for this product, was to terminate on September 29, 2007. However, during 2007 Inverness agreed to extend this carve-out to at least September 2008. We believe that additional sales may be realized to Mexico although there can be no assurance that this will occur.

With the additional revenues at higher margins as a result of the introduction of our FDA-approved rapid HIV tests in the United States, and continued growth in our export revenues from our rapid HIV tests, we increased our sales and gross margins significantly as compared with 2006. We believe that we will experience continued revenue growth from our HIV tests in 2008 as we believe that the market demand for rapid HIV tests will continue to increase in 2008, and we believe we will participate in this continued growth. We believe that growth in the United States market will occur as rapid tests continue to replace laboratory based technologies, as routine HIV testing recommendations by the CDC are increasingly implemented, and as our US marketing partner participates in this growth with our tests with our support. We also believe that the demand for rapid HIV tests will increase in the donor funded markets as large amounts of funding for testing is appropriated for PEPFAR in 2008 and beyond. However, in order to compete against manufacturers in Asia that currently dominate the supply of rapid HIV tests to PEPFAR-funded markets, we will need to underscore the quality of our fully-licensed, FDA-approved products and the justification for providing US-based manufacturers with a fair opportunity to participate in US taxpayer-funded programs. If we can continue to grow our revenues, we will also continue to realize economies of scale as we did in 2007, thereby improving margins. We have also implemented a series of process and efficiency projects that if successfully implemented will also improve margins and lower costs.

40

---



In 2007 we exclusively focused our business development efforts on Dual Path Platform (DPP™), a rapid, point-of-care testing technology platform for which we were granted a U.S. patent in March, 2007. This will continue in 2008. We have made significant progress in implementing our strategies for the deployment of our DPP technology. We have confirmed, through our own studies and those that we are performing for prospective marketing partners, that this technology has potential application to a broad range of point-of-care/point-of-use products and markets. We believe that our DPP intellectual property, product development and regulated manufacturing know-how and experience are core strengths. Because significant additional resources would be required for the associated product development and marketing needed to adequately address such a wide range of opportunities, a major aspect of our DPP business development strategy is to develop collaborations with premier organizations that have significant sales, marketing and distribution capabilities. We have received a substantial amount of interest in these kinds of collaborations. In each case we would be an exclusive development and long term manufacturing partner with these companies, and the companies would also acquire an exclusive license to our DPP intellectual property to market the product in the field of interest. Our focus is on opportunities with partners that can address large markets where the proposed product fills an unmet need. We believe that during 2008 we will complete additional commercial opportunities for the license, development and manufacture of new products based upon our DPP™ technology based upon this business development strategy.

On January 29, 2008 we signed three agreements with the Bio-Manguinhos division of the Oswald Cruz Foundation, part of Brazil's Ministry of Health, for three products (two neglected diseases, Leishmaniasis and Leptospirosis, and a confirmatory test for HIV-1) based on our DPP technology. Pursuant to these agreements, we have contracted to develop, supply and license these products, and transfer the production of these products to the Bio-Manguinhos facility. We believe that this agreement will enable us to scale up the development, validation, and production of DPP products, and this will facilitate additional development projects for DPP.

Provided we successfully develop these products and that they are granted regulatory approval in Brazil, these agreements provide us with the opportunity to realize a total of approximately \$3.4 million of product and license revenues. We anticipate that approximately \$1.7 million of these revenues will be realized during the 2<sup>nd</sup> half of 2008, and the balance in 2009. However there can be no assurance of the amount or timing of these revenues.

We are also pursuing under Chembio brands the development of products on the DPP platform that we believe will address market opportunities in point-of-care testing. We anticipate that we will select such products during the first quarter of 2008. We are attempting to identify products that could generate attractive revenues and margins, address significant market opportunities and that would feature the unique advantages of DPP™, such as its improved sensitivity, sample management and/or multiplexing features. There can be no assurance that these efforts will be successful in developing a Chembio-branded product or products, and that if developed such product or products will be successfully commercialized.

### **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 \$14,000.

*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 1.05% of accounts receivable. For example each additional 1% of accounts receivable that becomes uncollectible would reduce such balance of accounts receivable by approximately \$10,000.

*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 \$7,988,000 at December 31, 2007.

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 Company adopted the provisions of FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes (“FIN 48”) on January 1, 2007. FIN 48 prescribes a comprehensive model for recognizing, measuring, presenting and disclosing in the consolidated financial statements tax positions taken or expected to be taken on a tax return, including a decision whether to file or not to file in a particular jurisdiction.

