CHEMBIO DIAGNOSTICS, INC.
Form 10KSB
March 30, 2006

U.S. Securities and Exchange Commission
Washington, D.C. 20549

**FORM 10-KSB**

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

For the fiscal year ended December 31, 2005

**[ ] TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 [No Fee Required]**

For the transition period from _____ to _____.

Commission File No. 0-30379

**CHEMBIO DIAGNOSTICS, INC.**

(Name of small business issuer in its charter)

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

Check whether the issuer is not required to file reports pursuant to Section 13 or 15(d) of the Exchange 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 past 12 months (or for such shorter period that the registrant was required to file such report), and (2) has been subject to such filing requirements for the past 90 days. Yes X No__

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B (Sec. 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-KSB or any amendment to this Form 10-KSB. [ X ]

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

State issuer's revenues for its most recent fiscal year: $3,940,730.

As of March 22, 2006, the registrant had 9,178,764 common shares outstanding, and the aggregate market value of the common shares held by non-affiliates (*) was approximately $4,235,651. This calculation is based upon the closing sale price of $0.58 per share on March 22, 2006.

* Without asserting that any of the issuer's directors or executive officers, or the entities that own 1,875,918 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. DESCRIPTION OF BUSINESS

### General

Chembio Diagnostics, Inc. (the Company) and its subsidiaries, develop, manufacture, and market lateral flow rapid diagnostic tests that detect infectious diseases. These tests are sold in the U.S. and/or internationally to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments. The products are made under the label of Chembio Diagnostic Systems, Inc. (CDS) or the private labels of its distributors or their customers. The products are used in the diagnosis of infectious diseases and other conditions in humans and animals. The Company's main products presently commercially available are its three HIV Rapid Tests (SURE CHECK(R) HIV and HIV 1/2 STAT-PAK(TM) and HIV 1/2 STAT-PAK Dipstick) and its rapid test for Chagas Disease. The Company sold in 2004 substantially all of the remaining business related to its private label pregnancy test and is focusing on the products mentioned above.

### HIV Rapid Tests

We continue to believe our revenue growth in 2006 will come primarily from sales of our rapid HIV tests. 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 when 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 being tested, as the stigma associated with the disease is lessened and the ability to resume normal activities is substantially improved.

Our SURE CHECK HIV rapid test eliminates the need for a separate sample collection system when used to collect finger-stick whole blood samples. We believe this improves ease of use and safety. Our HIV 1/2 STAT-PAK and HIV 1/2 STAT-PAK Dipstick, like all competitive rapid HIV tests, require that the finger-stick whole blood sample first be transferred to the test device. HIV 1/2 STAT-PAK is value priced and more flexible than SURE CHECK for samples of venous whole blood, plasma and serum as well as finger-stick whole blood. HIV 1/2 STAT-PAK Dipstick is our most economical format and also flexible as to the aforementioned sample types. This product was designed in order to provide a low cost product with performance equal to our other products for resource-constrained markets in the developing world. All three of our HIV tests use a standardized test strip which we developed by using patented materials licensed non-exclusively to us from third parties as well as our own proprietary know-how and trade secrets. All three of our rapid HIV tests are qualitative yes/no tests for the detection of antibodies to HIV 1 & 2.

### Regulatory Status:

The Company has made substantial progress toward FDA approval of its SURE CHECK HIV and HIV 1/2 STAT-PAK products. A pre-approval inspection of its facility was conducted in the third quarter of 2005 and based upon communications with the agency the Company believes it has met the requirements of an "approvable" Pre-Marketing Approval (PMA) application, and expects to be so advised by the FDA during the first half of the second quarter of 2006; the Company further expects to complete the full process during the first half of 2006, which would include receipt from the FDA of a waiver under the Clinical Laboratory Improvement Act ("CLIA"). A CLIA waiver is essential in order to market the product into public health clinics and physicians offices where the level of training is less than clinical laboratories and hospitals. The Company is nearing completion of the CLIA waiver studies so it will be in a position to submit its waiver application immediately upon receipt of the PMA license from the FDA.

The Company's HIV products currently qualify under U.S. FDA export regulations to sell, subject to any required approval by the importing country, to customers outside the U.S. To date we have received approval from a number of potential importing countries, although Brazil and Uganda are the only countries in which we have significant sales. Our HIV 1/2 STAT-PAK and HIV 1/2 STAT-PAK Dipstick products were also evaluated by the World Health Organization in 2004 and as a result in 2005 they were qualified for inclusion in the WHO Bulk Procurement Scheme, which is a pre-requisite for these products being eligible for procurements from programs funded by the United Nations and their partners' programs. SURE CHECK HIV and HIV 1/2 STAT-PAK are also eligible for procurements pursuant to the President's Emergency Plan for AIDS Relief ("PEPFAR") as a result of a "waiver" status granted these products by the United States Agency for International Development.

