CHEMBIO DIAGNOSTICS, INC.
Form 10-K
March 18, 2009

UNITED STATES
Securities and Exchange Commission
Washington, D.C. 20549

FORM 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2008

or

[ ] TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to .

Commission File No. 0-30379
CHEMBIO DIAGNOSTICS, INC.
(Exact name of registrant as specified in its charter)

Nevada	88-0425691
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
3661 Horseblock Road, Medford, NY	11763
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code (631) 924-1135

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
None	None

Securities registered pursuant to section 12(g) of the Act:
Common Stock, $0.01 par value
(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes __ No X

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the

Act. Yes __ No X

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes X No__

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

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

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

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes __ No _X_

As of the last business day of the Company's most recently completed second fiscal quarter, the aggregate market value of voting and non-voting common equity held by non-affiliates* was $5,970,000.

As of March 17, 2009, the registrant had 61,944,901 common shares outstanding.

* Without asserting that any of the issuer's directors or executive officers, or the entities that own 38,252,448 shares of common stock are affiliates, the shares of which they are beneficial owners have been deemed to be owned by affiliates solely for this calculation.

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PART I

ITEM 1. BUSINESS

FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, and Section 27A of the Securities Act of 1933. Any statements contained in this report that are not statements of historical fact may be forward-looking statements. When we use the words "intends," "estimates," "predicts," "potential," "continues," "anticipates," "plans," "expects," "believes," "should," "could," "may," "will" or the negative of these ter comparable terminology, we are identifying forward-looking statements. Forward-looking statements involve risks and uncertainties, which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. These factors include our research and development activities, distributor channels, compliance with regulatory impositions; and our capital needs. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

Except as may be required by applicable law, we do not undertake or intend to update or revise our forward-looking statements, and we assume no obligation to update any forward-looking statements contained in this report as a result of new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. You should carefully review and consider the various disclosures we make in this report and our other reports filed with the Securities and Exchange Commission that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

For further information about these and other risks, uncertainties and factors, please review the disclosure included in this report under "Part I, Item 1A, Risk Factors."

General

Chembio Diagnostics, Inc. (referred to collectively with its subsidiaries as the "Company") and its subsidiaries develop, manufacture and market rapid diagnostic tests that detect infectious diseases. The Company's main products presently commercially available are three rapid tests for the detection of HIV antibodies in whole blood, serum and plasma samples, all of which employ lateral flow technology, and two of which were approved by the FDA in 2006. In addition, we have a fourth rapid HIV test, developed on our patented Dual Path Platform (DPP®) technology, for the detection of antibodies to HIV in oral fluid samples, as well as whole blood, serum and plasma samples. The products which employ lateral flow technology are manufactured and sold under a non-exclusive license we have from Inverness Medical Innovations, Inc. ("Inverness"), which is also our exclusive marketing partner for the FDA-approved products in the United States (as well as Europe and Asia for the product that is known as the "barrel" format product) 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 (in cassette and dipstick formats) are marketed outside the United States through different partners and channels under our license from Inverness.

On March 13, 2007, we were issued United States patent #7,189,522 for our Dual Path Platform (DPP®) rapid test system. Additional patent protection for DPP® is pending worldwide. DPP® enables Chembio to participate in the growing point–of-care diagnostics market with a patent-protected point-of-care platform technology. DPP® devices enable the development of products whose performance we believe exceeds that of comparable tests developed with lateral flow technology. As stated above we have completed development of an oral fluid HIV test on this new platform and are currently pursuing the commercialization of this product in several markets. We have also developed and/or are developing several other products on DPP®. We believe that DPP® provides significant advantages as a

point-of-care platform particularly where challenging sample matrices, such as oral fluid, are involved, or where multiplexing is desired. We are developing all of our new products using this platform. Our strategy for the development of this platform technology is also dual; we have entered and are seeking to enter exclusive collaborations with large marketing partners for whom we will develop and manufacture products on the DPP® and we are developing our own products that we may choose to market through selected distribution partners either under a Chembio, DPP® or other brand.

Our products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, and medical professionals. Our products are sold either under our DPP®, STAT-PAK® or SURE CHECK® registered trademarks and/or the private labels of our marketing partners, such as is the case with the Inverness Clearview® label for our rapid HIV tests in the United States.