The calculation of our tax liabilities involves the inherent uncertainty associated with the application of complex tax laws. We are subject to examination by various taxing authorities. We believe that as a result of our losses sustained to date, any examination would result in a reduction of our net operating losses rather than a tax liability. As such, we have not provided for additional taxes estimated under FIN 48, Accounting for Uncertainty in Income Taxes.

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 16,640 square feet of industrial space for \$10,680 per month. The space is utilized for research and development activities (approximately 2,600 square feet), offices (approximately 4,040 square feet) and production (approximately 10,000 square feet). The lease term expires on April 30, 2009, and the Company has 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 “Organization Within Last Five Years” section beginning on page 16 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.

42

---

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

Our common stock is quoted on the OTC Bulletin Board under the symbol “CEMI.” The table below sets forth the high and low bid prices per share of our common stock for each quarter of our two most recently completed fiscal years. These prices represent inter-dealer quotations without retail markup, markdown, or commission and may not necessarily represent actual transactions.

<b>F i s c a l</b>	<b>High</b>	<b>Low</b>
<b>Year 2007</b>	<b>Bid</b>	<b>Bid</b>
First Quarter	\$0.93	\$0.61
Second Quarter	\$0.65	\$0.47
Third Quarter	\$0.65	\$0.37
Fourth Quarter	\$0.57	\$0.26
<b>F i s c a l</b>		
<b>Year 2006</b>	<b>High</b>	<b>Low</b>
	<b>Bid</b>	<b>Bid</b>
First Quarter	\$0.75	\$0.33
Second Quarter	\$1.15	\$0.65
Third Quarter	\$0.85	\$0.68
Fourth Quarter	\$0.92	\$0.63

Rule 15g-9 of the Securities and Exchange Commission, known as the Penny Stock 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 penny stock issues. As a result of these rules, investors sometimes find it difficult to sell shares of penny stock issuers. At the present time, transactions in our common stock are not subject to the Penny Stock Rule because

our average revenue for 2005, 2006 and 2007 exceeded \$6 million per year. However, there can be no assurance that transactions in our common stock will not be subject to the Penny Stock Rule in the future.

**Holders**

As of April 2, 2008, there were approximately 905 record owners of our common stock.

43

---

## Dividends

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

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

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

## Equity Compensation Plan Information

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

Plan Category	Number of Securities		Number of Securities
	to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Remaining Available for Future Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	2,201,500	\$0.64	433,500
Equity compensation plans not approved by security holders	--	--	--
Total	2,201,500	\$0.64	433,500

## EXECUTIVE COMPENSATION

The following table summarizes all compensation recorded by the Company in each of the last two completed fiscal years for our principal executive officer, our two most highly compensated executive officers other than our principal executive officer whose annual compensation exceeded \$100,000, and 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, 2007.

Name / Principal Position	Year	Salary (\$)	Bonus (\$)	Option Awards (\$)	Stock Awards (\$)	All Other Compensation (\$)	Total (\$)
Lawrence A. Siebert	2007	\$ 249,135	\$ 26,000	\$ -	\$ -	9,314	\$ 284,449
CEO	2006	207,115	20,000	21,017	-	7,200	255,332

<b>Richard J. Larkin</b>							
	2007	\$ 153,654	\$ 15,000	\$ -	\$ -	1,304	\$ 169,958
<b>CFO</b>	2006	140,385	15,000	27,300	-	-	182,685
<b>Javan Esfandiari</b>							
	2007	\$ 180,192	\$ 21,000	\$ 99,993	\$ 89,850	\$ 5,510	\$ 396,545
<b>SVP-R&amp;D</b>	2006	150,385	12,000	41,390	-	4,800	208,575
<b>Tom Ippolito</b>							
	2007	\$ 155,481	\$ 12,000	\$ -	\$ -	\$ 381	\$ 167,862
<b>VP-Regulatory</b>	2006	140,385	9,000	7,754	-	-	157,139
<b>Richard Bruce</b>							
	2007	\$ 143,654	\$ 12,000	\$ -	\$ -	\$ 990	\$ 156,644
<b>VP-Operations</b>	2006	127,981	9,000	24,516	-	-	161,497

- 1 Salary is total base salary.
- 2 Any bonus earned was paid on a discretionary basis.
- 3 The estimated fair value of any option or common stock granted was determined at the date of grant by using the Black-Scholes option pricing model.
- 4 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.
- 5 Other compensation includes an employer match to 401(K) contributions and a car allowances where applicable.
- 44
-



