

CHEMBIO DIAGNOSTICS, INC.
Form POS AM
March 14, 2011

Registration No. 333-138266
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

POST EFFECTIVE AMENDMENT NO. 8 TO
FORM S-1/A

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 Other	(Primary	(I.R.S.
Jurisdiction of	Standard	Employer
Incorporation	Industrial	Identification
or	Classification	Number)
organization)	Code 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
3661 Horseblock Road
Medford, New York 11763

(631) 924-1135

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

Copy of all communications to:
Alan Talesnick, Esq.
James Muchmore, Esq.
Patton Boggs LLP
1801 California Street, Suite 4900
Denver, Colorado 80202
(303) 830-1776

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

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.

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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 [] Accelerated filer []
Non-accelerated filer [] Smaller reporting company [X]
(Do not check if a smaller reporting company)

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

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities To Be Registered	Amount To Be Registered	Proposed Maximum Offering Price Per Unit (1)	Proposed Maximum Aggregate Offering Price (1)	Amount of Registration Fee (2)
Common Stock, \$0.01 par value per share	20,008,319*	\$0.80	\$16,006,655	\$1,712.71

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

(2) The registrant previously paid such amount. Pursuant to Rule 429, the prospectus included herein also relates to 130,625 shares in relation to which a registration fee of \$4,090 was previously paid.

* This Post-Effective Amendment No. 8 registers the resale of 20,008,319 shares of common stock, however only an aggregate of [2,621,152] shares of common stock remain to be sold under this registration statement.

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

SUBJECT TO COMPLETION, DATED MARCH 11, 2011

PROSPECTUS

CHEMBIO DIAGNOSTICS, INC.

20,008,319 SHARES OF COMMON STOCK

This prospectus relates to 20,008,319 shares of our common stock, of which 2,621,152 shares of common stock issuable remain to be sold pursuant to the exercise of warrants, and additional shares of common stock which Selling Stockholders may receive at a later date pursuant to the anti-dilution provisions of certain warrants. We anticipate that the Selling Stockholders will offer the Shares for sale at prevailing market prices on the OTCQB tier of the OTC market on the date of such sale. We will not receive any proceeds from these sales. We are paying the expenses incurred in registering the Shares, but all selling and other expenses incurred by each of the Selling Stockholders will be borne by each Selling Stockholder..

Our common stock is quoted on the OTCQB tier of the OTC market under the symbol "CEMI." On March 11, 2011 the closing bid and ask prices for one share of our common stock were \$.41 and \$.44 respectively, as reported by the OTCQB Bulletin Board website. These over-the-counter quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

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

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

The date of this prospectus is _____, 2011

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PROSPECTUS SUMMARY

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

This Prospectus relates to 20,008,319 shares of our common stock, of which 2,621,152 shares remain to be sold pursuant to the exercise of warrants, options and additional shares of common stock which Selling Stockholders may receive at a later date pursuant to the anti-dilution provisions of certain warrants. We anticipate that the Selling Stockholders will offer the Shares for sale at prevailing market prices on the OTCQB tier of the OTC market on the date of such sale. We will not receive any proceeds from these sales. We are paying the expenses incurred in registering the Shares, but all selling and other expenses incurred by each of the Selling Stockholders will be borne by each Selling Stockholder.

Our Corporate Information

Chembio Diagnostic Systems Inc. was formed in 1985. Since inception we have been involved in developing, manufacturing, selling and distributing medical diagnostic tests, including rapid tests that detect a number of infectious diseases. On May 5, 2004, Chembio Diagnostic Systems Inc. completed a merger through which it became a wholly-owned subsidiary of Chembio Diagnostics, Inc., formerly known as Trading Solutions.com, Inc. As a result of this transaction, the management and business of Chembio Diagnostic Systems Inc. became the management and business of the Company. Our principal executive offices are located at 3661 Horseblock Road, Medford, New York 11763. Our telephone number is (631) 924-1135. Our website address is www.chembio.com.