Rapid HIV Tests

The major component of our revenue growth in 2008 was increased sales of our rapid HIV tests and related components. A large percentage of individuals that are HIV positive worldwide are unaware of their status. Part of the reason for this is that even those that do get tested in public health settings will often not return or call back for their test results if samples have to be sent out to a laboratory which can take at least several days to process. The increased availability, greater efficacy and reduced costs for anti-retroviral treatments (ARVs) for HIV is also having a tremendous impact on the demand for testing, as the stigma associated with the disease is lessened, and the ability to resume normal activities is substantially improved, providing a positive message to those potentially infected. All four of our rapid HIV tests are qualitative "yes/no" tests for the detection of antibodies to HIV 1 & 2 with results available within approximately 15 minutes. The tests differ principally only in the method of sample collection and test procedure, flexibility with different sample types, and cost of manufacture. Prior to our agreement with Inverness, our rapid HIV tests had been marketed under either our SURE CHECK® or STAT-PAK® trademarks. Pursuant to our agreement with Inverness Medical Innovations, Inc., the SURE CHECK® product (which incorporates a proprietary barrel format) is now being marketed by Inverness as Clearview® Complete HIV 1/2 and the cassette format of our HIV 1/2 STAT-PAK (we also have a third product known as HIV 1/2 STAT-PAK dipstick) is now being marketed by Inverness in the United States as Clearview® HIV 1/2 STAT-PAK®. We continue to market our STAT-PAK® cassette and dipstick outside the United States through other marketing channels. In addition, in 2008 we amended the agreement with Inverness, which previously had global exclusivity for the barrel format product, to a non-exclusive in Africa and Latin America. We will begin to market our DPP® oral fluid test globally (including in the United States) as we establish required regulatory clearances and authorizations, which we expect to receive during this year for certain markets in the developing world, though there is no assurance that this will occur.

Regulatory Status:

Rapid HIV Tests

The FDA approved our Pre-Market Applications (hereinafter "PMA"; see "Governmental Regulations" and Glossary) for our SURE CHECK HIV 1/2 (and also now Inverness' Clearview® Complete HIV 1/2) and HIV 1/2 STAT-PAK (now Inverness' Clearview® HIV 1/2 STAT-PAK in the United States only) products on May 25, 2006. A Clinical Laboratory Improvement Act ("CLIA") waiver was granted by the FDA for the HIV 1/2 STAT-PAK on November 20, 2006. Labeling changes to the Inverness Clearview® brands for both products were approved during the first quarter of 2007. CLIA waiver for the Clearview® Complete HIV 1/2 was granted on October 22, 2007. CLIA waiver is required in order to market the products for use in hospital emergency rooms, public health clinics and physicians' offices, where the level of training is traditionally less than the training at clinical laboratories and laboratories in hospitals. These settings constitute the largest portion of the available market for our products. Our third lateral flow rapid HIV test, HIV 1/2 STAT-PAK Dipstick and our DPP® oral fluid HIV test, though not FDA approved, qualify under FDA export regulations to sell, subject to any required approval by the importing country, to customers outside the United States. The dipstick product is our most competitively priced version of our three rapid HIV tests, and was designed primarily for resource-constrained, donor-funded markets that have large test volume needs. Although we have received approval from a number of potential importing countries for three of our lateral flow HIV tests, Brazil, Mexico, Nigeria, Ethiopia and Uganda are the countries in which we have realized significant sales. As a result of favorable evaluations of our HIV 1/2 STAT-PAK and HIV 1/2 STAT-PAK Dipstick products by the World Health Organization (the "WHO"), these products are qualified for procurement by programs funded by the United Nations and their partners' programs. All three of our lateral flow HIV tests have qualified for procurement under the President's Emergency Plan for AIDS Relief ("PEPFAR"). During the first quarter of 2009 we submitted our oral fluid DPP® HIV 1/2 test, to these same agencies for inclusion in these programs. We also have other evaluations ongoing for this new product and anticipate commencement of clinical trials in the United States in support of a PMA during this year.

Partners Involved in Marketing Our Products

On September 29, 2006 we executed marketing and license agreements with Inverness. These agreements provide for the marketing of our rapid HIV tests in the United States; the agreements also grant us a license to Inverness' lateral flow patents that may be applicable to certain of our other products, including those that we had under development at the time of the grant. As part of these agreements we also settled litigation that had been ongoing with another company, StatSure Diagnostics, Inc., relating to the proprietary barrel device that is incorporated into our Sure Check® HIV 1/2 product, which is also marketed exclusively as Inverness Clearview® Complete HIV 1/2 in the United States, Europe and Asia.