## 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. Esfandiari.** On April 23, 2007, Mr. Esfandiari and the Company entered into an employment agreement (the "Employment Agreement"), effective March 5, 2007, for Mr. Esfandiari to continue as the Company's Senior Vice President of Research and Development for an additional term of three years. Mr. Esfandiari's salary under the Employment Agreement is \$185,000 for the first year, \$210,000 for the second year, and \$235,000 for the final year. Mr. Esfandiari is eligible for a cash bonus of up to 50% of his base salary for each respective year, consisting of (i) a cash bonus of up to 37.5% of his calendar year base salary based on the performance of the Company's Dual Path Platform Technology, which is directly related to certain annual revenue targets budgeted by management of the Company, and (ii) a cash bonus of up to 12.5% of his calendar year base salary that is at the complete discretion and determination of the board of directors. The Company also granted Mr. Esfandiari a stock grant of 200,000 shares of the Company's common stock. 100,000 shares vested immediately, 50,000 shares vested on the first anniversary date of the effective date of the Employment Agreement, and 50,000 shares will vest on the second anniversary of the effective date of the Employment Agreement. In addition, Mr. Esfandiari is eligible to receive up to 50,000 shares of the Company's common stock for each of 2007 and 2008 based upon the performance of the Company's Dual Path Platform Technology, which is directly related to certain annual revenue targets budgeted by management of the Company. Pursuant to the Company's 1999 Equity Incentive Plan and Stock Option Agreement, the Company also granted Mr. Esfandiari incentive stock options to purchase 300,000 shares of the Company's common stock. The price per share of these options is equal to the fair market value of the Company's common stock on April 23, 2007, which is the date on which the Agreement was entered into. 100,000 shares of the stock options vested immediately, 100,000 shares of the stock options vested on the first anniversary of the effective date of the Employment Agreement, and 100,000 shares of the stock options will vest on the second anniversary of the effective date of the Employment Agreement. 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 twelve months.

None of the other officers of the Company has an employment contract with the Company.

## OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END 2007

Name	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price (\$)	Option Expiration Date	Option Vesting Date	Foot-note
<b>Lawrence A. Siebert</b>	10,000		0.75	12/31/2008	4/17/2006	2
	10,000		0.75	5/4/2011	4/17/2006	2
	50,000		0.75	5/28/2011	4/17/2006	2, 3
	50,000		0.75	5/28/2011	1/1/2007	2, 3
	50,000		0.75	5/4/2011	5/5/2004	4
<b>Richard J. Larkin</b>	25,000		0.75	5/17/2010	4/17/2006	2
	25,000		0.75	5/17/2010	1/1/2007	2
	18,750		0.62	3/24/2011	3/24/2006	1
	18,750		0.62	3/24/2011	1/1/2007	1
	50,000		0.45	9/15/2010	5/5/2004	4
<b>Javan Esfandiari</b>	30,000		0.75	3/31/2008	4/17/2006	2
	5,000		0.75	12/31/2008	4/17/2006	2
	25,000		0.75	5/17/2010	4/17/2006	2
	25,000		0.75	5/17/2010	1/1/2007	2
	18,750		0.62	3/24/2011	3/24/2006	1
	18,750		0.62	3/24/2011	1/1/2007	1
	5,000		0.75	5/4/2011	4/17/2006	2
	25,000		0.75	5/28/2011	4/17/2006	2
	25,000		0.75	5/28/2011	4/17/2006	2
	25,000		0.75	5/28/2011	5/28/2007	2
	30,000		0.75	5/4/2011	5/5/2004	4
	100,000		0.599	4/23/2012	4/23/2007	2, 3
	100,000		0.599	4/23/2012	3/5/2008	2, 3
		100,000	0.599	4/23/2012	3/5/2009	2, 3
<b>Tom Ippolito</b>	15,000		0.62	3/24/2011	3/24/2006	1
<b>Richard Bruce</b>	5,000		0.75	12/31/2008	4/17/2006	2
	12,500		0.75	5/17/2010	4/17/2006	2
	12,500		0.75	5/17/2010	1/1/2007	2
	12,500		0.62	3/24/2011	3/24/2006	1
	12,500		0.62	3/24/2011	1/1/2007	1
	5,000		0.75	5/4/2011	4/17/2006	2
	10,000		0.75	5/4/2011	5/5/2004	4
	20,000		0.588	5/4/2011	5/5/2004	4

1 All options issued with a \$.62 exercise price were issued during 2006 as part of the Company's 1999 Option Plan. Pursuant to this plan, the Company granted 244,000 options to all employees.

