CHEMBIO DIAGNOSTICS, INC.
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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 up to an aggregate of 2,838,379 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 10, 2010 the closing bid and ask prices for one share of our common stock were $.20 and $.22, 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 March 23, 2010

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PROSPECTUS SUMMARY

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

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 241,443 outstanding restricted shares, up to an aggregate of 2,707,754 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. 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.

Our Business

Chembio Diagnostics, Inc. (referred to collectively with its subsidiary as the "Company") and its subsidiary develop, manufacture and market rapid point-of-care diagnostic tests (POCTs) that detect infectious diseases. The Company's main products presently commercially available are four rapid tests for the detection of HIV antibodies. Three of these products employ lateral flow technology, can be used with all blood matrices as samples, and are manufactured in a standard cassette format, a dipstick format, and a proprietary barrel format. The tests employing the cassette and proprietary barrel formats were approved by the FDA in 2006 and are distributed by Inverness Medical Innovations, Inc. ("Inverness") in the United States. Our fourth rapid HIV test, which we more recently developed on our patented Dual Path Platform (DPP®) technology, detects antibodies to HIV in oral fluid samples, as well as all blood matrices.

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® has been issued or is pending worldwide. We participate in the point of care segment of the nearly $40 billion global in-vitro diagnostic market. The global point of care segment of the IVD industry is estimated to be $6-8 billion with an overall growth rate of 7% per annum. POCTS, by providing prompt and early diagnosis, can reduce patient stays, lower overall costs, improve therapeutic interventions and improve patient outcomes as a result of prompt & early diagnosis. They can also prevent needless hospital admissions, simplify testing procedures, avoid delays from central lab batching, and eliminate the need for return visits. This is not to say that every test should be done at the point of care. A careful analysis needs to be performed when evaluating whether there is a need for a rapid point of care test versus a laboratory test.

In the areas of infectious and sexually transmitted diseases (such as Influenza and HIV for example), the utility of a rapid point of care test has been well established, and large markets have been established for these kinds of tests globally. It is within these areas of infectious diseases and sexually transmitted diseases, which tend to have the higher growth rates in the point of care segment where we have and will continue to focus our business, with an emphasis on the U.S. market.

Summary Financial Data

The following table presents summary historical financial information for the fiscal years ended December 31, 2009 and 2008. 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.

	For The Years Ended	
	December 31, 2009	December 31, 2008
Revenue	$ 13,834,248	$ 11,049,571
Operating Expenses	5,543,078	5,922,389
Net Profit (Loss)	309,060	(1,948,770)
Current Assets	4,667,102	4,065,715
Total Assets	6,315,250	5,914,941
Current Liabilities	3,173,132	2,401,801
Total Liabilities	3,227,336	3,337,609
Stockholders' Equity	3,087,914	2,577,332

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.

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 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. In 2007, we received ISO 13.485 certification, in 2008, we received a CE registration for our Chagas test, and during 2009 we expected to receive CE registration for our two FDA approved HIV tests. However, additional data and documentation has been requested and there are no assurances that we will be able to secure this certification although 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 the 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 have developed 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 still have technical, manufacturing, regulatory and marketing challenges to meet before we will know whether we can successfully commercialize products incorporating this technology. There can be no assurance that we will overcome these challenges.

We have granted Inverness exclusive rights to market our SURE CHECK® HIV 1/2 in the United States and non-exclusive rights in the rest of the world and exclusive rights to market our HIV 1/2 STAT PAK® in the U.S. only. 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 several 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.

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

Although we have been granted non-exclusive licenses to the lateral flow patents owned by Inverness Medical Innovations, 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 Immunoassay Device patent application was 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 studies. We believe that this new 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 products. For example, the development of a safe and effective vaccine to HIV or treatments for other diseases or conditions that our products are designed to detect, could reduce, or eventually eliminate, the demand for our HIV or other diagnostic products and result in a loss of revenues.

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

Introducing and achieving market acceptance for our rapid HIV tests and other new products will require substantial marketing efforts and will require us or our contract partners, sales agents, or distributors to make significant expenditures of time and money. In some instances we will be significantly or totally reliant on the marketing efforts and expenditures of our contract partners, sales agents, distributors. 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.

Our revenues and gross margins have increased significantly in recent periods, and our operating and net losses have decreased significantly in recent periods. Nevertheless, prior to 2009 we sustained significant operating losses since 2004. At December 31, 2009, we had a stockholders' equity of $3.08 million and a working capital surplus of $1.49 million. The Company estimates that its resources are sufficient to fund its needs through the end of 2010 and beyond or that, in the alternative, it could raise additional capital although the terms under which that capital could be raised would likely be very dilutive to current shareholders. The Company's liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenues (the Company received $340,000 in 2009 for license fees for which we need to meet certain milestones to earn); (2) the extent to which, if any, that revenue level improves operating cash flows; (3) the Company's investments in research and development, facilities, marketing, regulatory approvals, and other investments it may determine to make; and (4) the Company's investment in capital equipment (including production equipment of $323,500 that the Company has contracted for) and the extent to which it improves cash flow through operating efficiencies. There are no assurances that the Company will remain profitable or generate positive cash flow in 2010 or, in the alternative, be successful in raising sufficient capital to fund its needs through 2010.

Approval and launch of our DPP® products in Brazil during 2010 and increased sales to other developing world markets in 2010 is critical to our business plan, if we fail to meet this objective, we may not generate revenues in the amounts we expect, or in amounts necessary to fund our planned research, development and regulatory expenses in 2010.

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;
- competition;
- pricing; 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 some foreign patents issued, and we are seeking additional patent protection in several other foreign jurisdictions for our DPP® technology. We have licenses to reagents (antigens and peptides) used in several of our products and products under development We also have a license to manufacture, use and sell products used to screen for antibodies to HIV-2. In addition, our SURE CHECK®, DPP® and STAT-PAK® trademarks have been registered in the U.S. Despite our efforts to protect our proprietary assets, and respect the intellectual property rights of others, we participate in several markets where intellectual property rights protections are of little or no value. This can place our products and our company at a competitive disadvantage.

During 2008 and in the first quarter of 2009 we terminated a number of employees who have had access to proprietary and confidential information. In connection with the termination of several of these employees whose positions were terminated, individuals executed severance agreements that include strong covenants by these former employees to keep our proprietary information confidential. Despite these and other efforts we make to protect our confidential information, such as entering confidentiality agreements in connection with new business opportunities, 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. 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, geographic considerations, our ability to offer competitive compensation , relocation packages, benefits, and/or other reasons.

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, provides that Mr. Siebert will serve as the Chief Executive Officer and President of the Company for an additional three-year term through May 11, 2012. The contract with Mr. Esfandiari has a term of three years ending March 2013. 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 PEPFAR Program, UN Global Fund initiatives and other programs funded by large donors. We have initiated several strategies to participate in these programs, such as introduction of our DPP® HIV test for use with oral fluid samples. Participation in these programs requires alignment and engagement 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, foreign governments and their agencies, 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.

Although we were profitable in 2009, we have a history of incurring net losses and we cannot be certain that we will be able to sustain profitability.

Since the inception of Chembio Diagnostic Systems, Inc. in 1985 and through the period ended December 31, 2008, we have incurred net losses. As of December 31, 2009, we have an accumulated deficit of $37 million. We incurred net losses of $1.9 million and $2.6 million in 2008 and 2007, respectively, while showing a net profit of $309,000 in 2009.

We expect to make substantial expenditures for sales and marketing, and continue to make expenditures for regulatory submissions, product development and other purpose that may make it more difficult to maintain profitability for any given period or periods. Our ability to continue 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, or adequately control and reduce our operating costs, our operating results would be materially harmed.

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

We may be held liable if any of our products, or any product which is made with the use or incorporation of any of the technologies belonging to us, causes injury of any type or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or usage. We have obtained product liability insurance, we have never received a product liability claim, and have generally not seen product liability claims for screening tests that are accompanied by appropriate disclaimers. Nevertheless, in the event there is a claim, 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

In the past, our Common Stock has been 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.