We have appointed distributors internationally so that we are positioned to service those markets. Our focus is on those countries that have received or will receive funding commitments for HIV prevention and treatment, of which rapid HIV testing is an essential part. The most significant program globally that funds HIV testing is the United States PEPFAR program, which primarily is focused in 15 countries in sub-Saharan Africa that are at the epicenter of the disease. During 2008 we shipped approximately 2.4 million test kits to Nigeria, 1.6 million test kits to Uganda, and approximately 600,000 test kits to Ethiopia, or a total of approximately 4.6 million tests, mostly through the PEPFAR procurement agency known as the Partnership for Supply Chain Management ("PSCM"). Lesser volumes were shipped to several other countries in Asia, and Latin America. We also shipped HIV test kit components to the Oswaldo Cruz Foundation for the manufacture of tests in Brazil pursuant to our 2004 technology transfer agreement.

Effective in January 2009, Nigeria changed from a parallel testing algorithm to a serial algorithm, and in this change our test's designation in two of their new protocols was changed to that of a confirmatory test and a tie-breaker test in the third protocol. This designation has resulted in a dramatic reduction of sales to this country which decrease we anticipate will likely continue for at least several months. During 2008, the implementation of our HIV 1/2 STAT-PAK® as the confirmatory test in Ethiopia's serial testing algorithm resulted in significantly increased sales to that country, which increases we anticipate may continue during 2009. We do not presently anticipate however that the increased sales in Ethiopia will in any case fully offset the decrease in Nigeria.

We are pursuing new opportunities for distribution of our existing lateral flow HIV tests and new DPP® oral fluid HIV test in a number of markets globally. As stated earlier, during 2008 we amended our agreement with Inverness so that we may now market the barrel product under Chembio's trademark, SURE CHECK® HIV 1/2 directly throughout South America and Africa, subject to the payment of royalties to Inverness in accordance with our license to their lateral flow patents.

OTHER RAPID TESTS

We also have commercially available lateral flow tests for Chagas Disease and also a line of tests for the detection of tuberculosis in humans and certain animal species. However, these products represented less than 4% of our product revenues during 2008 and are not part of the central focus of our current business and growth strategy.

Our Rapid Test Technologies

All of our commercially available current products employ either in-licensed lateral flow technology or our own patented Dual Path Platform (DPP®) technology.

Lateral flow technology involves a sample flowing from the point of application on a test strip to provide a test result, indicated with a labeling reagent that allows the result to be visually or otherwise detected, on a portion of a strip downstream from either the point of application of the sample. Lateral flow technology is well established and widely applied in the development of rapid diagnostic tests. The functionality of our lateral flow tests is based on the ability of an antibody to bind with a specific antigen (or vice versa) and for the binding to become visible through the use of the colloidal gold and/or colored latex that we use in our products. The colloidal gold or the colored latex produces a colored line if the binding has occurred (the test line), in which case it means there has been a reactive or positive result. In any case, a separate line (the control line) will appear to confirm that the test has been validly run in accordance with the instructions for use.

On March 13, 2007, we were issued United States patent number #7,189,522 describing a Dual Path Immunoassay system which we believe provides several advantages over lateral flow technology for certain applications (See "Intellectual Property"). The Dual Path Platform technology, or DPP®, uniquely provides for the sample application and migration toward the test zone area to be from an independent strip. This system enables improved sample control, multiplexing and certain other advantages. DPP® is providing the Company with significant new product

development and licensing opportunities, and we are devoting all of our research and development efforts toward these programs.

The sensitivity of a test indicates how strong the sample must be before it can be detected by the test. The specificity of a test measures the ability of the test to analyze, isolate, and detect only the matters targeted by the test. The sensitivity and specificity of our rapid HIV tests during our clinical trials undertaken in connection with our FDA PMAs were 99.7% and 99.9%, respectively. Both lateral flow technology and DPP® allow the development of accurate, low cost, easy-to-perform, single-use diagnostic tests for rapid, visual detection of specific antigen-antibody complexes on a test strip. This format provides a test that is simple (requires neither electricity nor expensive equipment for test execution or reading, nor skilled personnel for test interpretation), rapid (turnaround time approximately 15 minutes), safe (minimizes handling of potentially infected specimens), non-invasive (requires 5-20 micro liters of whole blood easily obtained with a finger prick, or alternatively, serum or plasma), stable (24 months at room temperature storage in the case of our HIV tests), and highly reproducible.

