

CHEMBIO DIAGNOSTICS, INC.

Form S-8

March 23, 2007

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-8
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Chembio Diagnostics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Nevada	88-0425691
<i>(State or</i>	<i>(I.R.S.</i>
<i>Other</i>	<i>Employer</i>
<i>Jurisdiction of</i>	<i>Identification</i>
<i>Incorporation</i>	<i>Number)</i>
<i>or</i>	
<i>Organization)</i>	

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)

1999 Equity Incentive Plan
(Full Name of Plan)

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 to:
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James J. Muchmore, Esq.
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Denver, Colorado 80264
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CALCULATION OF REGISTRATION FEE

Title of Securities to be Registered	Amount to be Registered	Proposed		Amount of Registration Fee (2)
		Maximum Offering Price per Share (2)	Proposed Maximum Aggregate Offering Price (2)	
Common Stock, par value \$.01 per share (3)	1,515,750	\$0.68	\$1,030,710	\$ 31.64
Common Stock, par value \$.01 per share (4)	165,000	\$0.68	\$112,200	\$ 3.45
Common Stock, par value \$.01 per share (5)	1,319,250	\$0.68	\$897,090	\$ 27.54
Total (6):	3,000,000	\$0.68	\$2,040,000	\$ 62.63

(1) Pursuant to Rule 416 under the Securities Act of 1933, as amended, this Registration Statement shall also cover additional shares of Common Stock that may become issuable by reason of any stock split, stock dividend, recapitalization or other similar transactions effected without consideration that results in an increase in the number of the Registrant's shares of outstanding Common Stock. In addition, this Registration Statement covers the resale by certain Selling Stockholders named in the Prospectus included in and filed with this Form S-8 of certain of the shares of the Registrant's Common Stock subject to this Registration Statement, for which no additional registration fee is required pursuant to Rule 457(h)(3).

(2) Solely for the purpose of calculating the registration fee, the offering price per share and the aggregate offering price have been calculated pursuant to Rules 457(c) and 457(h) of the Securities Act of 1933, as amended, computed on the basis of the market value of the shares of Common Stock on March 16, 2007 estimated in accordance with Rule 457(c).

(3) Represents shares underlying outstanding options granted under the 1999 Equity Incentive Plan.

(4) Represents restricted shares previously issued upon exercise of options granted under the 1999 Equity Incentive Plan.

(5) Represents shares available for future grants under the 1999 Equity Incentive Plan.

(6) Represents total restricted shares previously issued upon exercise of options, shares underlying options granted, and shares available for grant, of 3,000,000 under the 1999 Equity Incentive Plan.

EXPLANATORY NOTE

This Registration Statement on Form S-8 (this “Registration Statement”) registers shares of common stock, par value \$0.01 per share, of Chembio Diagnostics, Inc. (the “Company”), consisting of (i) shares previously issued upon the exercise of options granted under the Company’s 1999 Equity Incentive Plan (the “1999 Plan”); (ii) shares that will be issued, upon the exercise of options granted under the 1999 Plan; and (iii) shares available to be issued under the 1999 Plan.

This Registration Statement contains two parts. First, the materials that follow Part I of this Registration Statement on Form S-8 (this “Registration Statement”) up to Part II of this Registration Statement constitute the reoffer prospectus, prepared in accordance with Part I of Form S-3, in accordance with General Instruction C of Form S-8 (the “Prospectus”). The Prospectus permits reoffers and resales of those shares referred to above that constitute “restricted securities” or “control securities”, within the meaning of Form S-8, by certain of the Company’s stockholders, as more fully set forth therein. The second part contains information required to be set forth in the registration statement pursuant to Part II of Form S-8.

PART I

INFORMATION REQUIRED IN THE SECTION 10(a) PROSPECTUS

The documents containing the information required by Part I of this Registration Statement will be sent or given to our employees, officers and directors, as specified by Rule 428(b)(1) under the Securities Act of 1933, as amended (the “Securities Act”). Those documents do not need to be filed with the Securities and Exchange Commission (the “Commission”) either as part of this Registration Statement or as prospectuses or prospectus supplements pursuant to Rule 424 under the Securities Act. These documents and the documents incorporated by reference in this Registration Statement pursuant to Item 3 of Part II of this Registration Statement, taken together, constitute a prospectus that meets the requirement of Section 10(a) of the Securities Act. The Company will provide without charge to any person, upon written or oral request of such person, a copy of each document incorporated by reference in Item 3 of Part II of this Registration Statement (which documents are incorporated by reference in the Prospectus as set forth in Form S-8), other than exhibits to such documents that are not specifically incorporated by reference, the other documents required to be delivered to eligible employees pursuant to Rule 428(b) under the Securities Act and additional information about the 1999 Plan. Requests should be directed to the Company’s Secretary at 3661 Horseblock Road, Medford, New York 11763.

