CHEMBIO DIAGNOSTICS, INC.
Form SB-2/A
January 26, 2007

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Registration No. 333-138266

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM SB-2
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933
Amendment No. 2
Chembio Diagnostics, Inc.
(Name of small business issuer 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 and telephone number of principal executive offices)

Lawrence A. Siebert
3661 Horseblock Road
Medford, New York 11763
(631) 924-1135
(Name, address and telephone number of agent for service)

Copy of all communications to:

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

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

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

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. o

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. o

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

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

CALCULATION OF REGISTRATION FEE

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

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

(2) a. Includes (i) up to 9,812,500 shares issuable upon the conversion of 165 shares of the Registrant s 7% Series C Convertible Preferred Stock, (ii) up to 1,953,125 shares issuable upon the exercise of related warrants.

b. Includes (i) up to 520,000 shares issuable upon the exercise of warrants related to Debentures issued June 29, 2006, and (ii) 156,000 shares of common stock that may be issued to the Selling Stockholders under the anti-dilution provisions of the Debentures.

c. Includes (i) up to 163,933 shares issuable upon the conversion of 2 shares of the Registrant s 9% Series B Convertible Preferred Stock, (ii) up to 155,737 shares issuable upon the exercise of related warrants.

d. Represents shares of common stock registered for resale by the holders (the Selling Stockholders) of shares of 9% Series B Convertible Preferred Stock consisting of (i) 73,770 shares of common stock that may be issued to pay semi-annual dividends to the Selling Stockholders, and (ii) 118,042 shares of common stock that may be issued to the Selling Stockholders under the anti-dilution provisions of the 9% Series B Convertible Preferred Stock.

e. Represents shares of common stock registered for resale by the holders (the Selling Stockholders) of shares of 7% Series C Convertible Preferred Stock consisting of (i) 2,734,375 shares of common stock that may be issued to pay semi-annual dividends to the Selling Stockholders, and (ii) 3,750,000 shares of common stock that may be issued to the Selling Stockholders under the anti-dilution provisions of the 9% Series C Convertible Preferred Stock.

f. Includes (i) up to 172,082 shares currently held by the selling stockholders and (ii) up to 398,755 shares issuable upon the exercise of outstanding warrants.

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

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

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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 January 26, 2007
PROSPECTUS
CHEMBIO DIAGNOSTICS, INC.
20,008,319 SHARES OF COMMON STOCK

This prospectus relates to the sale by certain stockholders of Chembio Diagnostics, Inc. of up to 20,008,319 shares of our common stock which they own, or which they may at a later date acquire upon the conversion of shares of our 9% series B convertible preferred stock, upon the conversion of shares of our 7% series C convertible preferred stock, upon the exercise of warrants to purchase shares of our common stock, as payments of semi-annual dividends on our 9% series B convertible preferred stock and our 7% series C senior convertible preferred stock, upon the trigger of the anti-dilution provisions of the 9% series B convertible preferred stock, the warrants related to the debentures issued June 29, 2006 and the 7% series C senior convertible preferred stock. In this prospectus, we refer to these persons as the selling security holders.

Our common stock is quoted on the OTC Bulletin Board under the symbol CEMI. On January 12, 2007 the closing bid and ask prices for one share of our common stock were $0.69 and $0.73, respectively, as reported by the OTC Bulletin Board website. These over-the-counter quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

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

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

The date of this prospectus is , 2007

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PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. You should read the entire prospectus carefully before making an investment decision.

Overview

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, for a number of diseases and for pregnancy. On May 5, 2004, Chembio Diagnostic Systems Inc. completed a merger through which it became a wholly-owned subsidiary of Chembio Diagnostics, Inc., formerly known as Trading Solutions.com, Inc. (Chembio or the Company). As a result of this transaction, the management and business of Chembio Diagnostic Systems Inc. became the management and business of the Company.

Our Business

We are a developer and manufacturer of rapid diagnostic tests that aid in the detection of infectious diseases. On May 25, 2006 we received regulatory approval from the Food and Drug Administration (the FDA) of two pre-market applications for rapid HIV tests. One pre-market application approval was for our SURE CHECK® HIV 1/2, which incorporates the proprietary barrel technology; the other pre-market application approval was for our HIV 1/2 STAT PAK® rapid HIV test in a cassette format. We also have a third rapid HIV test, HIV 1/2 STAT PAK Dipstick that is only sold outside of the U.S. Applications for Clinical Laboratory Improvement Act waivers for these two FDA-approved tests have since been submitted to the FDA, and a CLIA waiver was granted by the FDA for HIV 1/2 STAT PAK on November 20, 2006. The CLIA waiver application for the SURE CHECK® HIV 1/2 is currently pending.