Our HIV tests are qualitative (reactive/non-reactive) tests. We have developed proprietary techniques that enable us to achieve high levels of sensitivity and specificity [see definition above] in our diagnostic tests using our proprietary colloidal gold conjugates and buffer systems. These techniques include the methods we employ in manufacturing and fusing the reagents with the colored latex, or colloidal gold, blocking procedures used to reduce false positives, and methods used in treating the materials used in our tests to obtain maximum stability and resulting longer shelf life. We also have extensive experience with a variety of lateral flow devices, including the sample collection device used in our SURE CHECK rapid HIV test which eliminates the need for transferring finger-stick whole blood samples from the fingertip onto a test device, because the collection of the sample is performed within a tubular test chamber that contains the lateral flow test strip. The whole blood sample is absorbed directly onto the test strip through a small opening in one end of the test chamber and an absorbent pad positioned just inside this same end of the test chamber.

During 2007 and 2008 we entered collaborations with companies that have developed hand held and desktop readers that can objectively measure, quantify, record and report test results. Certain of the products we have and/or are developing for our customer in Brazil, the Oswaldo Cruz Foundation, will incorporate some of these readers, and we are developing other products that may be used with or will require use of a reader.

Target Market

Rapid HIV Tests

The marketing of our FDA-approved and CLIA-waived rapid HIV tests in the United States was launched by Inverness during the first quarter of 2007, and we estimate to have approximately a 10% share of the U.S. rapid HIV test market. In the United States, the need for rapid HIV tests has been developing first in the public health and hospital emergency room segments, and also in the physicians' office laboratories. Of the estimated 25-30 million HIV tests performed in clinical settings in the United States, rapid HIV tests now account for approximately 20-25% of this market, or approximately 5-6 million tests of this total. We believe that the total number of HIV tests will continue to grow, and that the share available to rapid HIV tests will also grow.

The pace of the implementation of recommendations that were made in late 2006 by the United States Centers for Disease Control ("CDC") for routine HIV testing of all individuals between the ages of 13 and 64 will be a major factor in the rate of growth of the rapid HIV testing market in the United States. Endorsement of these recommendations by opinion leaders in the professional medical community are gradually helping to increase the demand for HIV testing in the United States. In addition, the revelation in a study disclosed in 2008 by CDC that annual new HIV cases in the US, which disproportionately impact African-Americans, had been under-reported for years by approximately 40%, underscored the need for improved prevention efforts in the United States. Although the most recent efforts to increase federal funding for STD prevention in the federal stimulus package were unsuccessful, we still believe that there is a good prospect that the current Congress and Administration will seek to increase these programs through other legislative appropriations.

In the international market, PEPFAR, the large United States funded international AIDS relief program focused on fifteen countries, was reauthorized last year for up to $48 billion for FY2009-2012 (up from $15 billion in 2004-2008); the appropriation for 2009 is approximately $5.5 billion, of which approximately 12% or $900 million is allocated to the Global Fund, the other large international program created in 2001 to combat HIV/AIDS, TB and Malaria. PEPFAR, The Global Fund and other global initiatives have succeeded in making life-saving treatments available now to well in excess of one million individuals. We believe that this is likely to have the effect of further encouraging more people to get tested, because with the availability of treatment, there is a clear reason to be tested. Other programs such as UNAIDS are significant participants in the global effort to prevent further transmission and save the lives of those already infected, as well as care for their families that are impacted.

Marketing Strategy

Our marketing strategy is to:

- Support, review and assess the marketing and distribution efforts of our rapid HIV tests by Inverness Medical Innovations, Inc. Inverness, which is a leading marketer of point-of-care diagnostic products, has significantly expanded its distribution footprint since we signed our agreement with Inverness, and we believe that this will enhance opportunities for Inverness to market our rapid HIV tests. In particular, Inverness has been very active in acquiring point-of-care product lines serving hospital emergency rooms and physicians' offices.

- Leverage our DPP® intellectual property and regulated product development and manufacturing experience to create new collaborations where Chembio can be the exclusive development and manufacturing partner with world class marketing partners.

- Develop a small number of Chembio or DPP® branded products that capitalize on the advantages of this newly patented point-of-care technology and select distribution partners for such products.

Competition

The diagnostics industry is a multi-billion dollar international industry and is intensely competitive. Many of our competitors are substantially larger and have greater financial, research, manufacturing and marketing resources.

