

CHEMBIO DIAGNOSTICS, INC.

Form S-1

March 25, 2010

As filed with the U.S. Securities and Exchange Commission on March 25, 2010

Registration No. 333-\_\_\_\_\_

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

\_\_\_\_\_  
Chembio Diagnostics, Inc.  
(Exact name of registrant as specified in its charter)

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

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

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Lawrence A. Siebert  
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(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copy of all communications to:  
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\_\_\_\_\_  
Approximate date of commencement of proposed sale to the public: As soon as practicable after this the effective date hereof.

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If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. [X]

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer”, “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>	Non-accelerated filer <input type="checkbox"/>	Smaller reporting company <input type="checkbox"/>
		(Do not check if a smaller reporting company)	

## CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price	Amount of registration fee(1)
Units, each unit consisting of ___ shares of Common Stock, \$0.01 par value, and warrants to purchase ___ shares of Common Stock	\$ 4,500,000	\$ 325
Common Stock included in the Units	\$ —	\$ —
Warrants included in the Units	\$ —	— (3 )
Common Stock issuable upon exercise of the warrants included in the Units (2)	\$ —	— (3 )
Warrants issued to placement agent	\$ —	— (3 )
Common Stock issuable upon exercise of placement agent warrants	\$ —	— (3 )
<b>Total</b>	<b>\$ 4,500,000</b>	<b>\$ 325</b>

- (1) Calculated pursuant to Rule 457(o) on the basis of the maximum aggregate offering price of all of the securities to be registered.
- (2) Pursuant to Rule 416, the securities being registered hereunder include such indeterminate number of additional shares of common stock as may be issuable upon exercise of warrants registered hereunder as a result of stock splits, stock dividends, or similar transactions.
- (3) No fee required pursuant to Rule 457(g).

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

The information in this Prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This Prospectus is not an offer to sell these securities and is not soliciting offers to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED \_\_\_\_\_, 2010

PROSPECTUS

\_\_\_\_\_ UNITS, EACH CONSISTING OF  
 \_\_\_\_\_ SHARES OF COMMON STOCK AND  
 \_\_\_\_\_ WARRANTS

We are offering up to \_\_\_\_\_ units, each unit consisting of \_\_\_\_\_ shares of our common stock and warrants to purchase an additional \_\_\_\_\_ shares of our common stock. Each warrant entitles its holder to purchase one share of our common stock at an exercise price of \$\_\_\_\_\_ per share. The units will separate immediately and the common stock and warrants will be issued separately and the common stock will trade separately. We are not required to sell any specific dollar amount or number of units, but will use our best efforts to sell all of the units being offered. The offering expires on the earlier of (i) the date upon which all of the units being offered have been sold, or (ii) \_\_\_\_\_. We and the placement agent may, upon request of any investor in this offering, sell units to such investor that exclude the warrants, provided that any sale of units that excludes such warrants shall be at the same offering price per unit as all other investors.

Our common stock is quoted on the OTC Bulletin Board under the symbol “CEMI.” We do not intend to apply for listing of the warrants on any securities exchange. On March 22, 2010, the closing bid and ask prices for one share of our common stock were \$.21 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 3 of this Prospectus before making a decision to purchase our stock.

	Per Unit	Total
Offering Price per Unit	\$	\$
Placement Agent’s Fees	\$	\$
Offering Proceeds before expenses	\$	\$

\_\_\_\_\_ has agreed to act as our placement agent in connection with this offering. In addition, the placement agent may engage one or more sub-placement agents or selected dealers. The placement agent is not purchasing the securities offered by us, and is not required to sell any specific number or dollar amount of units, but will assist us in this offering on a “best efforts” basis. We have agreed to pay the placement agent a cash fee equal to \_\_\_% of the gross proceeds of the offering of units by us, as well as “placement agent warrants” to purchase a number of shares of our common stock equal to \_\_\_% of the aggregate number of shares of common stock included in units sold in the offering. The placement agent warrants will have terms substantially similar to the warrants included in units offered hereby, except that the placement agent warrants will have a term of five years from a closing of the sale of units. We estimate the total expenses of this offering, excluding the placement agent fees, will be approximately \$\_\_\_\_. Because there is no minimum offering amount required as a condition to closing in this offering, the actual public offering amount,

placement agent fees, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above. See "Plan of Distribution" beginning on page 43 of this Prospectus for more information on this offering and the placement agent arrangements.

This offering will terminate on \_\_\_\_\_, unless the offering is fully subscribed before that date or we decide to terminate the offering prior to that date. In either event, the offering may be closed without further notice to you. All costs associated with the registration will be borne by us.

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 shares of Common Stock may be sold directly by us to investors, through agents designated from time to time. See "Plan of Distribution."

Brokers or dealers effecting transactions in these shares should confirm that the shares are registered under the applicable state law or that an exemption from registration is available.

The date of this Prospectus is \_\_\_\_\_, 2010

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TABLE OF CONTENTS

	Page
PROSPECTUS SUMMARY	1
ABOUT CHEMBIO	
SUMMARY OF THE OFFERING	
SUMMARY FINANCIAL DATA	
RISK FACTORS	3
FORWARD-LOOKING STATEMENTS	8
USE OF PROCEEDS	8
PRICE RANGE OF OUR COMMON STOCK	9
SELECTED FINANCIAL INFORMATION	10
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	11
DESCRIPTION OF BUSINESS	24
DESCRIPTION OF PROPERTY	33
DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS, CONTROL PERSONS	33
EXECUTIVE COMPENSATION	35
LEGAL PROCEEDINGS	38
SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT	39
CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS	40
DESCRIPTION OF SECURITIES	41
DISCLOSURE OF COMMISSION POSITION OF INDEMNIFICATION FOR SECURITIES ACT	
LIABILITIES	42
PLAN OF DISTRIBUTION	43
EXPERTS	44
LEGAL MATTERS	44
WHERE YOU CAN FIND ADDITIONAL INFORMATION	44
FINANCIAL STATEMENTS	F-1

## 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 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. References in this Prospectus to “we,” “us,” “our,” “Company” and “Chembio” refer to Chembio Diagnostic Systems, Inc.

## ABOUT CHEMBIO

### 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](http://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, respectively, 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 initial product revenues we generated from our DPP® products in 2009, and which we believe will increase significantly in 2010, are through OEM agreements with FIOCRUZ, which is part of the Brazilian Ministry of Health and from contract development agreements and grants all based on our DPP®. We have also completed development of some of our own DPP® products that which we are now beginning the regulatory approval process in order to commercialize under Chembio or DPP® brands. Specifically, Chembio has completed development of two unique rapid tests that we believe will address significant market opportunities in the United States public health market for HIV and Syphilis testing. The HIV test has already been approved by the PEPFAR program and U.S. clinical trials have started. This product could also be a candidate for U.S. over-the-counter approval once it is approved for the professional market. The syphilis test, which would be the first point of care test in the U.S. for syphilis, should begin testing by mid-year 2010. We are also planning to complete this year the development of DPP® POC rapid tests for Influenza A/B. We also envision several other products based on enhancements to DPP®.

The global point-of-care segment of the IVD industry is estimated to be \$6 to 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. 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 OF THE OFFERING

Securities offered:	Up to ___ units. Each unit will consist of ___ shares of our common stock and warrants to purchase up to an additional ___ shares of our common stock.
Offering Price:	\$_____ per unit.
Description of Warrants:	Each warrant constitutes the right to purchase one share of our common stock at an exercise price of \$__ per share.
Common stock outstanding prior to the offering:	_____ shares.
Common stock outstanding after the offering:	_____ shares, which does not include _____ shares of common stock issuable upon exercise of the warrants included in the offered units or the shares of common stock issuable upon the exercise of the placement agent warrants.
Use of proceeds:	We expect to use the proceeds received from the offering for product development, FDA submission-related activities, general corporate purposes, and working capital.
OTC BB Symbol:	CEMI.OB
Risk Factors:	See "Risk Factors" beginning on page 3 and the other information in this Prospectus for a discussion of the factors you should consider before you decide to invest in the units.