In the past, our Common Stock has been 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 2007, 2008 and 2009 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 101,000 shares per day over the three months ended March 1, 2010. 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 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.

As of March 10, 2010, our Common Stock was trading at $0.22 cents per share. If a large number of selling stockholders sell in large amounts after the post-effective amendment to the registration statement is declared effective, significant downward pressure could be placed on our stock price.

Holders of our Common Stock will experience substantial dilution, and a possible resulting decrease in the value of their shares of our Common Stock, upon the exercise of warrants underlying common stock that we are currently registering.

There are 2,713,754 shares of common stock underlying warrants and 124,625 shares of common stock underlying options registered in this registration statement. As of March 10, 2010, we have approximately 8.4 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 Shareholder Rights Agreement could discourage unsolicited takeover proposals.

We have adopted a Shareholder Rights Agreement, which under certain circumstances would significantly impair the ability of third parties to acquire control of us without prior approval of our Board of Directors thereby discouraging unsolicited takeover proposals. The rights issued under the Shareholder Rights Agreement would cause substantial dilution to a person or group that attempts to acquire us on terms not approved in advance by our Board of Directors.

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 Stockholders are 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 2,838,379 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 March 10, 2010 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	-	-
Alpha Capital AG [1]	1,894,024	548,113	1,345,911	2.15 %
BCMF Trustees, LLC	318,060	318,060	-	-
Bio-Business Science & Development LTDA [3]	327,721	327,721	-	-
BioEquity Partners, Inc. [3]	109,375	84,375	25,000	*
Bristol Investment Fund, Ltd.	219,740	219,740	-	-
Bushido Capital Master Fund, LP	1,891,144	195,638	1,695,506	2.73 %
CFRR Holdings, LLC	4,843	4,843	-	-
Cranshire Capital, LP	616,376	78,125	538,251	*
Ferrari, Braden	4,688	4,688	-	-
Imas, Ariel	6,250	6,250	-	-
Iroquois Master Fund, Ltd.	54,935	54,935	-	-
Kreger, Richard H.	1,090,404	188,230	902,174	1.45 %
Longview Fund, LP	1,467,128	390,625	1,076,503	1.73 %
Midtown Partners & Co., LLC [2]	261,122	40,522	220,600	*
Nnorom, Joseph [3]	6,000	6,000	-	-
Pierce Diversified Strategy Master Fund, LLC - Series BUS	760,481	195,313	565,168	*
Ralph Rabman	3,524	3,524	-	-
RHK Midtown Partners LLC	20,833	20,833	-	-
Rohan, J. Rory [2]	548,994	46,721	502,273	*
Smith, Robin	24,000	24,000	-	-
Tyson, John [3]	16,250	16,250	-	-
TOTALS	9,709,765	2,838,379	6,871,389	

* Less than 1%

(A) Includes 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] NASD member, assisted the Company in fundraising.
[3] Provided marketing consulting services.

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.

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DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS, CONTROL PERSONS

Directors and Executive Officers

Lawrence A. Siebert (53), President, Chief Executive Officer and Director. Mr. Siebert was appointed President of Chembio Diagnostics, Inc. and a member of our board of directors upon consummation of the merger. Mr. Siebert has been Chairman of Chembio Diagnostic Systems Inc. for approximately thirteen years and its President since May 2002. Mr. Siebert's background is in private equity and venture capital investing. From 1982 to 1991, Mr. Siebert was associated with Stanwich Partners, Inc, which during that period invested in middle market manufacturing and distribution companies. From 1992 to 1999, Mr. Siebert was an investment consultant and business broker with Siebert Capital Corp. and Siebert Associates LLC, and was a principal investor in a privately held test and measurement company which was sold in 2002. Mr. Siebert received a JD from Case Western Reserve University School of Law in 1981 and a BA with Distinction in Economics from the University of Connecticut in 1978. Mr. Siebert as president and CEO is an integral part of the Chembio management team. His experience in the rapid test field and financing markets made him an excellent candidate for serving on the board and as its chairman.

Richard J. Larkin (53), 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 (43), 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 (56), Vice President, Operations. Mr. Bruce was hired in April 2000 as Director of Operations. He is responsible for manufacturing, maintenance, inventory, shipping, receiving, and warehouse operations. Prior to joining Chembio Diagnostic Systems Inc., he held director level positions at Wyeth Laboratories from 1984 to 1993. From 1993 to 1998, he held various management positions in the Operations department at Biomerieux. From 1998 to 2000, he held a management position at V.I. Technologies. Mr. Bruce has over thirty 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.

Tom Ippolito (47), VP of Regulatory Affairs, QA and QC. Mr. Ippolito joined Chembio in June 2005. He has over twenty years experience with in vitro diagnostics for infectious diseases, protein therapeutics, vaccine development, Process Development, Regulatory Affairs and Quality Management. Over the years, Mr. Ippolito has held Vice President level positions at Biospecific Technologies, Corp. from 2000 - 2005, Director level positions in Quality Assurance, Quality Control, Process Development and Regulatory Affairs at United Biomedical, Inc. from 1987 -

2000. Mr. Ippolito is the Course Director for "drug development process" and "FDA Regulatory Process" for the BioScience Certificate Program at the New York State University of Stony Brook, a program he has been a part of since its inception in 2003.

Dr. Gary Meller (59), 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 was a limited partner and a member of the Advisory Board of Crestview Capital Master LLC, which was 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. Dr. Meller's experience in the medical field both domestic and foreign (especially his experience with CommSense Inc.) as well as his financing experience made him an excellent candidate for serving on the board.

Kathy Davis (53), 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 each of the Audit Committee and the Nominating And Corporate Governance Committee. Since January 2007, Ms. Davis has been the owner of Davis Design Group LLC, a company that provides analytical and visual tools for public policy design. Previously, from February 2005 to December 2006, 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, 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, University of Evansville Institute of Global Enterprise, Purdue College of Science Dean's Leadership Council and Indiana University School of Public and Environmental Affairs Dean's Advisory 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. Ms. Davis has varied experience in business, political and financial areas made her an excellent candidate for serving on the board.

Section 16(a) Beneficial Ownership Reporting Compliances

Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), requires the Company's directors, executive officers and beneficial owners of more than 10% of the Company's common stock to file with the Securities and Exchange Commission initial reports of ownership and reports of changes in ownership of common stock and other equity securities of the Company. The Company believes that during the year ended December 31, 2009, each person who was an officer, director and beneficial owner of more than 10% of the Company's common stock complied with all Section 16(a) filing requirements, except for the following: (i) one Form 4 for Gary Meller filed on October 30, 2009 that covered two reports and three transactions that were not reported on a timely basis; and (ii) one Form 4 for Lawrence Siebert filed on October 30, 2009 that covered one report and seven transactions; (iii) one Form 4 for Richard Larkin filed on October 30, 2009 that covered one report and seven transactions; (iv) one Form 4 for Katherine Davis that covered one report and two transactions; and (iv) one Form 4 for Javan Esfandiari that covered one report and eleven transactions.

Code of Ethics

The Company has adopted a code of ethics that applies to its principal executive officer, principal financial officer, principal accounting officer, controller, and persons performing similar functions. A copy of the Company's code of ethics is available on the Company's website at www.chembio.com.

Identification of Audit Committee; Audit Committee Financial Expert

The Company's board of directors has established an audit committee. Katherine L. Davis and Dr. Gary Meller each serves on the audit committee, with Ms. Davis serving as chairman. The Company's board of directors has determined that Ms. Davis is an audit committee financial expert and is independent.