During 2005 and 2006 year to date, we have had significant increases in sales of our rapid HIV tests to international customers. The majority of these sales have been to an agency of the Brazilian government, and for programs in Africa funded by major bi-lateral and multi-lateral programs, particularly the President s Emergency Plan for AIDS Relief. On September 29, 2006, we executed marketing and license agreements with Inverness Medical Innovations, Inc., pursuant to which Inverness will exclusively market both FDA approved products in the U.S., and SURE CHECK HIV 1/2, globally. Through these agreements, we have also received from Inverness a non-exclusive license to all of their lateral flow intellectual property for certain product lines we have and/or are developing. We also are focused on (1) marketing efforts to expand distribution of our Chagas disease rapid test; (2) efforts to complete development of, and to complete regulatory approval for our rapid tests for the detection of tuberculosis in a number of animal species; and (3) development of a number of other rapid test applications using our patent-pending Dual Path Platform (DPP) technology, including an oral fluid rapid HIV test and a human tuberculosis test.

Our main products are as follows:

HIV Rapid Tests: HIV 1/2 STAT-PAK® Cassette, HIV 1/2 SURE CHECKâ and HIV 1/2 STAT-PAK® Dipstick

Chagas Rapid Test: Chagas STAT-PAK

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

We also are in the process of developing rapid tests employing our patent-pending Dual Path Platform (DPP) technology including, but not limited to an oral fluid rapid HIV test and a human tuberculosis test.

We manufacture all of the products we sell. All of these products, as well as those that are under development, employ various formats of lateral flow technology. Lateral flow, whether single or dual path, generally refers to the process of a sample flowing from the point of application on a test strip to provide a test result on a portion of a strip downstream from either the point of application of the sample or of another reagent. We believe we have expertise and proprietary know-how in the field of lateral flow technology.

We have a history of losses and we continue to incur operating and net losses. We own no patents, though we have non-exclusive licenses to lateral flow patents held by Inverness and Abbott Laboratories, Inc. and to reagents including those that are used in our HIV rapid tests. These licenses do not necessarily insulate us from patent

challenges by other patent holders. We have filed applications for two lateral flow patents that incorporate features that we believe may further protect us from patent challenges. On January 16, 2007, the Company received notice that it is to receive a Notice of Allowance from the United States Patent & Trademark Office which substantially increases the likelihood that a patent for DPP will be issued.

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.

The Offering

By means of this prospectus, a number of our stockholders are offering to sell up to 172,082 shares of common stock which they own, up to 9,976,433 shares of common stock which they may at a later date acquire upon the conversion of our series B and/or

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series C preferred stock, up to 3,027,617 shares of common stock which they may at a later date acquire upon the exercise of warrants, up to 2,808,145 shares of common stock which they may at a later date acquire as dividends payable semi-annually on the series B and series C preferred stock, up to 3,868,042 shares of common stock which they may at a later date acquire pursuant to the anti-dilution provisions of the series B and series C preferred stock and up to 156,000 shares of common stock which they may at a later date acquire pursuant to the anti-dilution provisions of the debenture warrants. In this prospectus, we refer to these persons as the selling security holders.

As of January 12, 2007 we had 11,642,540 shares of common stock issued and outstanding, which includes shares offered by this prospectus. The number of outstanding shares of common stock does not give effect to common stock which may be issued pursuant to the conversion of our series A, B and C preferred stocks and the exercise of options and/or warrants previously issued by Chembio Diagnostics, Inc.

We will not receive any proceeds from the sale of common stock by the selling security holders pursuant to this prospectus. If any of the shares registered are not issued as dividends, or under the anti-dilution provisions, to the holders of the series B or series C preferred stock, we will not sell these shares to third parties and will de-register those shares.

Summary Financial Data

The following table presents summary historical financial information for the nine months ended September 30, 2006 and the fiscal years ended December 31, 2005 and 2004. The financial statements are set forth beginning on page F-1 of this prospectus, and you should read those financial statements for a more complete understanding of the following information.

	For the Nine months Ended September 30, 2006	**Year Ended December 31, 2005**	**Year Ended December 31, 2004**
Revenue	$ 3,893,093	$ 3,940,730	$ 3,305,932
Operating Expenses	$ 4,803,084	4,630,133	3,807,447
Net Loss	$ (3,965,076)	(3,252,000)	(3,098,891)
Current Assets	$ 5,612,940	2,468,193	1,211,060
Total Assets	$ 6,587,101	3,016,406	1,426,449
Current Liabilities	$ 3,776,304	1,818,474	1,663,196
Total Liabilities	$ 4,341,716	1,963,703	1,950,413
Convertible Redeemable Preferred	$ 3,143,415	n/a	2,427,030
Stockholders Equity (Deficit)	$ (898,030)	1,052,703	(2,950,994)