The total number of shares of our common stock outstanding is 61,996,651 and does not include the following:

1,521,350 shares of common stock reserved for future issuance under our equity incentive plans. As of March 22, 2010, there were options to purchase 5,870,150 shares of our common stock outstanding under our equity incentive plans with a weighted average exercise price of \$0.155 per share;

2,838,379 shares of common stock issuable upon exercise of outstanding warrants and options as of March 22, 2010, with exercise prices ranging from \$.40 per share to \$1.00 per share; and

\_\_\_\_\_ shares of common stock that will be issued upon exercise of warrants at an exercise price of \$\_\_ per share sold as part of the units in this offering.

## 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. The risks described below are those we currently believe may materially affect us. An investment in our securities 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, which would negatively affect our business.

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, as of December 31, 2009, production equipment of \$323,500 that the Company had 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; and
  - competition
  - pricing
- 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 relating to this Offering

We will have immediate and broad discretion over the use of the net proceeds from this offering.

There is no minimum offering amount required as a condition to closing this offering and therefore net proceeds from this offering will be immediately available to us to use at our discretion. We intend to use the net proceeds to further develop our products, for FDA submission-related activities and for working capital and general corporate purposes. Our judgment may not result in positive returns on your investment and you will not have an opportunity to evaluate the economic, financial or other information upon which we base our decisions.

Future sales by our stockholders may adversely affect our stock price and our ability to raise funds in new stock offerings.

Sales of our common stock in the public market following this offering could lower the market price of our common stock. Sales may also make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that our management deems acceptable or at all. All of the 61,996,651 shares of common stock outstanding as of March 22, 2010 are freely tradable without restriction, except for those shares that are held by our "affiliates" or have been held by a shareholder that was deemed an "affiliate" in the previous 90 days. Portions of the shares held by "affiliates" may be resold under Rule 144. The 8,708,529 shares issuable upon exercise of outstanding warrants and options could also lower the market price of our common stock.

You will experience immediate and substantial dilution as a result of this offering and may experience additional dilution in the future.

You will incur immediate and substantial dilution as a result of this offering. After giving effect to the sale by us of up to \_\_\_ units offered in this offering at a public offering price of \$\_\_\_ per unit, and after deducting placement agent commissions and estimated offering expenses payable by us, based upon the net tangible book value per share as of \_\_\_, 2010, investors in this offering can expect an immediate dilution of \$\_\_\_ per share, or \_\_%, at the public offering price, assuming no exercise of the warrants. In addition, in the past, we issued options and warrants to acquire shares of common stock. To the extent these options and warrants are ultimately exercised, you will sustain future dilution. We may also acquire or license other technologies or finance strategic alliances by issuing equity, which may result in additional dilution to our stockholders.

There is no public market for the warrants to purchase common stock in this offering.

There is no public trading market for the warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply for listing the warrants on any securities exchange. Without an active market, the liquidity of the warrants will be limited.

If the registration statement covering the common stock issuable upon exercise of the warrants contained in the units is no longer effective, the unit warrants will be issued with restrictive legends unless such shares are eligible for sale under Rule 144.

The offering may not be fully subscribed and, even if the offering is fully subscribed, we will need additional capital in the future. If additional capital is not available, we may not be able to continue to operate our business pursuant to our business plan or we may have to discontinue our operations entirely.

The placement agent in this offering will offer the units on a "best-efforts" basis, meaning that we may raise substantially less than the total maximum offering amounts. No refund will be made available to investors if less than all of the units are sold. Based on our proposed use of proceeds, we will likely need significant additional financing,

which we may seek to raise through, among other means, public and private equity offerings and/or debt financing. Any equity financing will be dilutive to existing stockholders, and any debt financings will likely involve covenants restricting our business activities. Additional financing may not be available on acceptable terms, or at all.

#### Risks related to our Common Stock

An investment in our common stock may be less attractive because it is not traded on a recognized public market.

Our common stock has traded on the OTC Bulletin Board, or OTCBB since 2004. The OTCBB and Pink Sheets are viewed by most investors as a less desirable, and less liquid, marketplace. As a result, an investor may find it more difficult to purchase, dispose of or obtain accurate quotations as to the value of its common stock.

Our common stock is subject to Rules 15g-1 through 15g-9 under the Exchange Act, which imposes certain sales practice requirements on broker-dealers who sell its common stock to persons other than established customers and "accredited investors" (as defined in Rule 501(c) of the Securities Act). For transactions covered by this rule, a broker-dealer must make a special suitability determination for the purchaser and have received the purchaser's written consent to the transaction prior to the sale. This rule adversely affects the ability of broker-dealers to sell Chembio's common stock and purchasers of our common stock to sell their shares of Chembio's 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 123,000 shares per day over the three months ended March 22, 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.

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.

#### 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 these words or other comparable terminology, we are identifying forward-looking statements. Forward-looking statements involve risks and uncertainties, which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. These factors include our research and development activities, distributor 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.”

## USE OF PROCEEDS

We estimate that we will receive up to \$\_\_\_\_\_ in net proceeds from the sale of units in this offering, based on an assumed price of \$\_\_\_ per unit and after deducting estimated placement agent fees and estimated offering expenses payable by us. We intend to use the net proceeds from this offering for product development, FDA submission-related activities, general corporate purposes, and working capital. As of the date of this prospectus, we cannot specify with certainty all of the particular uses of the proceeds from this offering. We will retain broad discretion over the use of such proceeds. Pending the use of net proceeds from this offering, we plan to invest the net proceeds in investment-grade, short-term, interest-bearing securities.

We also may also receive proceeds from the exercise of warrants. We cannot predict when or if the warrants will be exercised. It is possible that the warrants may expire and may never be exercised.

## PRICE RANGE OF OUR COMMON STOCK

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

Fiscal Year 2010	High Bid	Low Bid
First Quarter (through March 22, 2010)	\$.33	\$.20

  

Fiscal Year 2009	High Bid	Low Bid
First Quarter	\$.135	\$.075
Second Quarter	\$.18	\$.085
Third Quarter	\$.23	\$.12
Fourth Quarter	\$.39	\$.20

  

Fiscal Year 2008	High Bid	Low Bid
First Quarter	\$0.30	\$0.11
Second Quarter	\$0.26	\$0.08
Third Quarter	\$0.28	\$0.15
Fourth Quarter	\$0.21	\$0.10

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

#### Holders

As of March 8, 2010, there were approximately 1,350 record owners of our common stock. On March 22, 2010, the closing price for the common stock as quoted on the OTC Bulletin Board was \$.21. There were 61,996,651 shares of common stock outstanding at March 22, 2010.

Dividends

The Company has never paid cash dividends on its common stock and has no plans to do so in the foreseeable future.