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

The following table sets forth certain information regarding the beneficial ownership of our common stock by each person or entity known by us to be the beneficial owner of more than 5% of the outstanding shares of common stock, each of our directors and each of our "named executive officers" and all of our directors and executive officers as a group as of March 1, 2010.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Owner	Percent of Class	
Siebert, Lawrence (1) 3661 Horseblock Road Medford, NY 11763	6,933,615	11.10	%
Esfandiari, Javan (2) 3661 Horseblock Road Medford, NY 11763	777,573	1.24	%
Larkin, Richard (3) 3661 Horseblock Road Medford, NY 11763	267,672	0.43	%
Ippolito, Tom (4) 3661 Horseblock Road Medford, NY 11763	65,000	0.10	%
Bruce, Richard (5) 3661 Horseblock Road Medford, NY 11763	135,075	0.22	%
Meller, Gary (6) 3661 Horseblock Road Medford, NY 11763	534,300	0.86	%
Davis, Katherine L. (7) 3661 Horseblock Road Medford, NY 11763	150,650	0.24	%
GROUP (8)	8,863,585	13.89	%
Inverness Medical Innovations, Inc. 51 Sawyer Road, Suite 200 Waltham, MA 02453	5,367,840	8.66	%
Crestview Capital Offshore Fund, Inc. 95 Revere Drive, Suite A Northbrook, IL 60062	3,356,040	5.41	%

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

The beneficial ownership percent in the table is calculated with respect to the number of outstanding shares (61,944,901) of the Company's common stock outstanding as of March 11, 2010. 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.

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 2008, 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 2008.

(1) Includes 485,000 shares issuable upon exercise of options exercisable within 60 days. Does not include 400,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(2) Includes 557,500 shares issuable upon exercise of options exercisable within 60 days. Does not include 300,000 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. Does not include 275,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(4) Includes 65,000 shares issuable upon exercise of options exercisable within 60 days. Does not include 225,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(5) Includes 135,000 shares issuable upon exercise of options exercisable within 60 days. Does not include 225,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(6) Includes 234,000 shares issuable upon exercise of options exercisable within 60 days. Does not include 300,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(7) Includes 150,650 shares issuable upon exercise of options exercisable within 60 days. Does not include 300,000 shares issuable upon exercise of options that are not exercisable within the next 60 days.
(8) Includes footnotes (1)-(8).

Equity Compensation Plan Information

Combined Equity Compensation Plans - Information as of December 31, 2009				
Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)		Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column (a) (c)
Equity compensation plans approved by security holders1	5,586,900	1	$ 0.152	1,821,350
Equity compensation plans not approved by security holders	--		--	--
Total	5,586,900		$ 0.152	1,821,350

1 The “Number of Securities to be Issued Upon Exercise of Outstanding Warrants and Rights” represents 2,408,250 from the 1999 Stock Option Plan and 3,178,650 under the 2008 Stock Incentive Plan. The “Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans” represents shares issuable under the 2008 Stock Incentive Plan.

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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 305,904 shares of common stock.

DISCLOSURE OF COMMISSION POSITION OF INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

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

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

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TRANSACTIONS WITH RELATED PERSONS, PROMOTERS AND CERTAIN CONTROL PERSONS

The executive officers of the Company are as follows: Lawrence A. Siebert, president and chairman of the board of directors of the Company, Richard J. Larkin, chief financial officer of the Company, and Javan Esfandiari, executive vice president of Research and Development of the Company.

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 Stock Option 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 owned by the Company's officers and directors at that time under the 1999 Stock Option 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 existing officers at that time options to purchase the Company's common stock under the 1999 Stock Option Plan as follows: (i) Mr. Siebert, 75,000 options; (ii) Mr. Larkin, 75,000 options; (iii) Mr. Esfandiari, 60,000 options; (iv) Mr. Bruce, 50,000 options; (v) Mr. Ippolito, 50,000 options; and (vi) Mr. Aromando, 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. 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.

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. Mr. Aromando left the employ of the Company in August 2008 and since then his options have expired.

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, with beneficial ownership of approximately 30.5 percent of our common stock.

As referred to above, in January 2005, for a purchase price of $3 million, Crestview acquired 60 shares of our Series B Preferred Stock, and warrants to purchase 4,672,130 shares of our common stock at a warrant exercise price of $0.61 per share. As described below, in December 2007, these shares of Preferred Stock and warrants were exchanged for shares of the Company's common stock.

In March 2006, for a purchase price of $1 million, Crestview acquired 20 shares of Series B Preferred Stock 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.

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.

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. 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: 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; Mr. Larkin on December 19, 2007 pursuant to the Plan converted .50392 shares of his Series A Preferred Stock into 37,794 shares of common stock at $.40 per share, in addition he received 369 shares of common stock as payment of

dividends on the series A preferred. He also received 3,050 shares of common stock in the exercise of warrants pursuant to the Plan at $.40 per share, or a total of $1,220 in cash, Inverness' 40 shares of Series C Preferred Stock were converted into 4,166,666 shares of common stock, and Inverness 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 and Crestview's 82.32274 shares of Series B Preferred Stock were converted into 10,290,342 shares of the Company's common stock, Crestview's 40 shares of Series C Preferred Stock were converted into 4,166,666 shares of common stock, 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.

In June 2008, pursuant to the Plan (see above), Mr. Siebert, exercised 2,205,731 warrants, on a cashless basis, into 332,940 shares of common stock, Mr. Larkin exercised 27,436 warrants, on a cashless basis, into 4,141 shares of common stock, and Crestview exercised 6,169,055 warrants, on a cashless basis, into 931,177 shares of common stock.

During the quarter ended December 31, 2008, Inverness notified the Company that Inverness had entered into a contract with Bio-Rad Laboratories, Inc. ("Bio-Rad") for royalties on Bio-Rad's patent for the detection of HIV-2 antibodies. The agreement also provided for Inverness to pay past royalties. The agreements between the Company and Inverness provide that the Company is to share in this expense and as such Inverness requested it be reimbursed for the Company's share of past royalties. The Company negotiated with Inverness that this liability is to be paid from future revenues over approximately the next 18 months. In addition Inverness agreed to allow Chembio to pay its royalty obligation to Inverness on Chembio's sales to third parties in the same way and over the same period.

On May 7, 2009, the Compensation Committee of the Company reduced, to $0.13 per share, the exercise price of each outstanding employee option that was issued under the 1999 Equity Incentive Plan (the "1999 Plan") for which the exercise price was greater than $0.44 per share of the Company's common stock. There was no other change made to the terms of the stock options other than the reduction in the exercise price. A total of 1,036,750 options were affected. Mr. Siebert, Mr. Esfandiari and Mr. Larkin had options to purchase common stock that were so reduced of 160,000, 497,500 and 137,500, respectively.

In addition, on May 7, 2009 in accordance with the terms of the Company's 2008 Stock Incentive Plan, the Company granted certain employees of the Company, options to purchase an aggregate of 2,925,000 shares of the Company's common stock. The exercise price for these options is equal to $0.13 per share. The options become exercisable in thirds on the first, second and third anniversaries of the date of the grant. 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. Mr. Siebert, Mr. Esfandiari and Mr. Larkin received options to purchase common stock of 400,000, 300,000 and 275,000, respectively.

Director Independence

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

We are not currently subject to corporate governance standards defining the independence of our directors, and we have chosen to define an "independent" director in accordance with the NASDAQ Global Market's requirements for independent directors. Under this definition, we have determined that Katherine L. Davis currently qualifies as independent director. We do not list the "independent" definition we use on our Internet website.

DESCRIPTION OF BUSINESS

FORWARD-LOOKING STATEMENTS

This prospectus 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 prospectus 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 t 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 channels, 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 prospectus 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 prospectus 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 this prospectus under "Risk Factors".

Chembio Diagnostics, Inc. (referred to collectively with its subsidiary as the “Company”) and its subsidiary develop, manufacture and market rapid point-of-care diagnostic tests (POCTs) that detect infectious diseases. The Company’s main products presently commercially available are four rapid tests for the detection of HIV antibodies. Three of these products employ lateral flow technology, can be used with all blood matrices as samples, and are manufactured in a standard cassette format, a dipstick format, and a proprietary barrel format. The tests employing the cassette and proprietary barrel formats were approved by the FDA in 2006 and are distributed by Inverness Medical Innovations, Inc. (“Inverness”) in the United States. Our fourth rapid HIV test, which we more recently developed on our patented Dual Path Platform (DPP®) technology, detects antibodies to HIV in oral fluid samples, as well as all blood matrices.