RISK FACTORS

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

Risks related to our industry, business and strategy

Because we may not be able to obtain necessary regulatory approvals for some of our products, we may not generate revenues in the amounts we expect, or in the amounts necessary to continue our business.
All of our proposed and existing products are subject to regulation in the U.S. by the U.S. Food and Drug Administration, the U.S. Department of Agriculture and/or other domestic and international governmental, public health agencies, regulatory bodies or non-governmental organizations. In particular, we are subject to strict governmental controls on the development, manufacture, labeling, distribution and marketing of our products. The process of obtaining required approvals or clearances varies according to the nature of, and uses for, a specific product. These processes can involve lengthy and detailed laboratory testing, human or animal clinical trials, sampling activities, and other costly, time-consuming procedures. The submission of an application to a regulatory authority does not guarantee that the authority will grant an approval or clearance for product. Each authority may impose its own requirements and can delay or refuse to grant approval or clearance, even though a product has been approved in another country.

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The time taken to obtain approval or clearance varies depending on the nature of the application and may result in the passage of a significant period of time from the date of submission of the application. Delays in the approval or clearance processes increase the risk that we will not succeed in introducing or selling the subject products, and we may determine to devote our resources to different products.

Changes in government regulations could increase our costs and could require us to undergo additional trials or procedures, or could make it impractical or impossible for us to market our products for certain uses, in certain markets, or at all.

Changes in government regulations may adversely affect our financial condition and results of operations because we may have to incur additional expenses if we are required to change or implement new testing, manufacturing and control procedures. If we are required to devote resources to develop such new procedures, we may not have sufficient resources to devote to research and development, marketing, or other activities that are critical to our business.

For example, the European Union and other jurisdictions have recently established a requirement that diagnostic medical devices used to test human biological specimens must receive regulatory approval known as a CE mark, or be registered under the ISO 13.485 medical device directive. The letters CE are the abbreviation of the French phrase Conforme Européene which means European conformity. ISO (International Organization for Standardization) is the world s largest developer of standards with 148 member countries. As such, export to the European and other jurisdictions without the CE or ISO 13.485 mark is not possible. Although we are not currently selling products to countries requiring CE marking, we expect that we will do so in the near future in order to grow our business. We are in the process of implementing quality and documentary procedures in order to obtain CE and ISO 13.485 registration, and we are not aware of any material reason why such approvals will not be granted. However, if for any reason CE or ISO 13.485 registration is not granted, our ability to export our products could be adversely impacted.

We can manufacture and sell our products only if we comply with regulations of government agencies such as the FDA and USDA. We have implemented a quality system that is intended to comply with applicable regulations. Although FDA approval is not required for the export of our products, there are export regulations promulgated by the FDA that specifically relate to the export of our products. Although we believe that we meet the regulatory standards required for the export of our products, these regulations could change in a manner that could adversely impact our ability to export our products.

Our products may not be able to compete with new diagnostic products or existing products developed by well-established competitors, which would negatively affect our business.

The diagnostic industry is focused on the testing of biological specimens in a laboratory or at the point-of-care and is highly competitive and rapidly changing. Our principal competitors often have considerably greater financial, technical and marketing resources than we do. Several companies produce diagnostic tests that compete directly with our testing product line, including but not limited to , Orasure Technologies, Inverness Medical and Trinity Biotech. As new products enter the market, our products may become obsolete or a competitor s products may be more effective or more effectively marketed and sold than ours. Although we have no specific knowledge of any competitor s product that will render our products obsolete, if we fail to maintain and enhance our competitive position or fail to introduce new products and product features, our customers may decide to use products developed by competitors which could result in a loss of revenues and cash flow.

We are developing an oral fluid rapid HIV test as well as other applications utilizing our Dual Path Platform technology which we believe could enhance our competitive position in HIV rapid testing and other fields. However, we have not completed development of any DPP product, and we still have technical, manufacturing, regulatory and marketing challenges to meet before we will know whether we can successful commercialize products incorporating this technology. There can be no assurance that we will overcome these challenges.

We have granted Inverness exclusive rights to market our SURE CHECK® HIV 1/2 globally and our HIV 1/2 STAT PAK® in the U.S. Inverness has no rapid HIV tests that are approved for marketing in the U.S., we are not aware of any rapid HIV products that Inverness is even contemplating for the U.S., and Inverness is obligated to inform us of any such products as soon as it is able to do so. Inverness does have rapid HIV tests manufactured by certain of its subsidiaries outside the U.S. that are being actively marketed outside the U.S., primarily in developing countries. Our HIV 1/2 STAT PAK cassette and dipstick products compete against these Inverness Products, and we specifically

acknowledge in our agreements with Inverness the existence of such other products. Moreover, except for a product in the HIV barrel field as defined in our agreement with Inverness, Inverness is permitted under our agreements to market certain types of permitted competing rapid HIV tests in the U.S. Under these conditions, we could choose to terminate the applicable agreement with Inverness or change the agreement to a non-exclusive agreement, and Inverness would expand the lateral flow license granted to the Company to allow the Company to market the product independently or through other marketing partners. While we believe that Inverness is committed to successfully marketing our products particularly in the U.S. and other developed countries where our products are or become approved for

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marketing, Inverness may choose to develop or acquire competing products for marketing in the U.S. as well as other markets where they are marketing our SURE CHECK HIV 1/2 product, and such an action could have at least a temporary material adverse effect on the marketing of these products until such time as alternative marketing arrangements could be implemented. While we also believe that the expansion of our license to the Inverness lateral flow patents substantially facilitates our ability to make alternative marketing arrangements, there can be no assurance that the modification of marketing arrangements and the possible corresponding delays or suspension of sales would not have a material adverse effect on our business.