REOFFER PROSPECTUS

CHEMBIO DIAGNOSTICS, INC.

1,680,750 SHARES OF COMMON STOCK

Acquired or to be Acquired by the Selling Stockholders Under 1999 Equity Incentive Plan

This reoffer prospectus (this “Prospectus”) relates to an aggregate of up to 1,680,750 shares (the “Shares”) of common stock, par value \$0.01 per share (the “Common Stock”), of Chembio Diagnostics, Inc., a Nevada corporation (the “Company”), consisting of 165,000 outstanding restricted shares and 1,515,750 shares issuable upon exercise of currently outstanding options, which may be offered and sold from time to time by certain stockholders of the Company (the “Selling Stockholders”) who have acquired or will acquire such Shares pursuant to the Company’s 1999 Equity Incentive Plan (the “1999 Plan”). See “Selling Stockholders”.

This Prospectus covers the offering for resale of (i) shares acquired by the Selling Stockholders prior to the filing of the Registration Statement on Form S-8 of which this Prospectus is a part; (ii) shares to be acquired by the Selling Stockholders upon an exercise of currently outstanding options ((i) and (ii) collectively referred to as the “Restricted Shares”); and (iii) shares to be acquired by Selling Stockholders who may be deemed affiliates of the Company after the filing of a Registration Statement on Form S-8 pursuant to options currently held by those Selling Stockholders (“Control Shares”).

Shares acquired pursuant to the 1999 Plan prior to the effective date of a registration statement covering securities issued under the 1999 Plan are “restricted securities” pursuant to Rule 144, whether or not held by affiliates of the Company. This Prospectus has been prepared for the purpose of registering the shares under the Securities Act to allow for future sales by the Selling Stockholders, on a continuous or delayed basis, to the public without restriction. The Selling Stockholders may offer for their own account these Shares for resale from time to time.

The Selling Stockholders may sell the Shares covered by this Prospectus through various means, including directly or indirectly to purchasers, in one or more transactions on any stock market on which the Shares are traded at the time of sale, in privately negotiated transactions, or through a combination of these methods. Each Selling Stockholder that sells any Shares pursuant to this Prospectus may be deemed to be an “underwriter” within the meaning of the Securities Act of 1933, as amended (the “Securities Act”). Any commissions received by a broker or dealer in connection with resales of shares may be deemed to be underwriting commissions or discounts under the Securities Act. For additional information on the Selling Stockholders’ possible methods of sale, you should refer to the section in this Prospectus entitled “Plan of Distribution.”

We will not receive any proceeds from the sale of the Shares being offered by the Selling Stockholders. We will pay all of the expenses associated with this Prospectus. Brokerage commissions and similar selling expenses, if any, attributable to the offer or sale of the Shares will be borne by the Selling Stockholder.

Our Common Stock is quoted on the OTC Bulletin Board under the symbol “CEMI.” On March 16, 2007, the closing bid price of our Common Stock on such market was \$0.68 per share.

This investment involves a high degree of risk. **Please see “Risk Factors” beginning on page 3 of this Prospectus.**

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined whether this Prospectus is truthful or complete. Any

representation to the contrary is a criminal offense.

The date of this Prospectus is March 23, 2007.

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You should only rely on the information incorporated by reference or provided in this Prospectus or any supplement. We have not authorized anyone else to provide you with different information. The Common Stock is not being offered in any state where the offer is not permitted. You should not assume that the information in this Prospectus or any supplement is accurate as of any date other than the date on the front of this Prospectus.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

The Company is subject to the information requirements of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and, in accordance therewith, files reports, proxy statements and other information with the Securities and Exchange Commission (the “Commission”). The reports, proxy statements and other information filed by the Company with the Commission can be inspected and copied at the Public Reference Room of the Commission at 100 F Street, N.E., Washington, D.C. 20549. Copies of such material also may be obtained by mail from the Public Reference Room of the Commission, 100 F Street, N.E., Washington, D.C. 20549, at prescribed rates. Information regarding the operation of the Public Reference Room may be obtained by calling the Commission at 1-800-SEC-0330. Additionally, the Commission maintains an Internet site that contains reports, proxy and information statements and other information regarding registrants that file electronically with the Commission and that is located at <http://www.sec.gov>.