9

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## SELECTED FINANCIAL INFORMATION

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 DATAStatement of  
Operations Data:

	December 31, 2009	December 31, 2008	December 31, 2007	December 31, 2006	December 31, 2005
<b>TOTAL REVENUES</b>	\$13,834,248	\$11,049,571	\$9,230,948	\$6,502,480	\$3,940,730
<b>GROSS PROFIT</b>	5,860,405 42%	3,851,721 35%	2,795,710 30%	1,608,272 25%	944,648 24%
<b>OVERHEAD COSTS:</b>					
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
<b>INCOME (LOSS) FROM OPERATIONS</b>	317,327	(2,070,668)	(2,876,164)	(4,580,193)	(3,297,987)
<b>OTHER INCOME (EXPENSES):</b>	(8,267)	121,898	249,272	(414,827)	45,987
<b>NET INCOME (LOSS)</b>	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
<b>NET INCOME (LOSS) ATTRIBUTABLE TO COMMON STOCKHOLDERS</b>	\$309,060	\$(1,948,770)-18%	\$(8,272,202)-90%	\$(8,205,066)-126%	\$(6,769,022)-172%

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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 comparable terminology. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

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 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 Mark	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 the section entitled "Description of Property" on page 33 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 the section entitled "Executive Compensation" on page 35 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		\$ Change	% Change	
	December 31, 2009	December 31, 2008			
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		\$ Change	% Change	
	December 31, 2009	December 31, 2008			
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		\$ Change	% Change	
	December 31, 2009	December 31, 2008			
<b>Clinical &amp; Regulatory Affairs:</b>					
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	-	12,916	100.00	%
Clinical trials	69,499	138,792	(69,293 )	-49.93	%
Other	32,056	60,822	(28,766 )	-47.30	%
<b>Total Regulatory</b>	<b>\$ 471,861</b>	<b>\$ 489,036</b>	<b>\$ (17,175 )</b>	<b>-3.51</b>	<b>%</b>
<b>R&amp;D Other than Regulatory:</b>					
Wages and related costs	\$ 1,541,295	\$ 1,354,557	\$ 186,738	13.79	%
Consulting	74,194	138,436	(64,242 )	-46.41	%
Share-based compensation	62,180	84,935	(22,755 )	-26.79	%
Materials and supplies	462,806	282,281	180,525	63.95	%
Other	271,360	256,098	15,262	5.96	%
<b>Total other than Regulatory</b>	<b>\$ 2,411,835</b>	<b>\$ 2,116,307</b>	<b>\$ 295,528</b>	<b>13.96</b>	<b>%</b>
<b>Total Research and Development</b>	<b>\$ 2,883,696</b>	<b>\$ 2,605,343</b>	<b>\$ 278,353</b>	<b>10.68</b>	<b>%</b>

Expenses for Clinical & Regulatory Affairs for the year ended December 31, 2009 decreased by \$17,000 as compared to the same period in 2008. This was primarily due to expenses we incurred in 2008 for external clinical trials conducted in order to lower the age limitation of our FDA approved rapid HIV tests from 18 to 13 years of age in 2008, which did not recur. This decrease was partially offset by an increase in wages and related costs.

R&D expenses other than Clinical & Regulatory Affairs increased by \$295,000 in the year ended December 31, 2009 as compared with the same period in 2008 and were primarily related to an increase in personnel and material costs required to perform the work related to funded research and development contracts and grants all related to our patented DPP® technology. These increases were partially offset by a decrease in consulting cost and the reduced cost of share-based compensation related to the value of employee stock options issued and amortized.

## Selling, General and Administrative Expense:

## Selected expense lines:

	For the years ended			
	December 31, 2009	December 31, 2008	\$ Change	% Change
Wages and related costs	\$ 1,075,532	\$ 1,261,511	\$ (185,979 )	-14.74 %
Consulting	165,371	187,494	(22,123 )	-11.80 %
Commissions	302,515	365,774	(63,259 )	-17.29 %
Share-based compensation	98,356	187,908	(89,552 )	-47.66 %
Marketing materials	22,779	38,379	(15,600 )	-40.65 %
Investor relations	72,888	123,654	(50,766 )	-41.05 %
Legal, accounting and Sox 404 compliance	470,843	556,118	(85,275 )	-15.33 %
Travel, entertainment and trade shows	61,316	92,576	(31,260 )	-33.77 %
Other	389,782	503,632	(113,850 )	-22.61 %
Total S, G &A	\$ 2,659,382	\$ 3,317,046	\$ (657,664 )	-19.83 %

Selling, general and administrative expenses for the year ended December 31, 2009 decreased by 20% as compared with the same period in 2008. During the second half of 2008 and continuing in 2009 the Company implemented a series of cost reductions that have resulted in lower S,G&A expenses in almost every category in 2009 year to date with the exception of sales commissions which, decreased as a result of a decrease in commissionable sales (and not from the Company's cost reductions) as compared with the 2008 period.

## Other Income and Expense:

	For the years ended			
	December 31, 2009	December 31, 2008	\$ Change	% Change
Other income	\$ (6,696 )	\$ 95,812	\$ (102,508 )	-106.99 %
Interest income	9,032	34,403	(25,371 )	-73.75 %
Interest expense	(10,603 )	(8,317 )	(2,286 )	-27.49 %
Total Other Income and (Expense)	\$ (8,267 )	\$ 121,898	\$ (130,165 )	-106.78 %

Other income and (expense) for the year ended December 31, 2009 decreased 107% as compared with the same period in 2008 primarily as a result of a decrease in the net amounts received from New York State related to a program for qualified emerging technology companies. Interest income for the year ended December 31, 2009 decreased due to a decrease in available funds to invest in interest bearing accounts.

## RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED DECEMBER 31, 2009 AS COMPARED WITH THE THREE MONTHS ENDED DECEMBER 31, 2008

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
CONSOLIDATED STATEMENTS OF OPERATIONS  
FOR THE THREE MONTHS ENDED  
(UNAUDITED)

	December 31, 2009	December 31, 2008
<b>REVENUES:</b>		
Net product sales	\$ 3,127,454	\$ 2,244,753
License and royalty income	38,186	-
Research grant income	385,801	206,141
<b>TOTAL REVENUES</b>	<b>3,551,441</b>	<b>2,450,894</b>
Cost of product sales	1,920,636	1,835,604
<b>GROSS PROFIT</b>	<b>1,630,805</b>	<b>615,290</b>
<b>OPERATING EXPENSES:</b>		
Research and development expenses	755,836	652,906
Selling, general and administrative expenses	657,310	620,695
	1,413,146	1,273,601
<b>INCOME (LOSS) FROM OPERATIONS</b>	<b>217,659</b>	<b>(658,311 )</b>
<b>OTHER INCOME (EXPENSES):</b>		
Other income	-	107,363
Interest income	1,949	4,446
Interest expense	(2,394 )	(3,901 )
	(445 )	107,908
<b>INCOME (LOSS) BEFORE INCOME TAXES</b>	<b>217,214</b>	<b>(550,403 )</b>
Provision for income taxes	-	-
<b>NET INCOME (LOSS)</b>	<b>\$ 217,214</b>	<b>\$ (550,403 )</b>
Basic earnings (loss) per share	\$ 0.00	\$ (0.01 )
Diluted earnings (loss) per share	\$ 0.00	\$ (0.01 )
Weighted average number of shares outstanding, basic	61,950,988	61,944,901
Weighted average number of shares outstanding, diluted	75,365,550	61,944,901

See accompanying notes to consolidated financial statements

## Revenues:

Product Categories:	For the three months ended			
	December 31, 2009	December 31, 2008	\$ Change	% Change
HIV	\$ 2,963,671	\$ 1,963,383	\$ 1,000,288	50.95 %
DPP	-	126,000	(126,000 )	-100.00 %
Other	163,783	155,370	8,413	5.41 %
Net Product Sales	3,127,454	2,244,753	882,701	39.32 %
License and royalty income	38,186	-	38,186	100.00 %
R&D contracts and grants	385,801	206,141	179,660	87.15 %
Total Revenues	\$ 3,551,441	\$ 2,450,894	\$ 1,100,547	44.90 %

Revenues for our HIV tests during the three months ended December 31, 2009 increased by approximately 51% or \$1,000,000 over the same period in 2008. This was primarily attributable to increased sales in North America, primarily from sales to Inverness of our HIV products which increased by \$1,292,000 to \$1,833,000, and partially offset by a decrease in sales to Brazil of \$374,000. The increase in R&D contracts and grants was primarily due to revenue from our recent NIH grant for Leptospirosis, which was effective as of June 1, 2009. License and royalty income represents our royalties from Brazil under our 2004 technology transfer and license agreement.