In addition, the point-of-care diagnostics industry is undergoing rapid technological changes, with frequent introductions of new technology-driven products and services. As new technologies become introduced into the point-of-care diagnostic testing market, we may be required to commit considerable additional efforts, time and resources to enhance our current product portfolio or develop new products. We may not have the available time and resources to accomplish this and many of our competitors have substantially greater financial and other resources to invest in technological improvements. We may not be able to effectively implement new technology-driven products and services or be successful in marketing these products and services to our customers, which would materially harm our operating results.

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

Although we have been granted non-exclusive licenses to lateral flow patents owned by Inverness Medical Innovations, Inc. and Abbott Laboratories, Inc., there is no assurance that their lateral flow patents will not be challenged or that licenses from other parties may not be required, if available at all. In the event that it is determined that a license is required and it is not possible to negotiate a license agreement under a necessary patent, we may be able to modify our HIV rapid test products and other products such that a license would not be necessary. However, this alternative could delay or limit our ability to sell these products in the U.S. and other markets, which would adversely affect our results of operations, cash flows and business.

During 2005 and 2006, the Company has made substantial additions to its intellectual property portfolio as a result of the development of a new rapid test platform, Dual Path Platform (DPP). This platform has shown improved sensitivity as compared with conventional platforms in a number of preliminary studies using well characterized HIV, Tuberculosis and other samples. This technology has formed the basis of two patent applications that were filed, and may result in additional applications covering additional uses of this technology platform. On January 16, 2007, the Company received notice that it is to receive a Notice of Allowance from the United States Patent & Trademark Office which substantially increases the likelihood that a patent for DPP will be issued. Also, the Company believes that this new lateral flow platform is outside of the scope of currently issued patents in the field of lateral flow technology, thereby offering the possibility of a greater freedom to operate. There is no assurance that the patent application will be granted, or that its claims will not be modified upon review, or that the Company s patents or its products incorporating the patent claims will not be challenged at some time in the future.

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

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

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

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

have or commit the expertise and resources to effectively market the products that we manufacture, our operating results will be materially harmed.

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

Although the Company s revenues and gross margins increased significantly in recent periods, it sustained significant operating losses in the first nine months of 2006 and the years 2005 and 2004. At September 30, 2006, the Company had a Stockholders Deficiency of $898,030, and a working capital surplus of $1,836,636. Including the funds received from the Series C 7%

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Convertible Preferred Stock offering, (the Series C Offering see below), the Company believes its resources are sufficient to fund its needs through the end of 2007. The Company s liquidity and cash requirements will depend on several factors. These factors include: (1) the level of revenue growth; (2) the extent to which, if any, that revenue growth improves operating cash flows; (3) its investments in research and development, facilities, marketing, regulatory approvals and other investments it may determine to make; and (4) the investment in capital equipment and the extent to which it improves cash flow through operating efficiencies. If the Company s resources are not sufficient to fund its needs through 2007, there are no assurances that the Company will be successful in raising sufficient capital.

On March 30, 2006, the Company sold $1 million of additional Series B Preferred stock to a Series B Preferred shareholder pursuant to provisions of the January 2005 Series B 9% Preferred Stock financing agreements. Such provisions were exclusive to said shareholder.

On June 29, 2006, the Company borrowed $1,300,000. The loan was repaid in part on September 27, 2006 and the balance converted on October 5, 2006 and is secured by a lien on the assets of the Company. See Note 1 of the financial statements for further details.

On September 29, 2006 and October 5, 2006 the Company completed the Series C Offering for $8,150,000. Some of the proceeds were used to repay the loan borrowed on June 29, 2006. This Series C offering will be enough to supply the Company s cash needs through the end of 2007.

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

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

regulatory requirements and customs regulations;

cultural and political differences;

foreign exchange rates, currency fluctuations and tariffs;

dependence on and difficulties in managing international distributors or representatives;

the creditworthiness of foreign entities;

difficulties in foreign accounts receivable collection; and

economic conditions and the absence of available funding sources.