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® has issued or is pending worldwide. We participate in the point-of-care segment of the nearly $40 billion global in-vitro diagnostic market. The global point-of-care segment of the IVD industry is estimated to be $6-8 billion with an overall growth rate of 7% per annum. POCTs, by providing prompt and early diagnosis, can reduce patient stays, lower overall costs, improve therapeutic interventions and improve patient outcomes as a result of prompt and early diagnosis. They can also prevent needless hospital admissions, simplify testing procedures, avoid delays from central lab batching, and eliminate the need for return visits. This is not to say that every test should be done at the point-of-care. A careful analysis needs to be performed when evaluating whether there is a need for a rapid point-of-care test versus a laboratory test.

In the areas of infectious and sexually transmitted diseases (such as Influenza and HIV for example), the utility of a rapid point–of-care test has been well established, and large markets have been established for these kinds of tests globally. It is within these areas of infectious diseases and sexually transmitted diseases, which tend to have the higher growth rates in the point-of-care segment where we have focused and will continue to focus our business, with an emphasis on the U.S. market.

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PRODUCTS

Lateral Flow Rapid HIV Tests

The major component of our revenue growth in 2009 was increased sales of our lateral flow rapid HIV tests and related components. 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 if samples have to be sent out to a laboratory which can take at least several days to process. The increased availability, greater efficacy and reduced costs for anti-retroviral treatments (ARVs) for HIV is also having a tremendous impact on the demand for testing, as the stigma associated with the disease is lessened, and the ability to resume normal activities is substantially improved, providing a positive message to those potentially infected. All four 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. Prior to our agreement with Inverness and, more recently, the development of our DPP® HIV 1/2 Screening Assay for use with oral fluid or blood samples, our rapid HIV tests had been marketed under either our SURE CHECK® or STAT-PAK® trademarks. Pursuant to our agreement with Inverness, the SURE CHECK® product (which incorporates a proprietary barrel format) is now being marketed by Inverness as Clearview® Complete HIV 1/2 and the cassette format of our HIV 1/2 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. In addition, in 2009 we amended the agreement with Inverness, which previously had global exclusivity for the barrel format product, to a non-exclusive outside of North America.

Regulatory Status: The FDA approved our Pre-Market Applications (hereinafter "PMA"; see "Governmental Regulations" and Glossary) in April 2006 for our SURE CHECK HIV 1/2 (and also now Inverness' Clearview® Complete HIV 1/2) and for our HIV 1/2 STAT-PAK (now Inverness' Clearview® HIV 1/2 STAT-PAK in the United States only) products. A Clinical Laboratory Improvement Act ("CLIA") waiver was granted by the FDA for the HIV 1/2 STAT-PAK in November 2006 and for the two Inverness Clearview® brands in October 2007. CLIA waiver is required in order to market the products for use in hospital emergency rooms, public health clinics and physicians' offices, where the level of training is traditionally less than the training at clinical laboratories and laboratories in hospitals. These settings constitute the largest portion of the available market for our products. Our third lateral flow rapid HIV test, HIV 1/2 STAT-PAK Dipstick and our DPP® oral fluid HIV test, though not FDA approved, qualify 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 addition, we have received approval from a number of potential importing countries for our three lateral flow HIV tests. . All three of our lateral flow HIV tests have qualified for procurement under the President's Emergency Plan for AIDS Relief ("PEPFAR"). In October 2009 we submitted supplemental documentation that had been requested to our Notified Body in connection with our efforts to obtain CE marking for the two FDA-approved rapid HIV test products. In late January 2010 we were informed that additional data was being requested, and we are determining the time and cost.

DPP® HIV 1&2 Assay for Use with Oral Fluid (or Blood) Samples

We have also completed development of and are now commercializing our DPP® HIV 1&2 Assay for use with oral fluid samples. Oral fluid testing is an established alternative to blood testing for diagnostic tests, including HIV tests. It provides a fast and easy method for sample collection, enabling non-medical professionals to collect samples for testing. It is also often patient preferred, providing a more comfortable test. In certain public health clinics, staffs choose not to handle blood specimens; thus, oral sample collection provides a viable alternative. The DPP® HIV test, which is based on our patented DPP® technology, also includes a patent-pending system comprised of an oral fluid swab and sample buffer vial. This feature enables samples to be fully extracted in buffer solution before application to the test device, and also allows the extracted sample to be stored and retested. Internal and field studies have shown

sensitivity and specificity well in excess of FDA requirements on oral fluid as well as all blood matrices.

Regulatory Status: During 2008 Chembio conducted extensive internal panel studies of this product and a limited field study that suggested outstanding performance; two much larger field evaluations were completed in 2009 that will supplement our pending U.S. clinical studies. During the second half of 2009 we prepared a proposed clinical trial protocol and submitted it to the FDA in support of our application for an Investigational Device Exemption (IDE) which we submitted and was granted during the fourth quarter of 2009. This approved protocol permits us to move forward with the clinical trials performance data, along with other required product and manufacturing data, in support of a Pre-Marketing Approval (PMA) application to the FDA. We anticipate commencing and completing the clinical trials and submitting the PMA application during 2010 and receiving approval of the PMA during 2011.

PARTNERS INVOLVED IN MARKETING OUR HIV PRODUCTS

On September 29, 2006 we executed marketing and license agreements with Inverness. The marketing agreements (one for each of the two FDA approved products) each provide Inverness with a 10-year exclusive right for the marketing of our rapid HIV tests in the United States. The agreements also grant us a license to Inverness' lateral flow patents that may be applicable to certain of our other products, including those that we had under development at the time of the grant of the license. As part of these agreements, we also settled litigation that had been ongoing with another company, StatSure Diagnostics, Inc.(SDS), relating to the proprietary barrel device that is incorporated into our Sure Check® HIV 1/2 product, which is also marketed exclusively as Inverness Clearview® Complete HIV 1/2 in the United States, Europe and Asia. SDS is a party to the marketing agreement with Inverness and Chembio that pertains to that product.

We are beginning to register our DPP® oral fluid HIV test in selected markets receiving funding from the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). PEPFAR recently approved our product as qualified for procurement pursuant to the USAID waiver procedure (for use with oral fluid or blood samples). Also, as described above, our DPP® oral fluid HIV test is one of three products pending regulatory approval in Brazil pursuant to OEM technology transfer, supply and license agreements we have in place with FIOCRUZ as described below. We are considering various options for marketing this product in the United States including a direct sales model for certain or all market segments.

We have appointed distributors and OEM partners internationally for our lateral flow HIV tests. Our largest markets for our lateral flow HIV rapid tests outside the United States are several countries in Africa, Brazil (OEM) and Mexico. During 2009 we appointed Bio-Rad Laboratories, Inc. as our distributor of our HIV 1/2 STAT-PAK® product in Mexico. We have distributors interested in distributing our products in Europe once we receive the CE Marking, for which there can be no assurance.

OTHER LATERAL FLOW RAPID TESTS

We also have commercially available lateral flow tests for Chagas Disease and a line of tests for the detection of tuberculosis in humans and certain animal species. These products represented approximately 1.5% of our product revenues during 2009. . The Company entered the rapid test market segment with lateral flow technology and for many years, even before the development of our lateral flow HIV tests, our revenues were almost entirely based on this technology, primarily pregnancy tests. Because of the limited license we entered with Inverness to manufacture and market only certain applications of lateral flow technology, and also because we have now developed our own patent-protected rapid point-of-care technology platform (DPP®) which we believe provides certain advantages over lateral flow technologies, all of our other products and products that we are developing utilize this patented platform.