## Gross Margin:

Gross Margin related to  
Net Product Sales:

	For the three months ended			
	December 31, 2009	December 31, 2008	\$ Change	% Change
Gross Margin per Statement of Operations	\$ 1,630,805	\$ 615,290	\$ 1,015,515	160.05 %
Less:R&D contracts and grants, license and royalties	423,987	206,141	217,846	105.68 %
Gross Margin from Net Product Sales	\$ 1,206,818	\$ 409,149	\$ 797,669	194.96 %
Gross Margin %	38.59 %	18.23 %		

The increase in our gross margin resulted primarily from increased sales volume and average unit prices 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. The increase in our gross margin in the three months ended December 31, 2009 also includes a decrease of \$225,000 in the royalty expense paid to Inverness as partial reimbursement for Inverness' royalty payments to Bio-Rad Laboratories, Inc. pursuant to Inverness' HIV-2 sublicense agreement with Bio-Rad.





## Research and Development:

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

	For the three months ended				
	December 31,	December 31,			
	2009	2008	\$ Change	% Change	
<b>Clinical &amp; Regulatory Affairs:</b>					
Wages and related costs	\$ 96,284	\$ 67,294	\$ 28,990	43.08	%
Consulting	5,610	2,548	3,062	120.17	%
Share-based compensation	4,667	-	4,667	100.00	%
Clinical trials	23,448	-	23,448	100.00	%
Other	7,852	7,727	125	1.62	%
<b>Total Regulatory</b>	<b>\$ 137,861</b>	<b>\$ 77,569</b>	<b>\$ 60,292</b>	<b>77.73</b>	<b>%</b>
<b>R&amp;D Other than Regulatory:</b>					
Wages and related costs	\$ 420,088	\$ 361,630	\$ 58,458	16.17	%
Consulting	10,646	33,455	(22,809 )	-68.18	%
Share-based compensation	9,722	9,738	(16 )	-0.16	%
Materials and supplies	102,491	91,536	10,955	11.97	%
Other	75,028	78,978	(3,950 )	-5.00	%
<b>Total other than Regulatory</b>	<b>\$ 617,975</b>	<b>\$ 575,337</b>	<b>\$ 42,638</b>	<b>7.41</b>	<b>%</b>
<b>Total Research and Development</b>	<b>\$ 755,836</b>	<b>\$ 652,906</b>	<b>\$ 102,930</b>	<b>15.76</b>	<b>%</b>

Total expenses for Clinical & Regulatory Affairs for the three months ended December 31, 2009 increased by approximately \$60,000 as compared to the same period in 2008. An increase in compensation in Clinical and Regulatory Affairs of \$29,000, was the primary reason for the increase in wages and related costs. In addition, start up costs for clinical trials of our DPP® oral fluid HIV test also contributed to this increase.

Total expenses for R&D Other than Clinical & Regulatory Affairs increased by approximately \$43,000 in the three months ended December 31, 2009 as compared with the same period in 2008. These increases were primarily related to an increase in compensation, materials and supplies related to R&D contracts and grants, partially offset by a reduction in the use of consultants and other expenses.

## Selling, General and Administrative Expenses:

Selected expense lines:	For the three months ended		\$ Change	% Change	
	December 31,	December 31,			
	2009	2008			
Wages and related costs	\$ 324,131	\$ 257,778	\$ 66,353	25.74	%

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Consulting	22,250	45,912	(23,662 )	-51.54	%
Commissions	15,952	50,894	(34,942 )	-68.66	%
Share-based compensation	30,414	14,082	16,332	115.98	%
Marketing materials	5,419	15,831	(10,412 )	-65.77	%
Investor relations	35,839	11,906	23,933	201.02	%
Legal, accounting and Sox 404 compliance	123,500	81,562	41,938	51.42	%
Travel, entertainment and trade shows	13,849	20,730	(6,881 )	-33.19	%
Other	85,956	122,000	(36,044 )	-29.54	%
Total S, G &A	\$ 657,310	\$ 620,695	\$ 36,615	5.90	

Selling, general and administrative expenses (S,G&A) for the three months ended December 31, 2009 increased by 5.9% as compared with the same period in 2008. This was primarily due to increased wages and related expenses related to bonuses paid to compensate employees who had taken pay reductions during the first six months of the 2009 year.

## Other Income and (Expense):

	For the three months ended			
	December 31, 2009	December 31, 2008	\$ Change	% Change
Other income (expense)	\$ -	\$ 107,363	\$ (107,363 )	-100.00 %
Interest income	1,949	4,446	(2,497 )	-56.16 %
Interest expense	(2,394 )	(3,901 )	1,507	-38.63 %
Total Other Income and (Expense)	\$ (445 )	\$ 107,908	\$ (108,353 )	-100.41 %

Other income and (expenses) for the three months ended December 31, 2009 decreased approximately \$108,000 as compared with the same period in 2008, primarily as a result of a decrease in the net amounts received from New York State related to a program for qualified emerging technology companies.

## LIQUIDITY AND CAPITAL RESOURCES

	For the years ended			
	December 31, 2009	December 31, 2008	\$ Change	% Change
Net cash provided by (used in) operating activities	\$ 251,927	\$ (1,194,227 )	\$ 1,446,154	-121.10 %
Net cash used in investing activities	(376,988 )	(397,462 )	20,474	-5.15 %
Net cash provided by (used) in financing activities	(18,926 )	(23,458 )	4,532	-19.32 %
<b>NET DECREASE IN CASH AND CASH EQUIVALENTS</b>	<b>\$ (143,987 )</b>	<b>\$ (1,615,147 )</b>	<b>\$ 1,471,160</b>	<b>-91.09 %</b>

The Company had a decrease in cash for the year ended December 31, 2009 as compared to a greater decrease in cash for the same period in 2008. The decrease during the 2009 period is primarily attributable to cash used on deposits and acquisition of fixed assets, partially offset by cash provided from operations. The decrease in the 2008 period is primarily attributable to the cash used in operations.

The Company had a working capital surplus of \$1,494,000 at December 31, 2009 and a working capital surplus of \$1,664,000 at December 31, 2008. 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 and the Company expects to receive up to \$1 million in license fees from Brazil, although there can be no assurance); (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; (5) the payment of obligations and commitments (including a license fee payable of \$875,000 due at the end of 2010); and (4) the 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 become profitable or generate positive cash flow by the end of 2010 or, in the alternative, be successful in raising sufficient capital to fund its needs through 2010.

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

Please see section entitled Recent Events above.

In 2009 Chembio achieved record revenues, gross margin, operating results and cash flow, including its first ever quarterly and full year profits since its reverse merger in 2004. Following net losses from 2004-2008, including our smallest loss in 2008 of nearly \$2 million, we swung to net income of \$309,000 in 2009. This was a notable achievement given that 2009 was the worst economy since World War II. We believe this achievement was attributable to several factors, including: (1) the \$3.13 million, or 148%, increase in our rapid HIV test sales to Inverness more than offset a \$1.53 million, or 21.6%, decrease in our international HIV rapid test sales. Higher average selling prices in the U.S. market for rapid HIV tests helped to produce a 36.8%, or \$1.16 million, increase in our gross margin on product sales, from \$3.16 million in 2008 to \$4.32 million in 2009. These increased U.S. market revenues reflect the continued expansion in the U.S. rapid HIV test market, and relatively stable funding as rapid testing has taken hold, and expanded into more hospitals and public health testing venues. The increased average selling prices for our FDA PMA approved HIV rapid test products that are sold in the U.S. market as compared with those in the developing world provide us with a much more attractive return on the manufacturing, regulatory compliance and other costs (patent license fees and such as royalty expense) that are applicable to these products. This return is much lower on our international sales primarily due to the lower average selling prices of competitive products manufactured in Asia that do not have the same costs of regulatory compliance, labor and other items that we have in the United States with our products; (2) a 392%, or \$494,000, increase in DPP® product sales attributable to our OEM agreements for new DPP® products with FIOCRUZ in Brazil. While such amount was significantly less than what we had anticipated, and this product was used by FIOCRUZ for regulatory submissions for the three DPP® products that have been submitted for regulatory approval in Brazil, these shipments at least allowed us to bring these products through our manufacturing process. We are optimistic that the four DPP® products we have under agreement will produce significant DPP® product and technology revenues during 2010 and beyond, although there can be no assurance of this; (3) A 93%, or \$646,000, increase in R&D contracts and grants to \$1.34 million in 2009 from \$694,000 in 2008 more than offset the \$278,000 increase in our research and development expenses from \$2.61 million in 2008 to \$2.88 million in 2009, as more commercial, governmental and non-governmental organizations entered into development programs with us related to our DPP® technology as we reported during 2009; and (4) 20% reduction in our SG&A expenses from \$3.32 million in 2008 to \$2.66 million in 2009, which decrease followed an 11.9% reduction in 2008 over 2007 and a 21.3% reduction in 2007 over 2006.