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

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

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

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

Despite our efforts to protect our proprietary rights, unauthorized parties may attempt to copy aspects of our products or to obtain information that we regard as proprietary. We may be required to expend substantial resources in asserting

or protecting our intellectual property rights, or in defending suits related to intellectual property rights. Disputes regarding intellectual property rights could substantially delay product development or commercialization activities because some of our available funds would be diverted away from our business activities. Disputes regarding intellectual property rights might include state, federal or foreign court litigation as well as patent interference, patent reexamination, patent reissue, or trademark opposition proceedings in the U.S. Patent and Trademark Office.

To facilitate development and commercialization of a proprietary technology base, we may need to obtain additional licenses to patents or other proprietary rights from other parties. Obtaining and maintaining these licenses, which may not be available, may

require the payment of up-front fees and royalties. In addition, if we are unable to obtain these types of licenses, our product development and commercialization efforts may be delayed or precluded.

In order to sell our rapid HIV tests and generate expected revenue from these tests, we will need to arrange for a license to patents for detection of the HIV-2 virus, and we may not be able to do so.

Although the current licensor of the peptides used in our HIV tests claims an HIV-2 patent, other companies have also claimed such patents. Even though HIV-2 is a type of the HIV virus estimated to represent only a small fraction of the known HIV cases worldwide, it is still considered to be an important component in the testing regimen for HIV in many markets. HIV-2 patents often are found in most of the countries of North America and Western Europe, as well as in Japan, Korea, South Africa and Australia. Access to a license for one or more HIV-2 patents may be necessary to sell HIV-2 tests in countries where such patents are in force, or to manufacture in countries where such patents are in force and then sell into non-patent markets. Since HIV-2 patents are in force in the U.S., we may be restricted from manufacturing a rapid HIV-2 test in the U.S. and selling into other countries, even if there were no HIV-2 patents in those other countries. The license agreement that we have in effect for the use and sale of the Adaltis HIV 1 and 2 peptides that are used in our HIV rapid test does not necessarily insulate us from claims by other parties that we need to obtain a license to other HIV-1 and/or HIV-2 patents. Although we have discussed additional HIV-2 licenses that would be advantageous for some markets, if we are unable to complete these discussions successfully our business and operating results could be materially harmed.

Our continued growth depends on retaining our current key employees and attracting additional qualified personnel, and we may not be able to do so.

Our success will depend to a large extent upon the skills and experience of our executive officers, management and sales, marketing, operations and scientific staff. Although we have not experienced unusual retention and/or recruitment problems to date, we may not be able to attract or retain qualified employees in the future due to the intense competition for qualified personnel among medical products businesses.

If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will adversely affect our ability to effectively manufacture, sell and market our products, to meet the demands of our strategic partners in a timely fashion, or to support internal research and development programs. Although we believe we will be successful in attracting and retaining qualified personnel, competition for experienced scientists and other personnel from numerous companies and academic and other research institutions may limit our ability to do so on acceptable terms.

We have entered into employment contracts with our President, Lawrence Siebert and our Vice President of Research and Development, Javan Esfandiari. Due to the specific knowledge and experience of these executives regarding the industry, technology and market, the loss of the services of either one of them would likely have a material adverse effect on the Company. The contract with Mr. Siebert has a term of two years ending May 2008, and the contract with Mr. Esfandiari has a term of three years ending May 2007. We have obtained a key man insurance policy for Mr. Esfandiari.

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 interest to meaningfully participate in the Presidential Emergency Plan for Aids Relief Program, UN Global Fund initiatives and other programs funded by large donors. We have initiated several strategies to participate in these programs. Participation in these programs requires alignment with the many other participants in these programs including the World Health Organization, U.S. Center for Disease Control, U.S. Agency for International Development, non-governmental organizations, and HIV service organizations. If we are unsuccessful in our efforts to participate in these programs, our operating results could be materially harmed.

We have a history of incurring net losses and we cannot be certain that we will be able to achieve profitability.

Since the inception of Chembio Diagnostic Systems, Inc. in 1985 and through the period ended December 31, 2005, we have incurred net losses. As of December 31, 2005, we have an accumulated deficit of $(18,868,428). We incurred net losses of $(3,252,000) and $(3,098,891) in 2005 and 2004, respectively.

We expect to continue to make substantial expenditures for sales and marketing, regulatory submissions, product development and other purposes. Our ability to achieve profitability in the future will primarily depend on our ability

to increase sales of our products, reduce production and other costs and successfully introduce new products and enhanced versions of our existing products into the marketplace. If we are unable to increase our revenues at a rate that is sufficient to achieve profitability, our operating results would be materially harmed.