Our Business

The Company (Chembio Diagnostics, Inc. and its wholly-owned subsidiary Chembio Diagnostic Systems, Inc. are collectively referred to herein as the “Company”) develops, manufactures, markets and licenses 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 in-licensed and proprietary lateral flow technologies (see “Our Rapid Test Technologies”), can be used with all blood matrices as samples, and are manufactured in a standard cassette format, a dipstick format, and a proprietary barrel format. The tests employing the cassette and proprietary barrel formats were approved by the FDA in 2006 and are distributed by Alere, Inc., formerly Inverness Medical Innovations, Inc. (“Alere”), in the United States. Our fourth rapid HIV test, which we more recently developed on our patented Dual Path Platform (DPP®) and does not require in-licensing, detects antibodies to HIV in oral fluid samples as well as in all blood matrices. We anticipate launching this product under Chembio’s brand in 2012.

Our new product pipeline is based on this DPP® technology for which we were issued a United States patent in 2007 and for which additional patent protection has issued or is pending worldwide. With the DPP® proprietary platform, we can participate in the point-of-care market segment of the nearly \$40 billion global in-vitro diagnostic market that is estimated to be \$6-8 billion with an overall growth rate of 7% per annum. POCTs, by providing prompt and early diagnosis, can reduce patient stays, lower overall costs, improve therapeutic interventions and improve patient outcomes as a result of prompt and early diagnosis. They can also prevent needless hospital admissions, simplify testing procedures, avoid delays from central lab batching, and eliminate the need for return visits.

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. We have focused our product development activity within these areas as they tend to have the higher growth rates within the point-of-care segment.

Summary Financial Data

The following table presents summary historical financial information for the fiscal years ended December 31, 2010 and 2009. 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, 2010	December 31, 2009
Revenue	\$ 16,704,703	\$ 13,834,248
Operating Expenses	5,527,029	5,543,078
Net Income	2,513,344	309,060
Current Assets	7,636,734	4,667,102
Total Assets	9,086,174	6,315,250
Current Liabilities	3,076,457	3,173,132
Total Liabilities	3,277,230	3,227,336
Stockholders' Equity	5,808,944	3,087,914

RISK FACTORS

You should carefully consider each of the following risk factors and all of the other information provided in this Prospectus before purchasing our Common Stock. The risks described below are those we currently believe may materially affect us. An investment in our Common Stock involves a high degree of risk, and should be considered only by persons who can afford the loss of their entire investment.

Risks related to our industry, business and strategy

Because we may not be able to obtain or maintain the 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. Our existing products as well as our manufacturing facility must meet quality standards and are subject to inspection by a number of domestic regulatory and other governmental and non-governmental agencies.

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.

We can manufacture and sell our products only if we comply with regulations and quality standards established by government agencies such as the FDA and the USDA as well as by non-governmental organizations such as the ISO and WHO. 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, Alere 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 will enhance our competitive position in HIV rapid testing and other fields. During 2010 we made significant progress toward the commercialization of this product. 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 Alere 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. Alere has no rapid HIV tests that are approved for marketing in the U.S., we are not aware of any rapid HIV products that Alere is even contemplating for the U.S., and Alere is obligated to inform us of any such products as soon as it is able to do so. Alere 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 Alere products, and we specifically acknowledge in our agreements with Alere the existence of such other products. Moreover, except for a product in the HIV barrel field as defined in our agreement with Alere, Alere 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 Alere or change the agreement to a non-exclusive agreement, and Alere 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 Alere 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, Alere 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 Alere 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.