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

**3** Options issued in connection with an employment contract.

**4** All other options shown were issued prior to 2006 as part of the Company's 1999 Option Plan.

**5** On February 15, 2008, the Company's Compensation Committee approved the reduction of the exercise price to \$0.48 per share of each employee stock option award issued under the 1999 Equity Incentive Plan for which the exercise price was greater than \$0.48 per share, including all options listed in this table.

46

---

**DIRECTOR COMPENSATION**

<b>Name</b>	<b>Fees Earned or Paid in Cash (\$)<sup>1</sup></b>	<b>Option Awards (\$)<sup>2</sup></b>	<b>Total (\$)</b>
Alan Carus	\$ 30,500	\$ 38,148	\$ 68,648
Gary Meller	26,750	42,090	68,840
Katherine L. Davis	23,000	33,008	56,008
Gerald Eppner <sup>3</sup>	21,500	4,782	26,282

<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 \$10,000 in meeting fees paid during 2007; (b) Mr. Eppner received a \$20,000 fee as a member of the board of directors, and \$1,500 in meeting fees paid during 2007; (c) Dr. Meller received an \$18,000 annual fee as a member of the board of directors, and \$8,750 in meeting fees; (d) Ms. Davis received an \$18,000 annual fee as a member of the board of directors, and \$5,000 in meeting fees.

<sup>2</sup> Each outside member of the board of directors is granted the right to purchase 180,000 shares of the Company's common stock with an exercise price equal to the market price on the date of the grant as part of their annual compensation. One-fifth of these options are exercisable on the date of grant, one-fifth become exercisable on the first anniversary of the date of grant, and additional one-fifths become exercisable on the second through fourth 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>3</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 once every five years stock options to acquire 180,000 shares of the Company's common stock, with an exercise price equal to the market price on the date of the grant. Stock options to acquire 36,000 shares become exercisable on the date of grant, and options to acquire an additional 36,000 shares become exercisable on the date of each of the four succeeding annual meetings of stockholders if and to the extent that the non-employee director is reelected as a director at each such annual meeting. 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.

**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 S-1 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>.

**CHEMBIO DIAGNOSTICS, INC. AND  
SUBSIDIARIES**

**Index to Consolidated Financial Statements**

**—INDEX—**

	<b>Page(s)</b>
Report of Registered Independent Public Accounting Firm	F-2
<b>Consolidated Financial Statements:</b>	
<b>Balance Sheets</b>	
December 31, 2007 and 2006	F-3
<b>Statements of Operations</b>	
Years ended December 31, 2007 and 2006	F-4
<b>Statements of Changes in Stockholders' Equity (Deficit)</b>	
Year ended December 31, 2006	F-5
<b>Statements Of Changes in Stockholders' Equity (Deficit)</b>	
Year ended December 31, 2007	F-6
<b>Statements of Cash Flows</b>	
Years ended December 31, 2007 and 2006	F-7 - F-8
Notes to Consolidated Financial Statements	F-9 - F-25

**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, 2007 and 2006 and the consolidated statements of operations, stockholders' equity (deficit) and cash flows for the two years in the period ended December 31, 2007. 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, 2007 and 2006, and the consolidated results of its operations and its cash flows for the two years in the period ended December 31, 2007 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 7, 2008

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

- ASSETS -

	2007	2006
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 2,827,369	\$ 4,290,386
Accounts receivable, net of allowance for doubtful accounts of \$10,045 and \$42,967 for 2007 and 2006, respectively	946,340	1,350,240
Inventories	1,453,850	1,108,950
Prepaid expenses and other current assets	243,748	204,092
<b>TOTAL CURRENT ASSETS</b>	<b>5,471,307</b>	<b>6,953,668</b>
<b>FIXED ASSETS, net of accumulated depreciation</b>		
	<b>829,332</b>	<b>603,603</b>
<b>OTHER ASSETS:</b>		
Deposits and other assets	284,358	349,306
	<b>\$ 6,584,997</b>	<b>\$ 7,906,577</b>

**- LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)-**

<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$ 2,175,791	\$ 1,709,939
Deferred research and development revenue	43,334	-
Accrued interest payable	-	93,160
Current portion of obligations under capital leases	23,458	37,336
<b>TOTAL CURRENT LIABILITIES</b>	<b>2,242,583</b>	<b>1,840,435</b>
<b>OTHER LIABILITIES:</b>		
Obligations under capital leases - net of current portion	79,588	7,081
Series C preferred stock redemption put	-	449,677
<b>TOTAL LIABILITIES</b>	<b>2,322,171</b>	<b>2,297,193</b>

**COMMITMENTS AND CONTINGENCIES**



**PREFERRED STOCK - Series C**

7% Redeemable Convertible - \$.01

par value: None and 165 shares

issued and outstanding as of 2007

and 2006.