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

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

Risks related to our common stock

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

Our common stock is classified as penny stock. Penny stocks generally are equity securities with a price of less than $5.00 and trade on the over-the-counter market. As a result, an investor may find it more difficult to dispose of or obtain accurate quotations as to the price of the shares of the common stock being registered in this registration statement. In addition, the penny stock rules adopted by the Commission under the Securities Exchange Act of 1934, as amended (the Exchange Act), subject the sale of the shares of the common stock to regulations which impose sales practice requirements on broker-dealers, causing many broker-dealers to not trade penny stocks or to only offer the stocks to sophisticated investors that meet specified net worth or net income criteria identified by the Commission. These regulations contribute to the lack of liquidity of penny stocks.

The average daily trading volume of our common stock on the over-the-counter market was less than 33,000 shares per day over the three months ended December 31, 2006. If limited trading in our stock continues, it may be difficult for investors to sell their shares in the public market at any given time at prevailing prices. Since the certificates of designation creating our series A and series B preferred stock contain restrictions on our ability to declare and pay dividends on our common stock, the lack of liquidity of our common stock could negatively impact the rate of return on your investment.

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

At the time of effectiveness of the registration statement, the number of shares of our common stock eligible to be immediately sold in the market will increase significantly. If the selling stockholders sell significant amounts of our stock, our stock price could drop. Even a perception by the market that selling stockholders will sell in large amounts after the registration statement is effective could place significant downward pressure on our stock price.

You will experience substantial dilution upon the conversion of the shares of preferred stock and the exercise of warrants that we issued in three private placements and the warrants and options that were assumed in connection with the merger.

On May 5, 2004, we completed three separate private placements in which we issued 151.57984 shares of our series A preferred stock and warrants to acquire 9,094,801 shares of our common stock at an exercise price of $.90 per share. The shares of series A preferred stock are convertible into 7,578,985 shares of our common stock. We also issued warrants to purchase 425,000 shares of our common stock at an exercise price of $0.72 per share and warrants to purchase 510,000 shares of common stock at an exercise price of $1.08 per share to designees of our placement agents. We also issued warrants pursuant to an employment agreement with Mark L. Baum, our former president and former member of our board of directors, to purchase 425,000 shares and 425,000 shares of our common stock, respectively, at exercise prices of $0.60 and $0.90 per share respectively. In connection with the acquisition of Chembio Diagnostic Systems, Inc., we assumed the obligation to issue 690,000 shares of our common stock upon the exercise of warrants, which warrants are exercisable at prices ranging from $0.45 to $4.00 per share. We also adopted the stock option plan of Chembio Diagnostic Systems Inc. and assumed all of the obligation to issue 704,000 common shares upon the exercise of the options outstanding as of the merger date. On January 28, 2005, we completed a

private placement in which we issued 100 shares of our 9% Series B Convertible Preferred Stock, which we refer to as the Series B Stock, together with warrants to purchase 7,786,960 shares of our common stock. For each $.61 invested in this private placement, an investor received (a) $.61 of face amount of Series B Stock, which is convertible into one share of our common stock, and (b) a five-year warrant to acquire .95 of a share of our common stock. Each full share of the Series B Stock was purchased for $50,000, with fractional shares of Series B Stock being purchased by investments of less than $50,000. In connection with the January 28, 2005 offering, we also issued to the placement agent Series B Stock in an aggregate amount equal to 5% of the amount of cash proceeds from the private placement, together with accompanying warrants to purchase our common stock. We also issued to the placement agent warrants to purchase 737,712 shares of our common stock. As of March 31, 2006,

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there were 1,529,750 options issued and outstanding under the stock option plan and 1,470,250 options available for issuance under the stock option plan. As a result, the conversion of the outstanding preferred stock and the exercise of the outstanding warrants and options will result in substantial dilution to the holders of our common stock.

On March 30, 2006, we issued to an investor 20 shares (face amount $1,000,000) of the Company s series B preferred stock with warrants to purchase a total of 1,557,377 shares of Company s common stock at an exercise price of $0.61 per share for a period of five years. The Company agreed to issue, and the investor agreed to purchase for $1,000,000, the securities described above pursuant to the terms of a Securities Purchase Agreement dated January 26, 2005 by and among the Company and various purchasers. This transaction represents the second closing under the Agreement, and was triggered upon the Company s achieving, as of the fourth fiscal quarter of 2005, certain financial milestones. As compensation for services rendered to the Company by Midtown for the second closing, the Company agreed to issued to Midtown two shares (face amount $100,000) of its Series B Preferred and warrants to purchase a total of 155,738 shares of its Common Stock at an exercise price of $.061 per share for a period of five years.

On June 29, 2006, we issued $1,300,000 of secured debentures to four investors. Pursuant to the terms of these debentures, investors agreed to receive back from the Company the full amount of their principal investment, plus interest on the unpaid principal sum outstanding at the rate of 0.667% per month. Each investor was also granted a warrant to purchase up to 400 shares of common stock for each $1,000 of such investor s subscription amount, with an exercise price of $0.75 per share, exercisable for a five year term.