We plan to introduce our DPP® oral fluid HIV test, which test also can be used with blood samples, in the U.S. market under a Chembio brand once it is FDA approved, currently anticipated in 2012 but for which there can be no assurance. Under our 2006 Agreement with Alere, Alere has a right of first negotiation for the right to market any new rapid HIV antibody detection test that we develop. In accordance with this provision in our agreement, we presented this product to Alere in 2007 and in 2007 Alere waived its right of first negotiation under the agreement. While such waiver does not prevent Alere from reconsidering the marketing of this product, we have no reason to believe that they will. Also, although we believe that the main market opportunity for the DPP® HIV product is for those customers that have a clear preference for an oral fluid HIV test the product is also likely to compete with our FDA approved rapid HIV tests being marketed by Alere. Therefore this could have a material and adverse effect on our business with Alere.

More generally, 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 Alere, there is no assurance that its lateral flow patents will not be challenged or that licenses from other parties may not be required, if available at all. In addition, certain of the Alere patents will expire in the next couple of years which expiration could open the market to certain competitors. In the event that it is determined that a license is required and it is not possible to negotiate a license agreement under a necessary patent, we may be able to modify our HIV rapid test products and other products such that a license would not be necessary. However, this alternative could delay or limit our ability to

sell these products in the U.S. and other markets, which would adversely affect our results of operations, cash flows and business.

On March 13, 2007, our Dual Path Platform Immunoassay Device patent application was issued as United States patent no. 7,189,522. Additional protection for this intellectual property is pending worldwide. This platform has shown improved sensitivity as compared with conventional platforms in a number of studies. We believe that this new platform is outside of the scope of currently issued patents in the field of lateral flow technology, thereby offering the possibility of a greater freedom to operate. However there can be no assurance that our patents or our products incorporating the patent claims will not be challenged at some time in the future.

New developments in health treatments or new non-diagnostic products may reduce or eliminate the demand for our products.

The development and commercialization of products outside of the diagnostics industry could adversely affect sales of our products. For example, the development of a safe and effective vaccine to HIV or treatments for other diseases or conditions that our products are designed to detect, could reduce, or eventually eliminate the demand for our HIV or other diagnostic products and result in a loss of revenues.

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

Introducing and achieving market acceptance for our rapid HIV tests and other new products will require substantial marketing efforts and will require us or our contract partners, sales agents, or distributors to make significant expenditures of time and money. In some instances we will be significantly or totally reliant on the marketing efforts and expenditures of our contract partners, sales agents, distributors. If they do not have or commit the expertise and resources to effectively market the products that we manufacture, our operating results will be materially harmed.

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

Our revenues and gross margins have increased significantly in recent periods, and we have been profitable for two consecutive years. Nevertheless, prior to 2009 we sustained significant operating losses since 2004. At December 31, 2010, we had a stockholders' equity of \$5.8 million and a working capital surplus of \$4.6 million. The Company estimates that its resources are sufficient to fund its needs through the end of 2011 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; (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 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 2011 or, in the alternative, be successful in raising sufficient capital to fund its needs through 2011.

The launch of our DPP® products in Brazil, increased revenues from Alere, increased sales to developing world markets, and continued strength in our contract development and grant revenues are all critical for us to continue to fund our new product regulatory approval and commercialization programs. If we fail to meet any of these objectives, we may not generate revenues in the amounts necessary to fund our planned research, development and regulatory expenses in 2011.

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

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

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

Although we have an ethics and anti-corruption policy in place, and have no knowledge or reason to know of any practices by our employees, agents or distributors that could be construed as in violation of such policies, our business includes sales of products to countries where there is or may be widespread corruption.