20

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The December 31, 2009 cash balance was \$144,000 less than at December 31, 2008. This was primarily due to \$792,000 that was paid to Inverness pursuant to our agreement of December 2008 in which we agreed to amortize a \$1.01 million liability to Inverness based on a percentage of their sales of our products beginning in 2009. Based on Inverness' anticipated sales of our products in 2010, we anticipate that the liability mentioned above will be fully amortized in the first part of 2010, thereby freeing up this cash flow used to extinguish the obligation to Inverness for other corporate purposes. Also contributing to the cash decrease was a \$675,000 account receivable balance that was outstanding at the year end (which amount was paid in January 2010) and \$400,000 that we invested during 2009 in new equipment and facilities (primarily our new assembly system that we took delivery of in February 2010). Partially offsetting these cash outflows were our net income, non-cash expenses, and receipt of a \$340,000 license fee deposit from Bio-Rad Laboratories, Inc.

Our results in 2009 clearly guide our strategy for growth in 2010 and beyond. We believe we can best leverage our DPP® intellectual property together with our U.S.-based manufacturing and regulatory credentials by bringing proprietary products (such as our DPP® oral fluid HIV test and our Screen and Confirm Syphilis test) to the U.S. public health and other markets. Based on our current year and long range plan, we are optimistic that revenues will grow significantly in the foreseeable future, although there can be no assurance of this.

Significant revenue growth in 2010 could be realized, based on the following assumptions: (1) Increased sales of our rapid HIV tests in the U.S. market as the total market and our products' market share increases; (2) increased international sales of our HIV rapid tests primarily based on maintaining current accounts, increased sales to Nigeria where we resumed sales activity in the fourth quarter of 2009 for the first time since 2008; (3) DPP® product sales and license fees from our contracts with FIOCRUZ (including regulatory approvals required in Brazil) and completion of the product development phase in our program with Bio-Rad Laboratories, Inc. which would result in recognizing the \$340,000 license fee we received in 2009; (4) a substantial increase in our R&D contracts and grants primarily based on the \$900,000 development contract we entered in December 2009 with Battelle Memorial Institute and having a full year of the \$2.9 million NIH grant for Leptospirosis we received in June 2009, and; (5) improved manufacturing efficiencies based on the delivery in February of our customized automated assembly system which we invested in during 2009 for both our lateral flow and DPP® products, and lower costs for certain raw materials used in our HIV tests which we will realize as a result of our having bought out a license agreement in connection with the insolvency procedures of the licensor in 2009.

We have received purchase orders from FIOCRUZ for the three products pending regulatory approval for an aggregate of over \$2 million, and have an aggregate of approximately \$1 million in license fees that will be payable when the products are approved. However the fees will not be paid and these orders cannot be processed and shipped unless and until regulatory approval is obtained in Brazil, which we believe will occur during the first half of 2010, but for which there can be no assurance.

The anticipated increased product and research and development revenues, if realized will be accompanied by increased product costs and research and development expenses which will be attributable to the increased R&D work primarily required by the above-mentioned R&D contracts & grants; such expenses may also increase as a result of other initiatives that we have identified that we may be undertaking to further expand and enhance our technology portfolio.

In addition, we have commenced training for the conduct of clinical trials related to our planned FDA PMA application for our DPP® oral fluid HIV test. We anticipate that the total costs for thee trials during 2010 for this and related regulatory activities could approach \$2 million. Moreover, additional regulatory expenses for preparing our DPP® Syphilis Screen & Confirm test and our DPP® Flu A/B tests for 510(k) submissions will also require significant resources, though not nearly as much as the aforementioned PMA. We may attempt to enter an agreement with a marketing partner for one more of these products which could result in our being reimbursed for a portion of our regulatory expenses for one or more of these products, but there can be no assurance of this occurring or if

it occurs, its timing. We can also defer some or all of these costs to ensure that we can finance them with operating cash flow, though this would impact commercialization timetables.

Although we believe that there are still opportunities to increase our international HIV test sales and we plan to do so in 2010, we are cognizant that these markets will continue to be largely driven by price and therefore difficult for our U.S.-based cost structure (though still contributing margin), and very difficult to forecast due to their reliance on host governments' decisions which can suddenly and arbitrarily result in changes even though they are funded by foreign aid budgets, mainly PEPFAR. On the other hand, based on the outstanding data from a recent field study by the United States Centers for Disease Control of our oral fluid HIV test in Africa, where it was compared with two leading blood tests and an oral fluid test of a competitor's, we believe that there could well be significant opportunities for this product in the international market, in which we are one of only two oral fluid HIV tests approved for procurement by PEPFAR, as compared with dozens now that only work on blood matrices. Further, we believe that if studies that having been completed can show that oral fluid tests can improve prevention strategies by encouraging more people to be tested, and particularly if we can continue to lower our productions costs for this product to be more competitively priced for this market, the international opportunity for this product will be significant indeed.

If the assumptions set forth above hold true, of which there is no assurance – particularly where timing is concerned – we believe that our operating cash flow from our existing business will likely be sufficient to fund a substantial portion of the research and development and regulatory expenses required in order to begin commercializing these new products in 2011, though there can be no assurance of this. We believe that we must invest in these new product approvals in order to meet our long range plan for significant growth.

We will endeavor to time the increases in our research and development expenses, with the increased R&D contracts and grants we anticipate receiving as described above. However, delays in achievement of milestones and/or their approval for the purpose of funding of payments that may be due to us can occur.

We also anticipate that our SG&A expenses, after having decreased in each of the last three years, will not continue this trend into 2010. This is attributable to: a) our having reduced this expense so significantly over the last three years; b) expenses we may incur in 2010 that are associated with the potential establishment of our own Chembio/DPP® branded product line in 2011; and c) expenses we may incur related to expansion of our board of directors and investor relations activities as compared to 2009.

Accordingly, in order to increase the likelihood that the regulatory approvals and commercialization of new DPP® products occur on a timely basis, we may choose to raise some additional capital if we believe such capital will best ensure our ability to execute our business plan on a timely basis.

#### Equipment Purchase Commitment:

In January 2009, the Company entered into an agreement with an equipment manufacturer to design and build equipment that will be used to automate the assembling of our tests and lower our production costs. The estimated cost of \$323,500 was paid in installments and was delivered in February 2010. In addition in June and November of 2009, the Company entered into an agreement with an equipment manufacturer to design and build a mold for its DPP® tests. The estimated cost of \$113,800 is being paid in installments.

#### Critical Accounting Policies and Estimates

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

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

#### Revenue Recognition –

We sell our products directly through our sales force and through distributors. Revenue from direct sales of our product are recognized upon shipment to the customer. Income from R&D contracts and grants are recognized in earnings in the period in which the related expenditures are incurred. Sales are recorded net of discounts, rebates and returns.

#### Research & Development Costs –

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

Valuation of Inventories –

Inventories are stated at the lower of cost or market, using the first-in, first-out method (FIFO) to determine cost. Our policy is to periodically evaluate the market value of the inventory and the stage of product life cycle, and record a reserve for any inventory considered slow moving or obsolete. For example, each additional 1% of obsolete inventory would reduce such inventory by approximately \$15,000.