Industry competition in general is based on the following:

- Scientific and technological capability;
- Proprietary know-how;
- The ability to develop and market products and processes;
- The ability to obtain FDA or other required regulatory approvals;
- The ability to manufacture products that meet applicable FDA requirements, (i.e. FDA's Quality System Regulations) (see Governmental Regulation section);
- The ability to manufacture products cost-effectively;
- Access to adequate capital;
- The ability to attract and retain qualified personnel; and
- The availability of patent protection.

We believe our scientific and technological capabilities and our proprietary know-how relating to our in-licensed lateral flow technology rapid tests and to our proprietary know-how related to our patented dual path platform technology, particularly for the development and manufacture of tests for the detection of antibodies to infectious diseases such as HIV, are very strong.

Our ability to develop and market other products is in large measure dependent on our having additional resources and/or collaborative relationships. Some of our product development efforts have been funded on a project or milestone basis. We believe that our proprietary know-how in lateral flow technology and in our dual path platform technology has been instrumental in our obtaining the collaborations we have and that we continue to pursue. We believe that the patent protection that we have with our Dual Path Platform enhances our ability to develop more profitable collaborative relationships and to license out the technology.

We believe our regulatory certifications are also a strong asset for developing new products and collaborations. There are only two companies besides Chembio that have approved PMA's for lateral flow rapid tests, all HIV tests: Trinity Biotech (Ireland) and Orasure Technologies, Inc. (PA). We believe that this is a significant competitive advantage when considering new products and collaborations. During 2006 and 2007 we obtained CLIA waivers for each of our FDA PMA approved HIV tests. These products therefore represent two of the four CLIA-waived rapid HIV tests. During 2007 and 2008 we received facility and product licenses from the USDA, became certified under ISO 13.485, and received our initial CE mark (for our Chagas product). We anticipate receiving CE marks for our HIV products during the first half of 2009.

Our access to capital is much less than that of several of our competitors, and to the extent we would need to access large amounts of capital, this is a competitive disadvantage. We believe however that our access to capital is likely to increase if we continue our trend of improved operating results, and in the meantime we are focused on minimizing our capital requirements. Establishment of strategic collaborations for our DPP® technology also may provide us

with access to funding that is potentially less dilutive or non-dilutive. The simplification of our capital structure that was completed in December 2007 should also improve our access to capital (See Management's Discussion and Analysis of Financial Condition and Results of Operations – Overview).

To date, we believe we have been competitive in the industry in attracting and retaining qualified personnel. Because of the greater financial resources of many of our competitors, we may not be able to compete effectively for the same individuals to the extent that a competitor uses its substantial resources to attract any such individuals. Also, in order to control costs and conserve resources, we have implemented layoffs and salary reductions that larger companies with greater resources may not need to implement.

We have been able to obtain patent protection by entering into licensing arrangements for reagents and lateral flow technologies. The March 2007 issuance by the United States Patent & Trademark Office of our Dual Path Platform™ patent gives us our first patent protection for our own rapid test platform, which we believe enhances our competitive position. Additional protection of this intellectual property is pending worldwide.

Competitive factors specifically related to our HIV tests are product quality, delivery, sensitivity, specificity, ease-of-use, shelf life and price. Other factors can be sample size required, the presence of a true IgG control, and time to result. During the last few years, the competitive features of certain products produced by some international competitors have improved. Most of these companies, whose products are not and in most cases probably could not be FDA approved, typically have substantially lower costs of labor, regulatory approval and compliance, and intellectual property (if any) as compared with Chembio. Price has become an increasingly important factor since U.S. procurement rules still operate under a waiver of Buy America provisions, described below. Also, as described below, in most of the donor-funded markets in the developing world technical committees controlled by host governments are empowered to make final decisions as to which products will be used in screening programs. The leading competitors in the international rapid HIV test market are Trinity Biotech (Ireland), Inverness (U.S.) and Standard Diagnostics (Korea). Uni-Gold® HIV, marketed by Trinity Biotech of Ireland and Determine®, marketed by Inverness Medical, are the market leaders in the developing world, particularly sub-Saharan Africa, which is where most of the funding for rapid HIV tests is being allocated from donor funded programs such as PEPFAR. Neither the Trinity or Inverness products are FDA-approved, although Trinity does manufacture in Ireland an FDA-approved rapid HIV test, Uni-Gold Recombigen, for marketing in the United States. Inverness' Orgenics subsidiary in Israel also has a rapid HIV test, Double-Check Gold, as does its subsidiary in China, ABON; neither of these products is FDA-approved. As such, while Inverness is our exclusive marketing partner in the United States, it is also a principal competitor to our rapid HIV tests outside the United States. Furthermore, in 2006 Trinity Biotech settled litigation with Inverness, and as part of that settlement it committed to have ABON, an Inverness subsidiary, to manufacture all of Trinity's Uni-Gold® HIV products primarily for the African market. Standard Diagnostics of Korea also has a low-cost product that is very competitive against each of the other competitors in the developing world. There are a number of additional competitors, including several based in China and India of varying quality, that produce competitive rapid HIV tests.