OTHER DPP® PRODUCTS

Chembio-Branded DPP® Products

DPP® Syphilis Screen & Confirm- DPP® Syphilis Screen & Confirm is a simple multiplex point-of-care test that can detect both non-treponemal and treponemal antibodies to syphilis from a whole blood sample within 20 minutes. Studies have been performed at the CDC on a total of 459 banked specimens of which 219 were characterized as positive and 240 as negative by RPR (standard lab test for non-treponemal). Out of the 459 samples, 289 were characterized as positive and 170 characterized as negative by the TPPA test (standard lab treponemal test). DPP® Syphilis Screen & Confirm non-treponemal had a sensitivity of 90.5% and a specificity of 100% compared to RPR and a sensitivity of 93% and a specificity of 92% compared to TPPA. This assay offers several market advantages over the current two-tier system of screening and confirmatory testing. This is the first assay in the United States that would afford the opportunity for a single-visit diagnosis and treatment. Retrospective studies have been performed at Chembio and CDC during 2008 and 2009. A multi-phase field study sponsored by the WHO and

with participation by CDC is ongoing. Interference and cross-reactivity studies have been completed at an external laboratory. FDA regulatory clearance for this test is available through a 510(K) submission. The FDA has approved our proposed protocol (IDE) for the prospective clinical trials that will be part of this. We plan to commence the regulatory activities for FDA clearance during the second quarter of 2010 and anticipate that clearance will be granted in the first quarter of 2011.

OEM DPP® Products

Oswaldo Cruz Foundation OEM DPP® Agreements

During 2008 we signed four agreements with the Oswaldo Cruz Foundation (FIOCRUZ) in Brazil relating to products based on our DPP® technology for Leptospirosis, Canine Leishmaniasis, screening for HIV 1/2 with oral fluid samples, and a 5-band multiplex point-of-care confirmation test for HIV 1&2. These products will initially be manufactured by Chembio but will be distributed by FIOCRUZ under its Bio-Manguinhos Division's label. These entities are affiliated with the Brazilian Ministry of Health. We have completed development of three of these products (Leishmaniasis and the HIV screening and confirmation tests), and we have substantially completed development of the Leptospirosis test. The leishmaniasis and confirmatory tests have been submitted for and are still pending regulatory approval in Brazil; the HIV screening test regulatory submission has not been made yet. We now expect that these products will be approved by Brazilian regulatory authorities during the second quarter of 2010. These agreements contemplate an eventual transfer of the manufacture of the subject products to FIOCRUZ over stipulated periods of time subject to Chembio first receiving orders for a minimum amount of products for manufacture by Chembio; thereafter Chembio will receive royalty payments for a number of years based on product sold by FIOCRUZ to the public health programs in Brazil. In December 2009 Chembio received purchase orders from FIOCRUZ for the three products for which development has been completed and that are pending regulatory approval in the aggregate amount of approximately $2.4 million. The orders are of course in each case subject to the attainment of regulatory approval for the relevant product, of which there can be no assurance. In addition, upon attainment of regulatory approval of these three products, Chembio will be due fees from FIOCRUZ stipulated in these agreements in the aggregate amount of approximately $900,000.

Our Rapid Test Technologies

All of our commercially available current products employ either in-licensed lateral flow technology or our own patented Dual Path Platform (DPP®) technology and are visually read. Certain of our new DPP® products will incorporate reader technologies that can help record and report test results and reduce subjectivity of results sometimes found with visually read tests. Both lateral flow technology and DPP® allow the development of accurate, low cost, 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 potentially infected specimens), 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.

We can also use hand held and desktop readers to objectively measure, quantify, record and report test results. Certain of the products we have and/or are developing incorporate some of these readers, and we are developing other products that may be used with or will require use of a reader.

Target Markets

Rapid HIV Tests

There are approximately 53,000 new diagnoses of HIV infection in the United States each year, according to the CDC. In time, most of these infections progress to AIDS. The CDC estimates that approximately 1.1 million individuals in the U.S. are living with HIV, with an estimated 250,000 Americans, or more than 25%, unaware that they are infected. It is these 250,000 infected people that account for 54% of all new infections per year. 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 if samples have to be sent out to a laboratory which can take at least several days to process. Healthcare officials believe that by making more people aware of their HIV status, it will reduce the number of HIV transmissions.

Rapid HIV testing in the United States has now developed into a 5-6 million test market. This is from zero in 2003 when Orasure received FDA approval for the first rapid HIV test. We believe that the US professional HIV rapid test market (not including the OTC market) has the potential to increase to 15-18 million tests over the next several years, which would represent about 50% of all HIV tests done in the United States for clinical purposes. Assuming an average price to the manufacturers of $10.00 per test, a total potential market of $180 million U.S. market is inferred.

In 2006, the outlook for HIV testing was given a big boost with the release by the CDC of new guidelines for HIV testing. These new CDC recommendations now in place provide that an HIV test should be given as a routine test like any other for all patients between 13 and 64 years of age, regardless of risk, with an opt-out screening option and focused testing procedural (pre and post test counseling) guidelines. Adoption of the 2006 CDC recommendations by a number of states has begun to have an impact.

In addition, in December 2009 Medicare issued new rules that now require it to pay for HIV tests for individuals covered by Medicare.

In the United States, the need for rapid HIV tests has been developing first in the public health and hospital emergency room and labor and delivery room segments, and to some extent also in the physicians' office laboratories. Of the estimated 25-30 million HIV tests performed in clinical settings in the United States, rapid HIV tests now account for approximately 20-25% of this market, or approximately 6 million tests of this total. We believe that the United States market share available to rapid HIV tests will grow by approximately 15-20% per annum.

In the international market, PEPFAR, the large United States funded international AIDS relief program focused on fifteen countries, was reauthorized in 2008 for up to $48 billion for FY2009-2012 (up from $15 billion in 2004-2008). PEPFAR, The Global Fund and other global initiatives have succeeded in making life-saving treatments available now to well in excess of one million individuals. PEPFAR has a goal by 2013 of treating three million infected individuals and averting 12 million new cases. To achieve these goals more and more people are likely to get tested. As more effective treatments become available at lower costs there is a clearer reason to be tested. Other programs such as UNAIDS are significant participants in the global effort to prevent further transmission and save the lives of those already infected, as well as care for their families that are impacted.

For oral fluid testing we believe that in several markets there is a meaningful segment of individuals who will be more inclined to be tested for HIV when offered a non-invasive test. The most well-established market for oral fluid HIV testing is the United States. There is also now an opportunity to participate in the over-the-counter market for HIV tests. This opportunity received important support by the FDA and CDC in November 2009. While initial support from public health and regulatory officials was indicated in 2006, a follow-up November 2009 meeting of the FDA Blood Products Advisory Committee on this subject confirmed the support by public health and HIV positive community advocates, and provided further clarity as to the regulatory pathway for such market.

Syphilis Rapid Test

Recent data indicate that approximately 70,000-100,000 new cases of syphilis are occurring annually in the U.S. The CDC's latest Sexually Transmitted Disease study, released in November 2009, reported that: 1) although only 13,500 of new syphilis cases were reported in 2008 (<20% of total amount of estimated new cases), that is still an 18 percent increase from 2007, suggesting increased numbers of new cases, 2) 63 percent of syphilis cases were among men who have sex with men, and 3) syphilis rates among women increased 36 percent from 2007 to 2008.

Syphilis can be treated with antibiotics, but untreated can cause pelvic inflammatory disease, infertility, ectopic pregnancy and can infect newborns. Treatment cannot be provided without a confirmed diagnosis of an active, previously untreated case of syphilis.

Current testing algorithms require two different tests (called non-treponemal and treponemal markers), each requiring trained personnel in laboratory settings and several days to receive back results, in order to confirm an active, previously untreated case. This product is able to accurately detect the presence or absence of each of these markers in one rapid point-of-care test device, thereby enabling prescription of antibiotics at the point-of-care where there is the presence of both markers.

Development of the POC market for syphilis testing is expected to be comparable to the development of the POC market for HIV testing, as there is a significant public health value to being able to provide results at the point-of-care. There are several ways to assess the market opportunity for this unique rapid test, although we believe the U.S. rapid test opportunity is a minimum of 3 million tests, which is approximately 20% of the total number syphilis tests performed in the United States today. Unlike HIV testing, where a positive result first requires a confirmatory test, and even then further tests to measure viral load before expensive treatment decisions are made, an individual with a confirmed active case of syphilis can be prescribed antibiotics immediately.