This Prospectus constitutes part of a Registration Statement on Form S-8 filed on the date hereof (herein, together with all amendments and exhibits, referred to as the “Registration Statement”) by the Company with the Commission under the Securities Act. This Prospectus does not contain all of the information set forth in the Registration Statement, certain parts of which are omitted in accordance with the rules and regulations of the Commission. For further information with respect to the Company and the Common Stock, reference is hereby made to the Registration Statement. Statements contained herein concerning the provisions of any contract, agreement or other document are not necessarily complete, and in each instance reference is made to the copy of such contract, agreement or other document filed as an exhibit to the Registration Statement or otherwise filed with the Commission. Each such statement is qualified in its entirety by such reference. Copies of the Registration Statement together with exhibits may be inspected at the offices of the Commission as indicated above without charge and copies thereof may be obtained therefrom upon payment of a prescribed fee.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Prospectus contains forward-looking statements that may be affected by matters outside our control that could cause materially different results.

Some of the information in this Prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933. These statements express, or are based on, our expectations about future events. Forward-looking statements give our current expectations or forecasts of future events. Forward-looking statements generally can be identified by the use of forward-looking terminology, such as, “may,” “will,” “expect,” “intend,” “project,” “estimate,” “anticipate,” “believe” or “continue” or the negative thereof or similar terminology. They include statements regarding our:

- financial position;
- business strategy;
 - budgets;
- amount, nature and timing of capital expenditures;
 - acquisition risks;
- operating costs and other expenses; and
- cash flow and anticipated liquidity.

Although we believe the expectations and forecasts reflected in these and other forward-looking statements are reasonable, we can give no assurance they will prove to have been correct. They can be affected by inaccurate assumptions or by known or unknown risks and uncertainties. Factors that could cause actual results to differ materially from expected results are described under “Risk Factors” and include:

- general economic conditions;
- currency exchange volatility;
- the risks associated with acquiring and integrating new businesses;
 - our ability to generate sufficient cash flows to operate;
 - availability of capital;
- the strength and financial resources of our competitors;
 - regulatory risks and developments;
- our ability to find and retain skilled personnel; and
- the lack of liquidity of our Common Stock.

Any of the factors listed above and other factors contained in this Prospectus could cause our actual results to differ materially from the results implied by these or any other forward-looking statements made by us or on our behalf. We cannot assure you that our future results will meet our expectations.

When you consider these forward-looking statements, you should keep in mind these risk factors and the other cautionary statements in this Prospectus. Our forward-looking statements speak only as of the date made.

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 1,644,750 shares of our Common Stock, consisting of 165,000 outstanding restricted shares and 1,479,750 shares issuable upon exercise of currently outstanding options, which may be offered for sale from time to time by the Selling Stockholders identified in this Prospectus. We anticipate that the Selling Stockholders will offer the Shares for sale at prevailing market prices on the OTC Bulletin Board on the date of such sale. We will not receive any proceeds from these sales. We are paying the expenses incurred in registering the Shares, but all selling and other expenses incurred by each of the Selling Stockholders will be borne by such Selling Stockholder.

Chembio Diagnostics

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 no. 7,189,522 for its 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.

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.

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 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 DPP™ 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 successfully commercialize products incorporating this technology. There can be no assurance that we will overcome these challenges.

We have granted Inverness exclusive rights to market our SURE CHECK® HIV 1/2 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.

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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 the first nine months of 2006 and the years 2005 and 2004. At September 30, 2006, we 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% Convertible Preferred Stock offering, we believe our resources are sufficient to fund our needs through the end of 2007. 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 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 our resources are not sufficient to fund our needs through 2007, there are no assurances that

we will be successful in raising sufficient capital.

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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 provisions were exclusive to said shareholder.

On June 29, 2006, we 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 our assets.

On September 29, 2006 and October 5, 2006, we 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 our 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.