Under a now long-established waiver of Buy America provisions, products procured with US taxpayer funds need not be FDA approved or even made in the US so long as they meet reduced quality standards as compared to what would be required for an FDA approved product. Under the waiver guidelines, all manufacturers are invited by PEPFAR to be considered for procurement with United States taxpayer funds. The waiver, which was initially made available because of a dearth of suitable US-made or FDA approved products when PEPFAR was originally authorized, has continued even though there are now several products, including Chembio's, that are FDA approved. Also, in addition to competing against approximately thirty non-FDA approved, non-US made products that can be purchased under U.S. procurement rules, in order to realize sales in the markets where the donor (mostly U.S.) funds are allocated, the product must additionally be selected by a country's ministry of health or their designees to be part of a national testing protocol or "algorithm". The algorithms typically use multiple rapid tests in sequence or in parallel to screen and confirm patients at the point-of-care and are increasingly allowing for multiple tests to be qualified in these algorithms. Chembio's sales in Africa and certain other markets are therefore based on the fact that its test has been one of those selected. A product's designation in a donor-funded country's algorithm is largely followed by most of the implementing agencies and organizations, resulting in the selection process being critical to participation in donor funded procurements in such market, and limiting the impact of marketing activities once these selections have been made. The selection process in each of these countries is not predictable and is based upon a number of factors, including but not limited to product performance, price, and supply chain.

In the developed world, particularly the United States and Europe, the competitive landscape and market dynamics are quite different. Due to the costs of and quality system requirements associated with US FDA regulatory approval, there are currently only two companies besides Chembio that have products that are both FDA PMA-approved and also CLIA-waived: Orasure Technologies (Bethlehem, PA) with OraQuick®, and Trinity Biotech Ltd. (Ireland) with

Uni-Gold® Recombigen. The regulatory costs for FDA approval and fewer number of products in turn results in very different (higher) pricing in the US market as compared with the developing world, with prices in the US averaging $8-12 per test to end user. This compares to approximately $1.00 per test in the developing world. As the requirements for the PMA and CLIA waiver are difficult, costly, risky and time-consuming, particularly relative to the size of the market, and because such approval is not required for participation in PEPFAR under the above-described waiver guidelines, we do not anticipate that Inverness has any plan to submit any of its products produced outside the U.S. to the FDA. Further, our agreements with Inverness provide that in the event one of those submissions is made (or if Inverness acquires a competitive product in the United States), we have the right to terminate our agreement with Inverness or make Inverness' marketing rights non-exclusive. In either case, we would retain a license under the Inverness lateral flow patents to market the products under a Chembio brand and/or through third party distribution partners.

Orasure has an estimated market share in the U.S. of approximately 70% with its Oraquick ® product. This product's main advantages are that it was the first test to market and also that, at least for certain market segments (primarily public health), it can be performed with oral fluid samples, as compared with only blood samples, which is the case for our products as well as Trinity's. The main disadvantage of the Orasure product is its relatively higher price. Also, Orasure's claimed sensitivity with oral fluid samples is lower than with blood samples, and combined with some limited reports of performance (false positive) problems on oral fluid samples, this has created some opportunities for Inverness with our product, as well as for Trinity.

Orasure markets its products directly through its own sales organization to the public health market, has made a significant investment in that market, and has nearly 100% of the three largest states in this market (New York, California and Florida) that together constitute the majority of public health HIV testing in the US. For the hospital market segment Orasure had an exclusive marketing arrangement with Abbott Diagnostics, but as of January 2009 they terminated this agreement and are expanding their direct sales organization to market directly to the hospital market segment as well. Trinity also relies on its own sales force to market its product, and does not have any other rapid tests to sell to distributors. The Uni-Gold product that is marketed by Trinity accounts for an estimated 10% of the market. This product does not detect HIV-2, while our products and Orasure's both do. Though HIV-2 is a rare strain of HIV, it is an advantage to be able to detect, though there is a cost of 15% of Net Sales to the license for this claim. Trinity's product also requires a much larger sample size, and does not have a true IgG control. This means that a control line, which is intended to confirm that the test procedure has been performed correctly, will appear on their product so long as any liquid material is applied to its sampling area; Chembio's (and Orasure's) control line will appear only if a biological sample is applied. The shelf life of our HIV products is 24 months, which is twice that of both the Uni-Gold and Orasure products.