Allowance for doubtful accounts –

Our policy is to review our accounts receivable on a periodic basis, no less than monthly. On a quarterly basis an analysis is made of the adequacy of our allowance for doubtful accounts and adjustments are made accordingly. The current allowance is approximately 1.1% of accounts receivable. For example each additional 1% of accounts receivable that becomes uncollectible would reduce such balance of accounts receivable by approximately \$18,000.

Income Taxes –

Income taxes are accounted for under ASC740 "Accounting for Income Taxes." ASC740 requires the asset and liability method of accounting for deferred income taxes. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities. Deferred tax assets or liabilities at the end of each period are determined using the tax rate expected to be in effect when taxes are actually paid or recovered. For example, even though we have become profitable, we may be unable to utilize our deferred tax asset, which approximates \$8,418,000 at December 31, 2009.

ASC740 also requires that a valuation allowance be established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence needs to be considered, including a company's current and past performance, the market environment in which the company operates, length of carryback and carryforward periods and existing contracts that will result in future profits.

Forming a conclusion that a valuation allowance is not needed is difficult when there is negative objective evidence such as cumulative losses in recent years. Cumulative losses weigh heavily in the overall assessment. As a result, we determined that it was appropriate to establish a valuation allowance for the full amount of our deferred tax assets.

ASC740 also prescribes a comprehensive model for recognizing, measuring, presenting and disclosing in the consolidated financial statements tax positions taken or expected to be taken on a tax return, including a decision whether to file or not to file in a particular jurisdiction.

The calculation of our tax liabilities involves the inherent uncertainty associated with the application of complex tax laws. We are subject to examination by various taxing authorities. We believe that as a result of our losses sustained to date, any examination would result in a reduction of our net operating losses rather than a tax liability. As such, we have not provided for additional taxes estimated under ASC740, Accounting for Uncertainty in Income Taxes.

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

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

## DESCRIPTION OF BUSINESS

### General

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, respectively, 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 initial product revenues we generated from our DPP® products in 2009, and which we believe will increase significantly in 2010, are through OEM agreements with FIOCRUZ, which is part of the Brazilian Ministry of Health and from contract development agreements and grants all based on our DPP®. We have also completed development of some of our own DPP® products that which we are now beginning the regulatory approval process in order to commercialize under Chembio or DPP® brands. Specifically, Chembio has completed development of two unique rapid tests that we believe will address significant market opportunities in the United States public health market for HIV and Syphilis testing. The HIV test has already been approved by the PEPFAR program and U.S. clinical trials have started. This product could also be a candidate for U.S. over-the-counter approval once it is approved for the professional market. The syphilis test, which would be the first point of care test in the U.S. for syphilis, should begin testing by mid-year 2010. We are also planning to complete this year the development of DPP® POC rapid tests for Influenza A/B. We also envision several other products based on enhancements to DPP®.

The global point-of-care segment of the IVD industry is estimated to be \$6 to 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. 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.

## 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 Market

### 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.



## 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 5.41% 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.

<b>PROTOCOL</b>	A procedure pursuant to which an immunodiagnostic test is performed on a particular specimen in order to obtain the desired reaction.
<b>REAGENT</b>	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.
<b>RETROVIRUS</b>	A type of virus which contains the enzyme Reverse Transcriptase and is capable of transforming infected cells to produce diseases in the host such as AIDS.
<b>SAB</b>	Staff Accounting Bulletin
<b>SENSITIVITY</b>	Refers to the ability of an assay to detect and measure small quantities of a substance of interest. The greater the sensitivity, the smaller the quantity of the substance of interest the assay can detect. Also refers to the likelihood of detecting the antigen when present.
<b>SPECIFICITY</b>	The ability of an assay to distinguish between similar materials. The greater the specificity, the better an assay is at identifying a substance in the presence of substances of similar makeup.
<b>SPUTUM</b>	Expectorated matter; saliva mixed with discharges from the respiratory passages
<b>TB</b>	Tuberculosis (TB) is a disease caused by bacteria called Mycobacterium tuberculosis. The bacteria usually attack the lungs. But, TB bacteria can attack any part of the body such as the kidney, spine, and brain. If not treated properly, TB disease can be fatal. TB is spread through the air from one person to another. The bacteria are put into the air when a person with active TB disease of the lungs or throat coughs or sneezes. People nearby may breathe in these bacteria and become infected.
<b>UNAIDS</b>	Joint United Nations Program on HIV/AIDS
<b>USAID</b>	United States Agency for International Development
<b>USDA</b>	U.S Department of Agriculture
<b>WHO</b>	World Health Organization

## DESCRIPTION OF PROPERTY

Our administrative offices and research facilities are located in Medford, New York. We lease approximately 23,400 square feet of industrial space for \$14,683 per month. The space is utilized for research and development activities (approximately 2,600 square feet), offices (approximately 2,640 square feet) and production (approximately 18,160 square feet). The lease term expires on April 30, 2014. Additional space may be required as we expand our research and development activities. We do not foresee any significant difficulties in obtaining any required additional facilities. We entered into a second lease effective February 1st of 2010, the principle terms of this lease are the same as the one entered into in 2009 and are as follows: (a) a lease term ending April 30, 2014; (b) an initial rent of \$11,350 per month plus \$3,333 for the second lease (March and April of 2010 are free and the month of April in 2011, 2012 and 2013 is also free) ; (c) the monthly rent for year two of the lease (does not apply to second lease) will increase by the lower of (i) the change in the consumer price index, or (ii) five percent; and (d) the monthly rent for years three through five of the lease (years two through four of the second lease) will increase each year by the lower of (i) the change in the consumer price index, or (ii) two and one half percent.

## 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](http://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.

## EXECUTIVE COMPENSATION

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

Name / Principal Position	Year	Salary <sup>1</sup> (\$)	Bonus <sup>2</sup> (\$)	Option Awards <sup>3</sup> (\$)	Stock Awards (\$)	All Other Compensation <sup>5</sup> (\$)	Total (\$)
Lawrence A. Siebert <sup>4</sup> CEO	2009	\$ 265,000	\$ 110,200	\$ 37,950	\$ -	\$ 7,200	\$ 420,350
	2008	265,000	26,000	36,695	-	8,267	335,962
Javan Esfandiari VP-R&D	2009	\$ 230,192	\$ 29,400	\$ 28,200	\$ 5,000	\$ 4,883	\$ 297,675
	2008	215,692	16,000	45,297	28,702	5,872	311,563
Tom Ippolito VP-Regulatory	2009	\$ 181,500	\$ 35,600	\$ 21,150	\$ -	\$ 140	\$ 238,390
	2008	173,631	12,000	8,129	-	1,708	195,468

1 Salary is total base salary.

2 Bonuses earned in 2009 were partially based on reaching certain objectives, which included revenue dollar levels and operating profit levels, additional amounts earned were discretionary. Bonuses earned in 2008 were paid solely on a discretionary basis, and not pursuant to any bonus plan.

3 The estimated fair value of any option or common stock granted was determined in accordance with ASC 718, "Share-Based Payment".