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 Inverness, and we believe that this will enhance opportunities for Inverness 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 continue creating new collaborations where Chembio can be the exclusive development and manufacturing partner supporting leading marketing organizations.

- Establish strong distribution relationships for our Chembio-branded products in the U.S and abroad and establish a direct sales and marketing organization that is focused in the public health market segment.

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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 our in-licensed lateral flow technology rapid tests and to our proprietary know-how related to our patented dual path platform technology, particularly for the development and manufacture of tests for the detection of antibodies to infectious diseases such as HIV, 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 and in our Dual Path Platform (DPP®) technology has been instrumental in our obtaining the collaborations we have and that we continue to pursue. We believe that the patent protection that we have with our Dual Path Platform (DPP®) enhances our ability to develop more profitable collaborative relationships and to license out the technology.

Research and Development

During 2009 and 2008, $2.9 million and $2.6 million, respectively, were spent on research and development (including regulatory activities). These expenses were in part underwritten by funding from R&D contracts and grants of $1.3 million in 2009 and $.7 million in 2008. All of our new product development activities involve employment of our Dual Path Platform (DPP®) technology. These activities include completing development of certain products and making significant progress toward the development of additional products. Research and development and regulatory activities are explained in detail in Part II Item 7.

Employees

At December 31, 2009, we employed 104 people, including 103 full-time employees. 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, provides that Mr. Siebert will serve as the Chief Executive Officer and President of the Company for an additional three-year term through May 11, 2012. The contract with Mr. Esfandiari has a term of three years ending March 2013. We have obtained a key man insurance policy for Mr. Esfandiari.

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. Quality Systems (for medical devices). Failure to comply with the FDA's requirements can lead to significant penalties, both before and after approval or clearance.

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. FDA clearance of our DPP® Syphilis Screen & Confirm test will be by means of a 510(k) submission.

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-Marketing Application ("PMA") application before marketing can begin. PMA's must demonstrate, among other matters, that the medical device provides a reasonable assurance of safety and effectiveness. A PMA application is typically a complex submission, including the results of non-clinical and clinical studies. Preparing a PMA application is a much more expensive, detailed and time-consuming process as compared with a 510(K) pre-market notification. 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®. FDA approval of our DPP® HIV screening assay for use with oral fluid or blood samples will be pursued by means of a PMA application.

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. 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 or pending approval for marketing in several foreign jurisdictions, including but not limited to Brazil, Mexico, and India, as well as a number of other nations in the developing world.

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 rapid point-of-care testing, 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 and DPP® based 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

As part of our agreements in 2006 with Inverness for the marketing of our HIV tests, we were granted non-exclusive licenses to their lateral flow technology for certain products manufactured and marketed by Chembio including but not limited to our HIV tests. Although we believe our DPP® is outside of the scope of 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 Inverness' lateral flow patents will not be challenged or that other patents containing claims relevant to the Company's lateral flow or DPP® products will be not be granted and that licenses to such patents, if any, will be available on reasonable terms, if any. Inverness has aggressively enforced its lateral flow intellectual property. Most recently in 2008 Inverness brought a patent infringement lawsuit against Orasure. The suit was settled in late 2009 with a $3 million payment by Orasure to Inverness and other considerations.

The DPP® technology provides us with our own intellectual property and we believe it also enables tests to be developed with improved sensitivity as compared with comparable tests on lateral flow platforms. The Company has signed and anticipates signing new development projects based upon the DPP® technology that will provide new manufacturing and marketing opportunities. We have several other patents issued or pending related to other point-of-care technologies or applications thereof. The DPP® patent has been issued in certain other jurisdictions and is being prosecuted in many others.

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. In connection with their bankruptcy, during the third quarter of 2009 we bought out all of our remaining obligations under that agreement. We also have licensed the antigens used in other tests including our Chagas, Tuberculosis and Leishmaniasis tests. In prior years we concluded license agreements related to intellectual property rights owned by the United States associated with HIV- 1, and during the first quarter of 2008 we entered into a sub-license agreement for HIV-2 with Bio-Rad Laboratories N.A., the exclusive licensee of the Pasteur Institute's HIV-2 intellectual property estate.

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 in this Form 10-K to shares of our common stock have been adjusted to reflect this reverse split.

In February 2010, Crestview Capital Master, L.L.C. ("Crestview Master"), a Delaware limited liability company that held 18,907,431 shares of Chembio's common stock, spun off all these shares, constituting approximately 30.5% of Chembio's outstanding shares, to its three equity holders. One of the three equity holders of Crestview Master immediately spun off, to its approximately 126 equity holders, all of the 12,990,569 shares of Chembio stock that it received in this distribution. As a result, as of February 24, 2010, Crestview Master no longer owned any shares. The former direct and indirect equity holders of Crestview Master owned all these shares, with none of these individual

stockholders having beneficial ownership of more than 5.61% of the outstanding common stock of Chembio. Approximately 12,208,505 of the shares distributed are free of restrictions and may be sold or otherwise transferred immediately. An additional 2,560,822 of the distributed shares are expected to become eligible for resale on March 24, 2010. The other approximately 4,138,104 shares are expected to become eligible for resale on May 25, 2010.

Glossary

AIDS	Acquired Immunodeficiency Syndrome. AIDS is caused by the Human Immunodeficiency Virus, HIV.
ALGORITHM (parallel or serial)	For rapid HIV testing this refers both to method or protocol (in developing countries to date) 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. A parallel algorithm uses two screening tests from different manufacturers and a tie-breaker test only if there is a discrepancy between the screening tests results. A serial algorithm only uses a second confirmatory test if there is a positive result from the screening test, meaning that the number of confirmatory tests used is equal to the positivity rate in the testing venue. A tie-breaker test resolves discrepancies between the screen and the confirmatory test.
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
CLIA waiver	Clinical Laboratory Improvement Act designation that allows simple tests to be performed in point-of-care settings such as doctors offices, walk-in clinics and emergency rooms.
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
FAS	Financial Accounting Standard
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 –FDA approval classification for a medical device that is not substantially equivalent to a legally marketed device or is otherwise required by

	statute to have an approved application. Rapid HIV tests must have an approved PMA application before marketing of such a product can begin.
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.
SAB	Staff Accounting Bulletin
SENSITIVITY	Refers to the ability of an assay to detect and measure small quantities of a substance of interest. The greater the sensitivity, the smaller the quantity of the substance of interest the assay can detect. Also refers to the likelihood of detecting the antigen when present.
SPECIFICITY	The ability of an assay to distinguish between similar materials. The greater the specificity, the better an assay is at identifying a substance in the presence of substances of similar makeup.
SPUTUM	Expectorated matter; saliva mixed with discharges from the respiratory passages
TB	Tuberculosis (TB) is a disease caused by bacteria called Mycobacterium tuberculosis. The bacteria usually attack the lungs. But, TB bacteria can attack any part of the body such as the kidney, spine, and brain. If not treated properly, TB disease can be fatal. TB is spread through the air from one person to another. The bacteria are put into the air when a person with active TB disease of the lungs or throat coughs or sneezes. People nearby may breathe in these bacteria and become infected.
UNAIDS	Joint United Nations Program on HIV/AIDS
USAID	United States Agency for International Development
USDA	U.S Department of Agriculture
WHO	World Health Organization

SELECTED FINANCIAL DATA

Presented in this table are selected financial data for the past five years ending December 31, 2009. Prior year's financial statements have been reclassified to conform to current year presentation As of the year ended December 31, 2008 the Company reclassified its royalty and license expenses to cost of goods sold, instead of selling, general and administrative expenses.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
SELECTED HISTORICAL FINANCIAL DATA