We believe that Inverness, as a leading marketer of a broad range of point-of-care tests sold into all U.S. market segments, has a superior marketing organization as compared to either of our U.S. market competitors who are much smaller than Inverness. Inverness has made a significant investment in its launch of our products, in the training of a large marketing organization in the US, and in the acquisition of complementary product lines and sales organizations. For example, Inverness has significantly augmented its access to emergency room departments in hospitals through its acquisition of Bio-Site, which was the leading company in point-of-care tests for cardiac monitoring, and whose sales force can now add our product to its product portfolio for this important market segment. We believe that this is an example of the distribution advantages of our marketing partner.

Chembio's HIV Tests

One of our two product formats, the "barrel" format now marketed by Inverness as Clearview® Complete HIV 1-2, is a unique product format inasmuch as it is a unitized product, meaning that all components necessary to perform a single test are contained in a single pouch. This "barrel" format provides for a proprietary method of collecting finger-stick whole blood samples that eliminates the need for the step that all other devices require of transferring the sample from the fingertip to the sample well of the test. Also, the buffer solution in the barrel format is in a unitized vial that is pierced by the barrel tip to initiate the sample migration up the test strip contained inside the "barrel", and thereby creates a closed system that helps to minimize possible exposure to potentially infectious samples.

Our other FDA PMA approved rapid HIV test, marketed by Inverness as Clearview® HIV 1-2 STAT PAK®, is a rectangular-shaped lateral flow plastic cassette format test wherein the sample is transferred from the sample source (finger tip in the case of finger-stick whole blood samples) to the sample port in the cassette by means of a transfer loop. Though this step is not required in the barrel format, the cassette is less costly to manufacture, is a more familiar format to customers that have performed other standard design lateral flow tests, and is a more flexible format that utilizes the same procedure for all approved sample matrices (venous whole blood, finger-stick whole blood, serum and plasma). To date this format has accounted for almost all of the sales we have had through Inverness. However this is in part due to the fact that the barrel format was not CLIA waived until October 2007, approximately a year later than the cassette product, and we anticipate more sales of this product in the future, though still less than the

cassette.

Research and Development

During 2008 and 2007, $2.6 million and $1.9 million, respectively, were spent on research and development activities. Substantially all of our new product development activities involve employment of our Dual Path Platform (DPP®) technology for which we were awarded a U.S patent in 2007. We believe that this platform enables us to pursue many new product development and licensing opportunities. The DPP® technology can provide improved features on certain tests developed with it that include higher sensitivity, earlier detection, improved performance with more challenging sample types (such as oral fluid), and the improved ability to detect multiple analytes (multiplexing) in one test device.

During 2008 we made substantial progress in developing a portfolio of products based on the DPP® technology. These activities include completing development of certain products and making significant progress toward the development of additional products. These activities are further explained in Part II Item 7.

Regulatory Activities

We continue to make progress on obtaining a Community European (CE) marking for our products to indicate conformity with European Union health, safety and environmental requirements. We have submitted the HIV 1/2 STAT-PAK® technical file to our notified body and should complete all required steps for CE Marking of this product during the second quarter of 2009. Under our agreement with Inverness we are to obtain a CE Marking for the Clearview® Complete HIV 1/2. We are prepared to submit the technical file for this product on behalf of Inverness once we received final proposed labeling from Inverness.

We are also pursuing registrations of our lateral flow and DPP® HIV products in a number of other jurisdictions, and also pursing registrations with the USDA of additional claims for our veterinary tuberculosis products.

During 2008 we received FDA approval for the lowering of the age limits that the tests are approved for from 18 years to 13 years of age. This lowering of the lower age limit put our approved product claims in line with the 2006 CDC recommendations for routine test of all individuals between the ages of 13 and 64, and we believe that this additional marketing claim for the product will assist Inverness in certain market opportunities with our products.

Employees

At December 31, 2008, we employed 114 people, including 110 full-time employees. Effective May 2006, we entered into an employment agreement with Lawrence Siebert, President and Chairman. Effective March 2007, we entered into an employment agreement with Javan Esfandiari, Executive Vice-President of Research and Development.