On September 29, 2006 and October 5, 2006, we completed a private placement for $8,150,000, consisting of 165 shares of 7% series C convertible preferred stock, which we refer to as the Series C Stock, together with warrants to purchase 2,578,125 shares of our common stock. For each $0.80 of consideration received, an investor received (a) $0.80 of face amount of series C stock, which shall pay cumulative dividends in cash or shares at the rate of 7% per annum payable semiannually beginning in the year 2007, and which is convertible into one share of the common stock, and (b) a five-year warrant to acquire shares of our common stock, equal to 25% of the investor s subscription amount divided by $0.85, with an exercise price of $1.00 share. Each full share of the Series C Stock was purchased for $50,000, with fractional shares of series C preferred stock being purchased by investments of less than $50,000. In connection with this private placement, we employed Midtown Partners & Co., LLC to serve as the placement agent with respect to investors investing $1,000,000 in this offering. As compensation for services rendered to the Company, we agreed to (i) pay Midtown a cash fee equal to 5% of the amount of cash proceeds the Company received from the investors Midtown solicited, and (ii) issue to Midtown warrants to purchase 62,500 shares of our common stock. The warrants issued to Midtown are exercisable for a period of five years from their issuance and have an exercise price of $1.00 per share.

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

As of January 12, 2007, our named executive officers, directors and 5% stockholders beneficially owned approximately 26.14% of our voting power. For the foreseeable future, to the extent that our current stockholders vote similarly, they will be able to exercise control over many matters requiring approval by the board of directors or our stockholders. As a result, they will be able to:

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

USE OF PROCEEDS

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

preferred stock or the Series C preferred stock, we will not sell these shares to third parties and will de-register those shares.

DILUTION

We are not selling any common stock in this offering. The selling security holders are current stockholders of the Company. As such, there is no dilution resulting from the common stock to be sold in this offering.

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SELLING SECURITY HOLDERS

The securities are being offered by the named selling security holders below. The selling security holders hold one or more of the following securities which are described in the Description of Securities section: Common stock, series B preferred stock which is convertible into common stock at $.61 per share, series C preferred stock which is convertible into common stock at $.80 per share, or warrants to purchase common stock exercisable at prices ranging from $0.55 per share to $1.00 per share. However, the table below assumes the immediate conversion by series B and series C preferred stock into common stock and the immediate exercise of all warrants to purchase common stock, without regard to other factors which may determine whether such rights of conversion or purchase are exercised. These factors include but are not limited to the other rights associated with remaining a preferred stockholder, the terms of these agreements, and the specific conversion or exercise price of the securities held by such selling security holder and its relation to the market price. The selling security holders may from time to time offer and sell pursuant to this prospectus up to an aggregate of 172,082 shares of our common shares now owned by them, 163,933 shares issuable to them upon the conversion of series B preferred stock that they hold, 9,812,500 shares issuable to them upon the conversion of series C preferred stock that they hold, 3,027,617 shares issuable to them upon the exercise of warrants that they hold. The selling security holders may, from time to time, offer and sell any or all of the shares that are registered under this prospectus, although they are not obligated to do so.

The holders of the series B preferred stock may sell pursuant to this prospectus up to an aggregate of (i) 73,770 shares of common stock which they may at a later date acquire as dividends payable semi-annually on the series B preferred stock, and (ii) 118,042 shares of common stock which they may at a later date acquire pursuant to the anti-dilution provisions of the series B preferred stock, as described below in section Description of Securities Series B Preferred Stock. These shares are not included in the table below.

Further, the holders of the series C preferred stock may sell pursuant to this prospectus up to an aggregate of (i) 2,734,375 shares of common stock which they may at a later date acquire as dividends payable semi-annually on the series C preferred stock, and (ii) 3,750,000 shares of common stock which they may at a later date acquire pursuant to the anti-dilution provisions of the series C preferred stock, as described below in section Description of Securities Series C Preferred Stock. These shares are not included in the table below.

In addition, the holders of the Company s Secured Debentures dated June 29, 2006, may sell pursuant to this prospectus up to an aggregate of (i) 520,000 shares of common stock which they may at a later date acquire if they exercise warrants to purchase common stock at an exercise price of $0.75 per share, and (ii) 156,000 shares of common stock which they may at a later date acquire pursuant to the anti-dilution provisions of these secured debentures.

On March 30, 2006, the Company issued an investor 20 shares of its series B preferred stock. In connection with this issuance, the Company also issued this investor warrants to purchase a total of 1,557,377 shares of the Company s common stock at an exercise price of $0.61 per share for a period of five years. These series B preferred shares are convertible into 1,639,340 shares of common stock, which the investor may sell pursuant to this prospectus, and the holder may also sell up to 1,557,377 shares of Company s common stock issuable to them upon the exercise of the warrants that they hold. In addition, as compensation for services rendered to the Company for this private placement, the Company issued the placement agent two shares of the Company s series B preferred shares, as well as warrants to purchase the Company s common stock. These series B preferred shares are convertible into 163,933 shares of common stock, which the placement agent may sell pursuant to this prospectus, and the placement agent may sell up to 155,738 shares of the Company s common stock, which it may acquire pursuant to the warrants it was granted. These warrants are exercisable at an exercise price of $.061 per share for a period of five years.

