CHEMBIO DIAGNOSTICS, INC.
Form POS AM
April 04, 2007

Registration No. 333-138266

**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

**POST EFFECTIVE AMENDMENT NO. 1 TO**
**FORM SB-2**

**REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933**

**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. [**X**]

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. [ ]

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. [X]

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 | 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.

*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 APRIL 4, 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 April 2, 2007 the closing bid and ask prices for one share of our common stock were $.64 and $.65, 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.

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**These securities are speculative and involve a high degree of risk. You should consider carefully the “Risk Factors” beginning on Page 5 of this prospectus before making a decision to purchase our stock.**

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**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.**

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The date of this prospectus is _____, 2007

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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.*

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 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.

### 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 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, manufacturer and marketer of rapid diagnostic tests that detect infectious diseases. Our main products presently commercially available are three rapid tests for the detection of HIV antibodies in whole blood, serum and plasma samples, two of which were approved by the FDA last year. These products employ single path lateral flow technology which we have licensed from Inverness Medical Innovations, Inc. ("Inverness"), who is also our exclusive marketing partner for those two products in the United States under its Clearview® brand. Inverness launched its marketing of these products in the United States in February, 2007. Chembio's two HIV STAT-PAK® rapid HIV tests are marketed outside the United States through different partners and channels under license from Inverness. We also have a rapid test for Chagas disease (a parasitic disease endemic in Latin America) as well as a line of rapid tests for tuberculosis, including tests for tuberculosis in animals for which USDA approval is pending.

On March 13, 2007, we were issued United States patent # 7,189,522 for our Dual Path Platform ("DPP™") rapid test system. We believe that as a result of the patent protection we now have with DPP™, we have a significant opportunity to develop and license many new rapid tests in a number of fields including but not limited to infectious diseases. We have already completed initial development on some products in this new platform. We believe the DPP™ provides significant advantages over standard single path lateral flow assays, and we are developing most of our new products using this platform.

Our products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments. Our products are sold either under our STAT-PAK® or SURE CHECK® registered trademarks and/or the private labels of our marketing partners, such as the Inverness Clearview® label.

We have a history of losses, and we continue to incur operating and net losses. We have non-exclusive licenses to lateral flow patents held by Inverness and Abbott Laboratories, Inc., and to reagents including those that are used in our HIV rapid tests. These licenses do not necessarily insulate us from patent challenges by other patent holders. We have filed applications for two lateral flow patents that incorporate features that we believe may further protect us from patent challenges.

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Our main products are as follows:

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

· Chagas Rapid Test: Chagas STAT-PAK; and

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

We also are in the process of developing rapid tests employing our patented DPP™ technology including, but not limited to, an oral fluid rapid HIV test 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.

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.

**Summary Financial Data**

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

| | Year Ended December 31, 2006 | Year Ended December 31, 2005 |
|---|---|---|
| Revenue | $ 6,502,480 | $ 3,940,730 |
| Operating Expenses | 6,596,761 | 4,630,133 |
| Net Loss | (4,995,020) | (3,252,000) |
| Current Assets | 6,953,668 | 2,468,193 |
| **Total Assets** | 7,906,577 | 3,016,406 |
| Current Liabilities | 1,840,435 | 1,818,474 |
| **Total Liabilities** | 2,297,193 | 1,963,703 |
| **Convertible Redeemable Preferred** | 6,549,191 | n/a |
| **Stockholders' Equity (Deficit)** | (939,807) | (1,052,703) |

## RISK FACTORS

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

***Risks related to our industry, business and strategy***

**Because we may not be able to obtain necessary regulatory approvals for some of our products, we may not generate revenues in the amounts we expect, or in the amounts necessary to continue our business.**

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

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

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

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

For example, the European Union and other jurisdictions have 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 our competitors, which could result in a loss of revenues and cash flow.

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

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We have granted Inverness exclusive rights to market our SURE CHECK® HIV 1/2 globally and our HIV 1/2 STAT PAK® in the U.S. Inverness has no rapid HIV tests that are approved for marketing in the U.S., we are not aware of any rapid HIV products that Inverness is even contemplating for the U.S., and Inverness is obligated to inform us of any such products as soon as it is able to do so. Inverness does have rapid HIV tests manufactured by certain of its subsidiaries outside the U.S. that are being actively marketed outside the U.S., primarily in developing countries. Our HIV 1/2 STAT PAK cassette and dipstick products compete against these Inverness Products, and we specifically acknowledge in our agreements with Inverness the existence of such other products. Moreover, except for a product in the HIV barrel field as defined in our agreement with Inverness, Inverness is permitted under our agreements to market certain types of permitted competing rapid HIV tests in the U.S. Under these conditions, we could choose to terminate the applicable agreement with Inverness or change the agreement to a non-exclusive agreement, and Inverness would expand the lateral flow license granted to the Company to allow the Company to market the product independently or through other marketing partners. While we believe that Inverness is committed to successfully marketing our products particularly in the U.S. and other developed countries where our products are or become approved for marketing, Inverness may choose to develop or acquire competing products for marketing in the U.S. as well as other markets where they are marketing our SURE CHECK® HIV 1/2 product, and such an action could have at least a temporary material adverse effect on the marketing of these products until such time as alternative marketing arrangements could be implemented. While we also believe that the expansion of our license to the Inverness lateral flow patents substantially facilitates our ability to make alternative marketing arrangements, there can be no assurance that the modification of marketing arrangements and the possible corresponding delays or suspension of sales would not have a material adverse effect on our business.

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

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

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

During 2005 and 2006, we made substantial additions to our 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 formed the basis of two patent applications that we filed, and may result in additional applications covering additional uses of this technology platform. On March 13, 2007, one of these patent applications was approved by the United States Patent & Trademark Office, which issued United States patent no. 7,189,522 for our DPP™ rapid test system. Also, we believe that this new lateral flow platform is outside of the scope of currently issued patents in the field of lateral flow technology, thereby offering the possibility of a greater freedom to operate. There is no assurance that our patents or our products incorporating the patent claims will not be

challenged at some time in the future.

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

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

**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 our revenues and gross margins increased significantly in recent periods, we sustained significant operating losses in 2006, 2005 and 2004. At December 31, 2006, we had a stockholders' deficiency of $940,000 and a working capital surplus of $5,113,000. Including the funds received from the Series C 7% Convertible Preferred Stock offering, we believe our resources are sufficient to fund our needs through the end of 2007 and into early 2008. Our liquidity and cash requirements will depend on several factors. These factors include: (1) the level of revenue growth; (2) the extent to which, if any, that revenue growth improves operating cash flows; (3) our investments in research and development, facilities, marketing, regulatory approvals and other investments we may determine to make; and (4) our investment in capital equipment and the extent to which this investment improves cash flow through operating efficiencies. If our resources are not sufficient to fund our needs through 2007, there are no assurances that we will be successful in raising sufficient capital.

On March 30, 2006, we 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