Governmental Regulation

The manufacturing and marketing of the Company's existing and proposed diagnostic products are regulated by the United States Food and Drug Administration ("FDA"), United States Department of Agriculture ("USDA"), certain state and local agencies, and/or comparable regulatory bodies in other countries. These regulations govern almost all aspects of development, production and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing and record keeping. The Company's FDA and USDA regulated products require some form of action by each agency before they can be marketed in the United States, and, after approval or clearance, the Company must continue to comply with other FDA requirements applicable to marketed products, e.g. Quality Systems (for medical devices). Failure to comply with the FDA's requirements can lead to significant penalties, both before and after approval or clearance.

Most point-of-care diagnostic products are regulated as medical devices by the FDA Centers of Device and Radiological Health, though some are regulated by the FDA Center of Biologics Evaluation and Research. There are two review procedures by which medical devices can receive FDA clearance or approval. Some products may qualify for clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, in which the manufacturer provides a pre-market notification that it intends to begin marketing the product, and shows that the product is substantially equivalent to another legally marketed product (i.e., that it has the same intended use and is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness). In some cases, the submission must include data from human clinical studies. Marketing may commence when the FDA issues a clearance letter finding such substantial equivalence. An applicant must submit a 510(k) application at least 90 days before marketing of the affected product commences. Although FDA clearance may be granted within that 90-day period, in some cases as much as a year or more may be required before clearance is obtained, if at all.

If the medical device does not qualify for the 510(k) procedure (either because it is not substantially equivalent to a legally marketed device or because it is required by statute and the FDA's implementing regulations to have an approved application), the FDA must approve PMA application before marketing can begin. PMA's must

demonstrate, among other matters, that the medical device provides a reasonable assurance of safety and effectiveness. A PMA application is typically a complex submission, including the results of non-clinical and clinical studies. Preparing a PMA application is a much more expensive, detailed and time-consuming process as compared with a 510(K) pre-market notification. Once a PMA has been submitted, the FDA is required to review the submission within a statutory period of time. However, the FDA's review may be, and often is, much longer, often requiring one year or more, and may include requests for additional data. The Company has approved PMAs for the two rapid HIV tests now marketed by Inverness Medical as Clearview® Complete HIV 1-2 and Clearview® HIV 1-2 STAT PAK®.

Every company that manufactures medical devices distributed in the United States must comply with the FDA's Quality System Regulations. These regulations govern the manufacturing process, including design, manufacture, testing, release, packaging, distribution, documentation and purchasing. Compliance with the Quality System Regulations is required before the FDA will approve an application, and these requirements also apply to marketed products. Companies are also subject to other post-market and general requirements, including compliance with restrictions imposed on marketed products, compliance with promotional standards, record keeping and reporting of certain adverse reactions or events. The FDA regularly inspects companies to determine compliance with the Quality System Regulations and other post-approval requirements. Failure to comply with statutory requirements and the FDA's regulations can lead to substantial penalties, including monetary penalties, injunctions, product recalls, seizure of products, and criminal prosecution.

The Clinical Laboratory Improvement Act of 1988 ("CLIA") prohibits laboratories from performing in vitro tests for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of, the health of human beings unless there is in effect for such laboratories a certificate issued by the United States Department of Health and Human Services (via the FDA) applicable to the category of examination or procedure performed. Although a certificate is not required for the Company, it considers the applicability of the requirements of CLIA in the design and development of its products. The statutory definition of "laboratory" is very broad, and many of our customers are considered labs. A CLIA waiver will remove certain quality control and other requirements that must be met for certain customers to use the Company's products and this is in fact critical to the marketability of a product into the point-of-care diagnostics market. The Company has received a CLIA waiver for each of the two rapid HIV tests now marketed by Inverness Medical as Clearview® Complete HIV 1/2 and Clearview® HIV 1/2 STAT PAK®. The CLIA waiver was granted by the FDA for HIV 1/2 STAT-PAK on November 20, 2006 and for the Clearview® Complete HIV 1/2 on October 22, 2007.

In addition, the FDA regulates the export of medical devices that have not been approved for marketing in the United States. The Federal Food, Drug and Cosmetic Act contains general requirements for any medical device that may not be sold in the United States and is intended for export. Specifically, a medical device intended for export is not deemed to be adulterated or misbranded if the product: (1) complies with the specifications of the foreign purchaser; (2) is not in conflict with the laws of the country to