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

5 Other compensation includes an employer match to 401(K) contributions and car allowances where applicable.

## Employment Agreements

Mr. Siebert. Effective May 11, 2009, the Company's Board of Directors approved the Company's extension of the June 15, 2006 employment agreement (the "Employment Agreement") with Lawrence A. Siebert, the Company's President and Chief Executive Officer, for an additional three-year term. On June 15, 2006, Mr. Siebert and the Company entered into an Employment Agreement, effective May 10, 2006, which was to terminate on May 10, 2008, extended in 2008 to May 10, 2009. Pursuant to the Employment Agreement, Mr. Siebert serves as the President and Chief Executive Officer of the Company and received an initial salary of \$240,000 per year, which had been increased to \$265,000 per year until Mr. Siebert agreed to a 15 percent reduction, to \$225,000, effective January 19, 2009. Mr. Siebert's salary was restored to \$265,000 per annum effective in July 2009. Mr. Siebert also is eligible for a bonus of up to 50% of his salary, consisting of (i) a bonus of up to 25% of his salary that is at the complete discretion and determination of the board of directors, and (ii) a bonus of up to an additional 25% of his salary that will be determined based upon revenue and earnings performance criteria established each year by the board of directors. Mr. Siebert is eligible to participate in any profit sharing, stock option, retirement plan, medical and/or hospitalization plan, and/or other benefit plans except for disability and life insurance that the Company may from time to time place in effect for the Company's executives during the term of Mr. Siebert's employment agreement. If Mr. Siebert's Employment Agreement is terminated by the Company without cause, or if Mr. Siebert terminates his Employment Agreement for a reasonable basis, including within 12 months of a change in control, the Company is required to pay as severance Mr. Siebert's salary for six months. Mr. Siebert has agreed for a period of two years after the termination of his employment with the Company not to induce customers, agents, or other sources of distribution of the Company's business under contract or doing business with the Company to terminate, reduce, alter, or divert business

with or from the Company. The terms of the extended May 11, 2009 and May 11, 2008 Employment Agreements are identical to the June 15, 2006 Employment Agreement, except that under the May 11, 2008 extended Employment Agreement, Mr. Siebert received additional consideration in the form of incentive stock options to purchase 250,000 shares of the Company's common stock exercisable at \$0.13 per share, which was the closing price of the Company's common stock on June 3, 2008. The incentive stock options are immediately exercisable and they expire on the June 3, 2013.

35

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Mr. Esfandiari. 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. Mr. Esfandiari's salary under the Employment Agreement is \$245,000 for the first year, \$255,000 for the second year, and \$265,000 for the final year. Mr. Esfandiari is eligible for a cash bonus of up to 50% of his base salary for each respective year, consisting of (i) a cash bonus of up to 30% of his calendar year base salary based on the performance of the Company's Dual Path Platform Technology, which is directly related to certain annual revenue targets budgeted by management of the Company; (ii) a cash bonus of up to 10% of his calendar year base salary based on the attainment of certain specific research and development objectives, as determined by the Board, and (iii) a cash bonus of up to 10% of his calendar year base salary that is at the complete discretion and determination of the board of directors. The Company also granted Mr. Esfandiari, pursuant to the Company's 2008 Stock Incentive Plan, incentive stock options to purchase 300,000 shares of the Company's common stock. The price per share of these options is equal to the fair market value of the Company's common stock as of the close of the market on March 5, 2010, which is the date on which the Agreement was effective. Of these stock options to purchase 100,000 shares vest on the effective date, options to purchase an additional 100,000 shares of the stock options vested on the second anniversary of the Employment Agreement, and options to purchase an additional 100,000 shares of the stock options vested on the third anniversary of the Employment Agreement. Mr. Esfandiari is eligible to participate in any profit sharing, stock option, retirement plan, medical and/or hospitalization plan, and/or other benefit plans except for disability and life insurance that the Company may from time to time place in effect for the Company's executives during the term of Mr. Esfandiari's employment agreement. If Mr. Esfandiari's employment agreement is terminated by the Company without cause, or if Mr. Esfandiari terminates his employment agreement for a reasonable basis, as defined in the Employment Agreement including within 12 months of a change in control, the Company is required to pay as severance Mr. Esfandiari's salary for twelve months.

Mr. Ippolito does not have an employment contract with the Company.

#### Executive Bonus Plan

The Company has established a bonus plan for its executives who do not have a contract. For the fiscal year ended December 31, 2010, there were three executives eligible for this bonus plan. Each executive can earn up to 25% of that executive's salary in the form of a bonus. Half of the amount, or 12.5%, is determined by the Compensation Committee in its discretion, and the other half is subject to the Company's attaining certain objectives based on revenue and operating profit levels for the fiscal year for which the bonus is paid. The plan, during 2009, called for a sliding percentage of the executive's salary, from zero to 6.25% for attaining 85% to 100% of revenue goals, and from zero to 6.25% of the executive's salary for attaining between zero percent to 150% of the designated operating profit goals. The Company achieved 98.3% of its revenue goals for 2009, resulting in a bonus of 5.5% of each executive's salary, and achieved greater than 150% of its operating profit goal, resulting in a bonus of 6.25% of salary, for a total of 11.75% of salary. In addition, the Compensation Committee approved approximately 8% of salary in discretionary bonuses for the subject executives, bringing the total bonus to approximately 20% of salary. Goals for 2010 have not yet been established.

## OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END 2009

Name	Option Awards					Stock Awards		Foot-note
	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options (#)	Option Exercise Price (\$)	Option Expiration Date	Option Vesting Date	Number of Shares of Stock That Have Not Vest (#)	Market Value of Shares of Stock That Have Not Vested (\$)	
Lawrence A. Siebert		133,333	0.13	5/6/2014	5/6/2012			5
			133,333	0.13	5/6/2014	5/7/2011		5
			133,333	0.13	5/6/2014	5/6/2010		5
		250,000		0.13	6/3/2013	6/3/2008		3
		75,000		0.22	2/15/2013	2/15/2008		2
		50,000		0.13	5/28/2011	1/1/2007		1, 4
		50,000		0.13	5/28/2011	4/17/2006		1, 4
		10,000		0.13	5/4/2011	4/17/2006		4
	50,000		0.13	5/4/2011	5/5/2004		4	
Javan Esfandiari		100,000	0.13	5/6/2014	5/6/2012			5
			100,000	0.13	5/6/2014	5/7/2011		5
			100,000	0.13	5/6/2014	5/6/2010		5
		100,000		0.13	4/23/2012	3/5/2009		1, 4
		100,000		0.13	4/23/2012	3/5/2008		1, 4
		60,000		0.22	2/15/2013	2/15/2008		2
		25,000		0.13	5/28/2011	5/28/2007		4
		100,000		0.13	4/23/2012	4/23/2007		1, 4
		18,750		0.13	3/24/2011	1/1/2007		4
		25,000		0.13	5/17/2010	1/1/2007		4
		25,000		0.13	5/28/2011	4/17/2006		1, 4
		25,000		0.13	5/28/2011	4/17/2006		1, 4
		5,000		0.13	5/4/2011	4/17/2006		4
		25,000		0.13	5/17/2010	4/17/2006		4
		18,750		0.13	3/24/2011	3/24/2006		4
	30,000		0.13	5/4/2011	5/5/2004		4	
Tom Ippolito		75,000	0.13	5/6/2014	5/6/2012			5
			75,000	0.13	5/6/2014	5/7/2011		5
			75,000	0.13	5/6/2014	5/6/2010		5
		50,000		0.22	2/15/2013	2/15/2008		2
		15,000		0.13	3/24/2011	3/24/2006		4

1 Stock issued in connection with an employment contract and under the 1999 Stock Option Plan.

2 On February 15, 2008 the Company granted options under the 1999 Stock Option Plan.

3 Options issued in connection with an employment contract and under the 2008 Stock Incentive Plan.

4 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 and the fair value difference of the options before and after the reduction was \$31,660 and was expensed in the three months ended June 30, 2009.

5 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. The fair value of these options is being amortized over the vesting life of the options.

## DIRECTOR COMPENSATION

Name	Fees Earned or Paid in Cash (\$) <sup>1</sup>	Option Awards (\$) <sup>2</sup>	Total (\$)
Katherine L. Davis	\$ 29,500	\$ 31,950	\$ 61,450
Gary Meller	26,500	\$ 31,950	58,450
James D. Merselis <sup>3</sup>	1,000	-	1,000

<sup>1</sup> Fees earned or paid in cash represents a yearly fee and fees for meeting expenses: (a) Ms. Davis received an \$18,000 annual fee as a member of the board of directors, a \$2,500 annual fee as audit committee chairman and \$9,000 in meeting fees paid during 2009; (b) Mr. Meller received an \$18,000 annual fee as a member of the board of directors, and \$8,500 in meeting fees; (c) Mr. Merselis received \$1,000 in meeting fees.