Statement of Operations Data:	December 31, 2009		December 31, 2008		December 31, 2007		December 31, 2006		December 31, 2005	
TOTAL REVENUES	$13,834,248		$11,049,571		$9,230,948		$6,502,480		$3,940,730	
GROSS PROFIT	5,860,405	42%	3,851,721	35 %	2,795,710	30 %	1,608,272	25 %	944,648	24 %
OVERHEAD COSTS:										
Research and development expenses	2,883,696	21%	2,605,343	24 %	1,906,653	21 %	1,401,472	22 %	1,364,898	35 %
Selling, general and administrative expenses	2,659,382	19%	3,317,046	30 %	3,765,221	41 %	4,786,993	74 %	2,877,737	73 %
	5,543,078		5,922,389		5,671,874		6,188,465		4,242,635	
INCOME (LOSS) FROM OPERATIONS	317,327		(2,070,668)		(2,876,164)		(4,580,193)		(3,297,987)	
OTHER INCOME (EXPENSES):	(8,267)		121,898		249,272		(414,827)		45,987	
NET INCOME (LOSS)	309,060	2 %	(1,948,770)	-18%	(2,626,892)	-28%	(4,995,020)	-77 %	(3,252,000)	-83 %
Dividends accreted/payable in stock to preferred stockholders and a beneficial conversion feature	-		-		5,645,310		3,210,046		3,517,022	
NET INCOME (LOSS) ATTRIBUTABLE TO COMMON STOCKHOLDERS	$309,060		$(1,948,770)	-18%	$(8,272,202)	-90%	$(8,205,066)	-126%	$(6,769,022)	-172%

Basic income (loss) per share	$0.00	$(0.03)	$(0.57)	$(0.80)	$(0.88)
Diluted income (loss) per share	$0.00	$(0.03)	$(0.57)	$(0.80)	$(0.88)
Weighted average number of shares outstanding, basic	61,946,435	61,266,954	14,608,478	10,293,168	7,705,782
Weighted average number of shares outstanding, diluted	75,041,932	61,266,954	14,608,478	10,293,168	7,705,782

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 ongoing 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 prospectus 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," "
"anticipates," "believes," "estimates," "predicts," "potential," "continues" or the negative of these terms or other compa
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 prospectus 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 prospectus 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.

All of the Company's future products that are currently being developed are based on its patented Dual Path Platform (DPP®), which is a unique diagnostic point-of-care platform that has certain advantages over lateral flow technology. The Company has completed development of four products that employ the DPP® technology, two of which will be marketed under Chembio's label (DPP® HIV 1/2 Screening Assay and DPP® Syphilis Screen & Confirm) and two that have been developed specifically related to private label agreements with The Oswaldo Cruz Foundation ("FIOCRUZ") for the Brazilian public health market, as explained below. The DPP® HIV Screening Assay, will be manufactured as an OEM product for the Brazilian market pursuant to one of our agreements with FIOCRUZ.

The Company has a number of additional products under development that employ the DPP® technology. These product development activities are further described below.

Oswaldo Cruz Foundation OEM DPP® Agreements - During 2008 we signed four agreements with the Oswaldo Cruz Foundation (FIOCRUZ) in Brazil relating to products based on our DPP® technology for Leptospirosis, Canine Leishmaniasis, screening for HIV 1/2 with oral fluid samples, and a 5-band multiplex point-of-care confirmation test for HIV 1&2. We have completed development of three of these products (Leishmaniasis and the HIV screening and confirmation tests), and we have substantially completed development of the Leptospirosis test. Two of the three products developed have been submitted for regulatory approval evaluations in Brazil and we expect the third will be filed very shortly; we expect that these products will be approved by Brazilian regulatory authorities (ANVISA for HIV tests and MAPA for canine test), although there can be no assurance, during the first part of 2010, triggering initial orders as well as approximately $1 million in technology transfer fee payments to the Company.

During 2009, we received purchase orders from FIOCRUZ for the three products for which development has been completed and that are pending regulatory approval in the aggregate of approximately $2.4 million. These orders are subject to regulatory approval, of which there can be no assurance. If regulatory approval is obtained, we anticipate additional orders in 2011. We are currently considering entering additional agreements based on a similar model with them in 2010.

Bio-Rad Laboratories OEM DPP® Agreement- On April 6, 2008, we entered a development agreement with Bio-Rad Laboratories N.A., a division of Bio-Rad Laboratories Inc (NYSE:BIO), a leading in-vitro diagnostic and life science company. The agreement with Bio-Rad is for the development of a six band multiplex product on our DPP®. We will complete development of this product by the middle of 2010, by which time Bio Rad will have paid us approximately $600,000 in development costs plus $340,000 for a DPP® license limited to this product. Thereupon, CE marking and FDA approval will be sought by Bio-Rad with Chembio in a supporting role as manufacturer. We believe that Bio-Rad has begun discussions with the FDA to discuss this product, its proposed performance claims and the intended clinical protocol to support its regulatory submission.

Battelle/CDC DPP® Influenza Immunity Test – In December 2009 Chembio entered into a milestone-based development agreement for up to approximately $900,000 in connection with the development and initial supply of a multiplex, rapid point-of-care ("POC") influenza immunity test. The agreement contemplates a period of approximately nine months in which the development activity is to be completed. Chembio entered this agreement with Battelle Memorial Institute which has a master contract with the United States Centers for Disease Control and Prevention ("CDC") to enter into, implement and provide technical oversight of agreements relating to pandemic preparedness on behalf of CDC. Our work plan has been delivered and been approved, which are the first two milestones triggering approximately $178,000 in payments to Chembio. No agreement is in place for the manufacture, commercialization or license for this product assuming it is successfully developed in accordance with the specifications.

The objective of the project is to develop a product that can determine an individual's immunity to seasonal and novel influenza viruses, including novel swine H1N1, either in the field or in an outpatient setting. The test will have six different parameters (representing different influenza strains) plus a control line on a single POC DPP® device. The test will allow visual interpretation of results and/or will be used with a portable digital reader that will be customized for this application. Public health experts believe that rapid responses in the field require a POC test for influenza immunity, as well as infection. Current test platform technologies for infection and immunity are not suitable for reliable POC testing.

DPP® Hepatitis C and DPP® Hepatitis C/HIV Oral Fluid Antibody Tests - Prototypes of these products have been developed and are being evaluated in a study that has been organized by the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) at the Centers for Disease Control and Prevention (CDC) of the Department Of Health and Human Services. The evaluation will be completed during 2010 and the results should be useful in helping to ascertain the performance characteristics of these products in comparison to other products that will also be in this evaluation. Chembio’s DPP® HIV 1/2 test is also being evaluated in this study.

DPP® Influenza –We have developed a prototype multiplex test for FLU A/B Antigen Detection. [This is not to be confused with the immune status antibody detection test we are developing for the U.S. CDC]. This prototype, if successfully developed into a commercial product, would be competitive to the current point-of-care FLU A/B products marketed by Quidel, Meridian, Binax (Inverness) and others. We believe that we can develop a test that performs better than the current market leaders, and so that there is therefore a significant opportunity to participate in this market. We are also considering additional parameters for this product that would further differentiate it in the market. This product will be our first commercial antigen detection test on DPP® and we believe that this has independent value to demonstrate the capabilities of our technology to access large markets beyond serological antibody detection markets. Our current plan is for development to be completed and initiation of our FDA 510(k) submission activities during 2010.

DPP® Leptospirosis – In June, as we previously reported, we were awarded a three-year $3 million Small Business Innovative Research (SBIR) Phase II grant from the United States National Institutes of Health (NIH) to fully develop, validate, and commercialize a rapid diagnostic test for Leptospirosis for general use worldwide, and our work is progressing on schedule. The test will be developed with DPP® and will utilize proprietary reagents developed by

Cornell University and the Oswaldo Cruz Foundation at the Brazilian Ministry of Health. Development of the test will be in collaboration with the Division of Infectious Diseases, Weill Medical College, Cornell University in New York and the Oswaldo Cruz Foundation, the largest biomedical research institution in Latin America. In the Phase I work completed in 2008, which occurred with this same collaborative group, novel diagnostic targets were identified and evaluated in a prototype test in Chembio's patented DPP® format. The studies demonstrated that the test prototype had an overall sensitivity of 85% and a specificity of 90% using serum samples of Leptospirosis patients from Brazil and Thailand. Furthermore, the DPP® prototype had a sensitivity of 78% in identifying Leptospirosis in the first 7 days of illness, the "window-of-opportunity" during which initiation of antimicrobial therapy provides the greatest benefit.