- 6,549,191

**STOCKHOLDERS' EQUITY****(DEFICIENCY):**Preferred Stock – 10,000,000 shares  
authorized:

Series A 8% Convertible - \$.01 par

value: None and 149.92119 shares

issued and outstanding as of 2007

and 2006, respectively.

- 2,504,313

Series B 9% Convertible - \$.01 par

value: None and 113.93591 shares

issued and outstanding as of 2007

and 2006, respectively.

- 3,555,786

Common stock - \$.01 par value;

100,000,000 shares authorized

60,537,534 and 11,296,961 shares

issued and outstanding as of 2007

and 2006, respectively

605,375 112,970

Additional paid-in capital

39,003,148 19,960,618

Accumulated deficit

(35,345,697) (27,073,494)

**TOTAL STOCKHOLDERS'****EQUITY (DEFICIENCY)**

4,262,826 (939,807)

\$ 6,584,997 \$ 7,906,577

*See accompanying notes*

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**FOR THE YEARS ENDED**

	December 31, 2007	December 31, 2006
<b>REVENUES:</b>		
Net sales	\$ 8,764,877	\$ 6,294,012
Research grant income	466,071	208,468
<b>TOTAL REVENUES</b>	<b>9,230,948</b>	<b>6,502,480</b>
Cost of sales	5,368,645	4,485,912
<b>GROSS PROFIT</b>	<b>3,862,303</b>	<b>2,016,568</b>
<b>OPERATING EXPENSES:</b>		
Research and development expenses	1,906,653	1,401,472
Selling, general and administrative expenses	4,831,814	5,195,289
	<b>6,738,467</b>	<b>6,596,761</b>
<b>LOSS FROM OPERATIONS</b>	<b>(2,876,164)</b>	<b>(4,580,193)</b>
<b>OTHER INCOME (EXPENSES):</b>		
Other income	120,862	30,000
Loss on extinguishment of debt	-	(386,895)
Interest income	145,289	29,532
Interest expense	(16,879)	(87,464)
	<b>249,272</b>	<b>(414,827)</b>
<b>LOSS BEFORE INCOME TAXES</b>	<b>(2,626,892)</b>	<b>(4,995,020)</b>
Provision for income taxes	-	-
<b>NET LOSS</b>	<b>(2,626,892)</b>	<b>(4,995,020)</b>
Dividends payable in stock to preferred stockholders	1,385,593	1,022,897
Non-recurring deemed dividend	4,259,717	-
Dividend accreted to preferred stock for associated costs and a beneficial conversion feature	-	2,187,149
<b>NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS</b>	<b>\$ (8,272,202)</b>	<b>\$ (8,205,066)</b>
<b>Basic and diluted loss per share</b>	<b>\$ (0.57)</b>	<b>\$ (0.80)</b>
<b>Weighted average number of shares outstanding, basic and diluted</b>	<b>14,608,478</b>	<b>10,293,168</b>

*See accompanying notes*

F-4

---

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS 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	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Amount	Amount	Amount
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)	\$ 1,052,000
<b>Preferred Stock</b>									
<b>Issued:</b>									
Cash	-	-	20.00000	1,000,000	-	-	(112,750)	-	887,250
Fees	-	-	2.00000	100,000	-	-	(100,000)	-	-
Dividends	-	-	1.79797	89,899	-	-	(89,899)	-	-
Recognition of fair value to warrants	-	-	-	(481,470)	-	-	1,880,185	-	1,398,715
Recognition of value of beneficial conversion	-	-	-	(463,434)	-	-	2,187,149	-	1,723,715
Conversion of preferred	-	366,563	-	508,751	-	-	-	(1,022,897)	(147,573)
Conversion of beneficial conversion	-	-	-	463,434	-	-	-	(2,187,149)	(1,723,715)
Payment of dividends	-	(369,123)	-	(473,982)	959,608	9,596	633,284	-	(200,000)
<b>Common Stock</b>									
<b>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	-	139,638
<b>Warrants and Options:</b>									
Consultants/Advisory	-	-	-	-	-	-	137,022	-	137,022
For CEO warrant	-	-	-	-	-	-	34,000	-	34,000
Exercised	-	-	-	-	240,691	2,407	143,914	-	146,311
Issued for bridge	-	-	-	-	-	-	-	-	-