<sup>2</sup> Each outside member of the board of directors is granted, once every five years, the right to purchase 375,000 shares of the company's common stock with an exercise price equal to the market price on the date of the grant as part of their annual compensation. One-fifth of these options are exercisable on the date of grant, one-fifth become exercisable on the first anniversary of the date of grant, and additional one-fifths become exercisable on the second through fourth anniversary of the date of grant. The fair value of options at the date of grant was estimated using the Black-Scholes option pricing model.

<sup>3</sup> Mr. Merselis resigned from our Board of Directors on February 9, 2009.

## Director Compensation

All non-employee directors are paid an \$18,000 annual retainer, semi-annually, and once every five years, on the date of the annual meeting of stockholders that directors are elected or re-elected (every 5 years), receive stock options to acquire 375,000 shares of the Company's common stock, with an exercise price equal to the market price on the date of the grant. Stock options to acquire 75,000 shares become exercisable on the date of grant, and options to acquire an additional 75,000 shares become exercisable on the date of each of the four succeeding annual meetings of stockholders if and to the extent that the non-employee director is reelected as a director at each such annual meeting. The audit committee chairman is paid an annual retainer of \$2,500, paid semi-annually. In addition, the non-employee directors are paid \$1,000 in cash for each board of directors' meeting attended, and paid \$500 in cash for each telephonic board of directors meeting. The non-employee directors who are members of a committee of the board of directors are paid \$500 in cash for each committee meeting attended, or \$750 in cash for each committee meeting attended if that non-employee director is the committee chairman.

## Compensation Committee Interlocks and Insider Participation

No executive officer of the Company served as a member of the Board of any other public company during the year ended December 31, 2009. No member of the Compensation Committee serves as an executive officer of any other public company during the year ended December 31, 2009. No interlocking relationship exists between the members of our Compensation Committee and the Board or compensation committee of any other company.

## 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.

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 22, 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 (61,996,651) of the Company's common stock outstanding as of March 22, 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 holders <sup>1</sup>	5,586,900	1	\$ 0.152	1,821,350
Equity compensation plans not approved by security holders	--		--	--
<b>Total</b>	<b>5,586,900</b>		<b>\$ 0.152</b>	<b>1,821,350</b>

<sup>1</sup> 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.

## CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

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.

In June 2008, 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.

## 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.

### Preferred Stock

Our Board of Directors is authorized, subject to certain limitations prescribed by law, without further stockholder approval, to issue from time to time up to an aggregate of 10,000,000 shares of preferred stock in one or more series and to fix or alter the designations, preferences, rights and any qualifications, limitations or restrictions of the shares of each such series thereof, including the dividend rights, dividend rates, conversion rights, voting rights and terms of redemption of shares constituting any series or designations of such series. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change of control. 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 preferred stock 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.

The preferred shares can become issuable upon an approved resolution by the board of directors and the filing of a Certificate of Designation with the state of Nevada.

## Warrants and non-Plan Options

As of March 22, 2010, warrants and options for the issuance of 2,838,379 shares of our common stock were outstanding, all of which are exercisable at a weighted average exercise price of \$.498 per share, all of which are exercisable through various dates expiring between August 3, 2010 and February 5, 2012. The table below provides a breakdown of outstanding warrants and options:

TYPE	Number of Shares	Warrant/Option	Average Price	Expires
Warrants issued pursuant to the issuance of Secured Debentures on June 29, 2006	549,350	Warrant	0.5461	6/29/2011
Commission fees paid in warrants	333,721	Warrant	0.6962	8/2010-2/5/2012
Series B Warrant issued pursuant to the January 26, 2005 Securities Purchase Agreement	172,868	Warrant	0.4946	3/30/2011
Series C Warrant issued pursuant to the Securities Purchase Agreement dated October 5, 2006	1,523,439	Warrant	0.4308	10/5/2011
Series C Warrant issued to Placement Agents pursuant to the October 5, 2006 Securities Purchase Agreement	134,376	Warrant	0.4419	10/5/2011
Consultant fees paid in options during first half of fiscal year ended 2004	124,625	Option	0.6522	6/30/2011
	2,838,379		0.4984	

The descriptions of the warrants are only a summary and are qualified in their entirety by the provisions of the forms of the warrant, which are attached or referenced to the registration statement of which this Prospectus forms a part.

## Unit Warrants

The warrants offered in this offering will be issued in the form that will be filed as an exhibit to the registration statement of which this prospectus is a part. You should review a copy of the form of warrant for a complete description of the terms and conditions applicable to the warrants. The following is a brief summary of the warrants and is subject in all respects to the provisions contained in the form of warrant.

In connection with this offering, we will issue warrants to purchase up to \_\_\_\_\_ shares of common stock. Each warrant entitles the holder to purchase one share of common stock at an exercise price of \$ \_\_\_\_\_ per share subject to adjustment as described below. After the expiration of the exercise period, unit warrant holders will have no further rights to exercise such unit warrants.

The unit warrants may be exercised only for full shares of common stock, and may be exercised on a “cashless” basis. If the registration statement covering the shares issuable upon exercise of the warrants contained in the units is no longer effective, the unit warrants will be issued with restrictive legends unless such shares are eligible for sale under Rule 144. We will not issue fractional shares of common stock or cash in lieu of fractional shares of common stock. Unit warrant holders do not have any voting or other rights as a stockholder of our company. The exercise price and the number of shares of common stock purchasable upon the exercise of each unit warrant are subject to adjustment upon the happening of certain events, such as stock dividends, distributions, and splits.

## Transfer Agent and Registrar

Action Stock Transfer acts as our transfer agent and registrar.

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.

42

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## 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.

## PLAN OF DISTRIBUTION

We are offering up to \_\_\_\_\_ units, each consisting of \_\_ shares of common stock and warrants to purchase an additional \_\_ shares of common stock for \$\_\_ per unit. Pursuant to an engagement letter agreement, we engaged \_\_\_\_\_ as our placement agent for this offering. \_\_\_\_\_ [Placement Agent] is not purchasing or selling any units, nor is it required to arrange for the purchase and sale of any specific number or dollar amount of units, other than to use its “best efforts” to arrange for the sale of units by us. Therefore, we may not sell the entire amount of units being offered.

Upon the closing of the offering, we will pay the placement agent a cash transaction fee equal to \_\_% of the gross proceeds to us from the sale of the units in the offering.

Certain institutional investors are prohibited, pursuant to their investment charter or other governing documents, from acquiring warrants. Accordingly, we and the placement agent may, upon request of any investor in this offering, sell units to such investor that exclude the warrants, provided that any sale of units that excludes such warrants shall be at the same offering price per unit as all other investors.

In addition, we agreed to grant a five-year compensation warrant to the placement agent to purchase a number of shares of our common stock equal to \_\_% of the number of shares of common stock contained in the units sold by us in the offering, but excluding the shares that may be issued upon exercise of the warrants included in the offering. The compensation warrants: (i) will have an exercise price equal to 110% of the lowest per share purchase price paid for the shares of common stock contained in the units sold by us in this offering; (ii) may be exercised via cashless exercise; (iii) will have the same registration rights with respect to the shares of common stock underlying the compensation warrants as the shares of common stock issued in this offering; and (iv) will be substantially on the same terms as the warrants included in the offering, except that the compensation warrants, in accordance with FINRA Rule 5110(g)(1), will provide that for a period of six months after the issuance date of the compensation warrants (which shall not be earlier than the closing date of the offering pursuant to which the compensation warrants are being issued), neither the compensation warrants nor any warrant shares issued upon exercise of the compensation warrants shall be (A) sold, transferred, assigned, pledged, or hypothecated, or (B) the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of the offering pursuant to which the compensation warrants are being issued, except the transfer of any security as permitted by FINRA rules.

The following table shows the per-unit and total placement agent fee to be paid by us to the placement agent. This amount is shown assuming all of the units offered pursuant to this prospectus are issued and sold by us.

Total

Placement Agent  
Fee Per  
Unit