Chembio has a policy in place prohibiting its employees, distributors and agents from engaging in corrupt business practices, including activities prohibited by the United States Foreign Corrupt Practices Act (FCPA). Nevertheless, because we work through independent sales agents and distributors (and do not have any employees or subsidiaries) outside the United States, we do not have control over the day-to-day activities of such independent agents and distributors. In addition, in the donor-funded markets in Africa where we sell our products, there is significant oversight from PEPFAR, the Global Fund, and advisory committees comprised of technical experts concerning the development and establishment of national testing protocols. This is a process that includes an overall assessment of a product which includes extensive product performance evaluations, a manufacturer's quality systems, as well as price and delivery. In Brazil where we have six product collaborations with FIOCRUZ, those programs that our products

are or may be deployed in are all funded by the Brazilian Ministry of Health. Although FIOCRUZ is affiliated with the Brazilian Ministry of Health, it is not its exclusive supplier. However because each of our collaborations with FIOCRUZ incorporates a technology transfer aspect, we believe we have a competitive advantage versus other suppliers to the Brazilian Ministry of Health, assuming other aspects of our product offering through FIOCRUZ are otherwise competitive in comparison. We have no knowledge or reason to know of any activities by our employees, distributors or sales agents of any actions which could be in violation of the FCPA, although there can be no assurance of this.

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. 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.

Despite 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 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 in part on our ability to participate in large testing 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 large testing programs. 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 and 2010 we cannot be certain that we will be able to sustain profitability in 2011.

From the inception of Chembio Diagnostic Systems, Inc. in 1985 through the period ended December 31, 2008, we incurred net losses and we have only become profitable during the last two years. While we anticipate growth in our

product revenues in 2011 as compared with 2010, there can be no assurance of this. Moreover in 2011 we expect to make substantial expenditures for regulatory submissions, product development and other purpose that may make it more difficult to maintain profitability in 2011. 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 to successfully introduce new products and enhanced versions of our existing products into the marketplace. If we are unable to increase our revenues at a rate that is sufficient to achieve profitability, or adequately control and reduce our operating costs, our operating results would be materially harmed.

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

We may be held liable if any of our products, or any product which is made with the use or incorporation of any of the technologies belonging to us, causes injury of any type or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or usage. We have obtained product liability insurance we have never received a product liability claim, and have generally not seen product liability claims for screening tests that are accompanied by appropriate disclaimers. Nevertheless, in the event there is a claim, this insurance may not fully cover our potential liabilities. In addition, as we attempt to bring new products to market, we may need to increase our product liability coverage which would be a significant additional expense that we may not be able to afford. If we are unable to obtain sufficient insurance coverage at an acceptable cost to protect us, we may be forced to abandon efforts to commercialize our products or those of our strategic partners, which would reduce our revenues.

Risks related to our Common Stock

In the past, our Common Stock has been classified as penny stock, and it continues to be extremely illiquid, so investors may not be able to sell as much stock as they want at prevailing market prices.

In the past, our Common Stock has been classified as penny stock. Penny stocks generally are equity securities with a price of less than \$5.00 and trade on the over-the-counter bulletin board market (OTCBB, currently on the QTCQB). 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 2008, 2009 and 2010 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 49,000 shares per day over the three months ended March 11, 2011. 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 management and larger stockholders exercise significant control over our Company.

As of March 11, 2011, our named executive officers, directors and 5% stockholders beneficially owned approximately 15.4% of our voting power. For the foreseeable future, to the extent that these parties vote similarly, they may be able to exercise significant control over many matters requiring approval by the board of directors or our stockholders. As a result, they may be able to:

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

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

At the time that this post-effective amendment to the registration statement is declared effective by the SEC, a significant number of shares of our Common Stock will be eligible to be immediately sold in the market.

As of March 11, 2011, our Common Stock was trading at \$0.418 cents per share. If a large number of selling stockholders sell in large amounts after the post-effective amendment to the registration statement is declared effective, significant downward pressure could be placed on our stock price.

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

There are 2,514,527 shares of common stock underlying warrants and registered in this registration statement, and 100,625 shares of common stock underlying options registered in another registration statement. As of March 11, 2011, we have approximately 8.15 million warrants and options outstanding. As a result, the exercise of the outstanding warrants and options will result in substantial dilution to the holders of our Common Stock.

Our Shareholder Rights Agreement could discourage unsolicited takeover proposals.

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

USE OF PROCEEDS

We will not receive proc