Other Research & Development Activities - Chembio continues to work with commercial, governmental and private organizations in order to obtain R&D contracts & grant funding for development projects. These programs have subsidized the Company's development expenses while expanding the applications for and know-how related to DPP® and creating important collaborative relationships. We have other grant applications pending. In April 2009 we entered into a Services Agreement with the Infectious Disease Research Institute to develop DPP® products for Leishmaniasis and Leprosy for which we have received $125,000 and which, subject to attainment of development milestones, will additionally provide us with approximately $125,000 within the next six months. The second year provides for another $150,000, subject to the attainment of development milestones. During the first quarter of 2009 we entered into a funded feasibility study agreement with the Foundation for Innovative and Novel Diagnostics (FIND), a non-profit organization funded by the Gates Foundation, related to development of serological tests for Tuberculosis and Malaria using our DPP®. The Company received $165,000 from FIND and as a result of our achievement of all milestones, we recognized revenue of $99,000 in the first and second quarters as well as $66,000 during the third quarter with further development activity pending a full evaluation and comparison of results.

There can be no assurance that any of these projects will continue, meet regulatory or other technical requirements and specifications, and/or that if continued, will result in completed products, or that such products, if successfully completed, will be successfully commercialized.

Platform Enhancements - In addition to the specific products we plan to commercialize we also are pursuing enhancements to our DPP® technology platform during 2010 and 2011. These enhancements include enabling a simplified test procedure, lowering the overall manufacturing costs, enabling development of combination antibody and antigen assays, and integrating molecular sample amplification systems with our detection system. We are active in each of these areas and also are pursuing patent protection where applicable.

Regulatory Activities
CE Mark for FDA approved HIV tests – we provided all testing and related documentation that was requested by our Notified Body during the second quarter, however additional data was requested in correspondence we received in January and we are evaluating the cost/benefit of producing this information at this time. Under our agreement with Inverness, as now amended, we no longer have the obligation to obtain a CE Marking for the Clearview® Complete HIV 1/2.

Regulatory Approvals in Brazil through the Oswaldo Cruz Foundation (FIOCRUZ) – We anticipate that FIOCRUZ will receive required approvals from its regulatory agencies during the first and/or second quarter of 2010 for the DPP® Leishmaniasis, HIV Confirmatory, and the DPP® HIV screening tests.

DPP® HIV 1/2 Screening Assay for Oral Fluid - Field evaluations in Africa have been completed of this product that will supplement our pending U.S. clinical studies: During the second half of 2009 we prepared a proposed clinical trial protocol and submitted it to the FDA in support of our application for an Investigational Device Exemption (IDE) which we submitted and was approved during the fourth quarter of 2009. This approved protocol permits us to move forward with the clinical trials performance data, along with other required product and manufacturing data, in support of a Pre-Marketing Approval (PMA) application to the FDA. We have commenced the clinical trials at two sites and we anticipate completing the clinical trials and submitting the PMA application during 2010 and receiving approval of the PMA during 2011.

DPP® Syphilis Screen & Confirm - The first phase of a multi-center evaluation sponsored by the World Health Organization commenced during the third quarter and we have received only limited first phase results. During the third quarter, we submitted a proposed clinical plan to the FDA (Pre-IDE "Investigational Device Exemption") and we are currently reviewing the FDA response. We have also begun to identify clinical testing sites, have performed additional validation, interfering substance, and cross-reactivity studies on the product at Chembio and at external

laboratories. There is no point-of-care test for syphilis cleared for marketing in the United States, and we believe that our product, with its multiplexed capacity to identify both treponemal and non-treponemal markers, provides a reliable indication of an active, untreated case of syphilis at the point-of-care.

The table below provides a preliminary summary estimated timetable for the regulatory approval and commercialization of the DPP® HIV Screening Assay and the DPP® Syphilis Screen & Confirm Assay in major markets. There can be no assurance that these dates will be accurate.

Market	DPP® HIV 1/2 Screening Assay	DPP® Syphilis Screen & Confirm
Developing World	2010	2010
CE Mark0	2nd Half 2011	First Half 2010
US FDA	2nd Half 2011	First Half 2011

Recent Events

In May 2009, certain warrants to purchase an aggregate of 2,489,120 shares of common stock expired, at an average exercise price of $.764. These warrants were related to the Series A Preferred Stock Offering and other warrants related to the 2004 merger.

In January 2010, certain warrants to purchase an aggregate of 4,960,370 shares of common stock expired, at an average exercise price of $.474. These warrants were related to the initial 2005 Series B Preferred Stock Offering (see Form 8-K filed on January 31, 2005 with the SEC for further details on this offering).

We entered into a lease effective February 1, 2010 for additional warehouse space; see Item 2 for more information.

In February 2010, the Company took possession of the automated assembly equipment (mentioned below under Equipment Purchase Commitment). This equipment is expected to provide for faster throughput and thereby increasing capacity of our manufacturing facility, in addition to reducing labor costs. The machine will need to go through a validation process and is expected to be in serviced during the second quarter of 2010.

The Company entered into an employment agreement dated March 4, 2010, and to be effective March 5, 2010 (the "Employment Agreement"), with Mr. Esfandiari to continue as the Company's Senior Vice President of Research and Development for an additional term of three years. Please see Item 11 of this Form 10-K for further details.

RESULTS OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2009 AS COMPARED WITH THE YEAR ENDED DECEMBER 31, 2008

Revenues:

Selected Product Categories:	For the years ended			
	December 31, 2009	December 31, 2008	$ Change	% Change
HIV	$ 10,792,947	$ 9,192,297	$ 1,600,650	17.41 %
DPP	619,530	126,000	493,530	391.69 %
Other	960,016	1,037,471	(77,455)	-7.47 %
Net Product Sales	12,372,493	10,355,768	2,016,725	19.47 %
License and royalty income	121,896	-	121,896	100.00 %
R&D contracts and grants	1,339,859	693,803	646,056	93.12 %
Total Revenues	$ 13,834,248	$ 11,049,571	$ 2,784,677	25.20 %

Revenues for our HIV tests and related components during the year ended December 31, 2009 increased by $1.60 million over the same period in 2008. This was primarily attributable to increased sales to our distributor in the United States which increased 148%, or $3.13 million, to $5.24 million in 2009 as compared with $2.11 million in 2008. This increase offset reduced sales to Africa, which decreased by 21.6%, or $1.53 million, to $5.55 million in 2009 as compared with $7.08 million in 2008. Sales of our DPP product increased because we are working with our partner in Brazil to get several products approved in Brazil. The increase in R&D contracts and grants involving our patented DPP® technology, of which $1,161,000 was received and $1,340,000 was earned in 2009, adding $21,000 to deferred revenues as of December 31, 2009.

Gross Margin:

Gross Margin related to Net Product Sales:	For the years ended			
	December 31, 2009	December 31, 2008	$ Change	% Change
Gross Margin per Statement of Operations	$ 5,860,405	$ 3,851,721	$ 2,008,684	52.15 %
Less:R&D contracts and grants, license and royalties	1,461,755	693,803	767,952	110.69 %
Gross Margin from Net Product Sales	$ 4,398,650	$ 3,157,918	$ 1,240,732	39.29 %
Gross Margin %	35.55 %	30.49 %		

The increase in our gross margin resulted primarily from increased average unit prices on product sales as a result of the increased sales to Inverness, which are at higher average unit prices, and decreased sales to Africa, which are at lower average unit prices.

Research and Development:

This category includes costs incurred for product research and development, regulatory approvals, technical support, evaluations and registrations.

Selected expense lines:	For the years ended				
	December 31, 2009	December 31, 2008	$ Change	% Change	
Clinical & Regulatory Affairs:					
Wages and related costs	$ 321,830	$ 262,191	$ 59,639	22.75	%
Consulting	35,560	27,231	8,329	30.59	%
Share-based compensation	12,916	-			