Certain of the entities or individuals listed below acquired the shares offered hereby in connection with our September 29, 2006 private placement of series C preferred stock. Pursuant to this private placement; we received $8,150,000 in cash as payment for (a) 165 shares of preferred stock that are convertible into 10,312,500 shares of common stock, and (b) warrants to acquire 2,578,125 shares of common stock at an exercise price of $1.00 per share. Based on the $50,000 paid per series C preferred share, the purchase price per common share is $0.80, without allocating any portion of the purchase price to the warrants. Also in connection with these private placements, we agreed to prepare and file at our expense, as promptly as practical, and in any event, on or before 45 days after

September 29, 2006, a registration statement with the SEC covering the resale of the shares of common stock issuable upon conversion of the series C preferred stock and the shares of common stock issuable upon exercise of the warrants. In the event this registration statement is not declared effective by the SEC within 120 days of September 29, 2006 (within 150 days of such date in the event of a full review by the SEC), then we will be subject to the payment of liquidated damages equal to 1% of the aggregate purchase price we received from each respective subscriber. $600,245 of the private placement resulted from conversion of previously outstanding convertible debt of the Company. Based on the terms of the previously outstanding convertible debt, the $600,245 of debt was converted at a discount of 12.5% to the price paid by the other investors.

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

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purchase up to 400 shares of common stock for each $1,000 of such investor s subscription amount, with an exercise price of $0.75 per share, and exercisable for a five year term.

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

the number of shares of common stock beneficially owned as of January 12, 2007 and prior to the offering contemplated hereby;

the number of shares of common stock eligible for resale and to be offered by each selling security holder pursuant to this prospectus;

the number of shares owned by each selling security holder after the offering contemplated hereby assuming that all shares eligible for resale pursuant to this prospectus actually are sold;

the percentage of shares of common stock beneficially owned by each selling security holder after the offering contemplated hereby; and

in notes to the table, additional information concerning the selling security holders including any NASD affiliations and any relationships, excluding non-executive employee and other non-material relationships, that a selling security holder had during the past three years with the registrant or any of its predecessors or affiliates.

Selling Security Holders[C]	Number of Shares of Common Stock Owned Before Offering [A]	Number of Shares To Be Offered [B]	Number of Shares Owned After Offering	Percentage of Shares of Common Stock Owned After Offering
Alpha Capital AG [1]	2,057,539	746,875	1,310,664	10.15%
Big Bend XXXI Investments, LP	2,343,750	2,343,750		0.00%
Bristol Investment Fund, Ltd.	160,000	160,000		0.00%
Bushido Capital Master Fund, LP	1,171,875	1,171,875		0.00%
C.E. Unterberg, Towbin Capital Partners I, L.P.	666,875	666,875		0.00%
Bio-Business Science & Development LTDA	294,340	252,923	41,417	0.35%
Cranshire Capital, LP	390,625	390,625		0.00%
Crestview Capital Master, LLC [2]	16,572,249	2,000,000	14,572,249	57.72%
Ferrari, Braden	1,875	1,875		0.00%
Frankenthal, Stuart J.	234,375	234,375		0.00%
Howard M. Rossman Revocable Trust	234,375	234,375		0.00%
Imas, Ariel	2,500	2,500		0.00%
Inverness Medical Innovations, Inc.	3,125,000	3,125,000		0.00%
Investor Relations Group	288,750	255,414	33,336	0.28%
Iroquois Master Fund, Ltd.	40,000	40,000		0.00%
Jordan, Bruce[3]	107,006	35,092	71,914	0.61%

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

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

(C) It is our understanding that any selling security holder

that is an affiliate of a broker-dealer purchased the securities offered hereunder in the ordinary course of business, and at the time of the purchase, had no agreements or understanding to distribute the securities.

[1] Konrad Ackerman has ultimate control over Alpha Capital AG and the shares held by Alpha Capital AG.

[2] Affiliated with Dillion Capital, a NASD member. Robert Hoyt has ultimate control over Crestview Capital Master, LLC and the shares held by Crestview Capital Master, LLC.

[3] Employee of Midtown Partners & Co., LLC, investment banking services.

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Selling security holders [C]	Number of Shares of Common Stock Owned Before Offering [A]	Number of Shares To Be Offered [B]	Number of Shares Owned After Offering	Percentage of Shares of Common Stock Owned After Offering
Kreger, Richard H. [3]	650,821	165,160	485,661	3.96%
Longview Fund, LP	781,250	781,250		0.00%
Midtown Partners & Co., LLC				