**Partners Involved in the Product:**
In 2004 we entered into a thirteen-year supply and technology transfer agreement with FIOCRUZ-Bio-Manguinhos, an affiliate of the Ministry of Health of Brazil relating to our HIV 1/2 STAT-PAK product. FIOCRUZ-Bio-Manguinhos will supply this product, which will eventually be produced completely in Brazil, to the Brazilian public health market and potentially other markets in the region.

In September 2005 we were designated as the confirmatory test in Uganda's national rapid testing protocol and through the offices we have established in East Africa and Nigeria, we hope to be selected in more such national testing protocols. In February 2006 our HIV ½ STAT-PAK was designated by the Nigerian Ministry of Health in four out of the eight screening protocols in the Nigerian Interim Rapid Testing Algorithm. At the same time, we are identifying and appointing distributors in these regions, and are engaged with the multitude of stakeholders that are responsible for the delivery of rapid testing and related services in the markets. Our focus is on those African countries that are receiving funding from PEPFAR and other large relief programs.

In January of 2006 we became one of four recommended global suppliers to Former President Clinton's HIV/AIDS Initiative ("CHAI"), and through that we expect to generate revenues in many of the fifty countries that have agreements with CHAI.

For the US market, we are in discussions with potential marketing partners and direct customers in the United States as we near US FDA approval.

**CHAGAS RAPID TEST**
Chembio has completed development of a rapid test for the detection of antibodies to Chagas Disease. This product, Chagas STAT-PAK, was developed in collaboration with a consortium of leading researchers in Latin America that have granted us an exclusive license to their recombinant antigens. Chagas Disease is endemic only in regions of Latin America yet there are an estimated 16-18 million Chagas Disease cases resulting in approximately 20,000 deaths annually, with an estimated 300,000 new cases each year. It is transmitted by a parasitic bug which lives in cracks and crevices of poor-quality houses usually in rural areas, through blood transfusion or congenitally from infected mother to fetus. There is an effective therapy available to treat the early chronic phase, but it only eliminates the infection if administered to children that are diagnosed with it. Chagas STAT-PAK is the only rapid test for Chagas disease to have performed well in multi-center studies in endemic regions of Latin America.

The Company received, in January of 2006, an order for $1.2 million to supply its Chagas Disease rapid test to be delivered in the first half of 2006. This procurement is being made by the Pan American Health Organization, headquartered in Washington D.C., which is affiliated with the World Health Organization. The procurement will be used to implement a nationwide Chagas screening program for all children under the age of 10 in endemic regions of Bolivia. The Company is actively looking at developing additional business opportunities for this product in Bolivia, and other markets in Latin America that are impacted by this disease.

Prior to 2005, a majority of our revenues were from the contract manufacture of private label pregnancy tests for regional pharmacies, drug stores and mass merchants in the United States, Europe, Canada, and Central America. However, as a result of pricing pressures, regulatory changes and potential patent litigation in this field, and in order to focus our efforts on rapid HIV tests we sold substantially all of the business related to our private label pregnancy test. We have retained a profit share derived from the sales of these products by the buyer. This has resulted in a substantial reduction of our revenues from these products during 2004 and 2005. The extent to which we will derive a benefit from sales of these products is difficult to estimate because of uncertainties in regulatory changes, product pricing, manufacturing cost changes, and patent litigation.

As described below, we also have other commercially available products, such as rapid tests for Lyme disease and other products, the aggregate of whose revenues are currently not material to us. We also are involved, as described

below under “Research and Development,” in the development of new products.

**Lateral Flow Technology**

All our current products employ lateral flow technology, which 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 the strip downstream from the point of application. 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.

Our lateral flow technology allows the development of 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 specimens potentially infected), non-invasive (requires 5-20 microliters 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.

We can develop and produce lateral flow tests that are qualitative (reactive/non-reactive), as in the case of our HIV tests, and we can develop semi-quantitative tests, reflecting different concentrations of the target marker(s) using different colored latex test lines for each concentration We can also develop tests for multiple conditions, using different colored lines. We have developed proprietary techniques that enable us to achieve high levels of sensitivity and specificity [see definition below] in our diagnostic tests using our proprietary latex conjugate 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 HIV rapid test which we believe is easier to use than other finger-stick whole blood rapid tests. SURE CHECK 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. ***Please refer to the section entitled "Legal Proceedings" for a discussion of the legal issues we face with regard to SURE CHECK.***

During 2005 we developed a patent-pending lateral flow platform, which we believe provides several advantages for next generation product development *(*See *"Intellectual Property").*

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.

**Target Market**

**HIV Rapid Tests**

We believe that the prevention and treatment goals that have been established by large programs financed to thwart the spread of HIV will drive the growth and demand for rapid HIV tests geometrically in the coming years. Chembio is one of only two US-based manufacturers of rapid HIV tests and the only one with products that it believes can meet the various demands of the global market.

Based upon an analysis done by the Global Business Coalition of HIV/AIDS, approximately 500 million people will need to be tested with at least one rapid test (also a confirmatory rapid test will be needed in the case of a positive result) over the next three years in order to insure that treatment targets are achieved[1] . This is not just because of the

continuing growth in the epidemic, but more importantly, because anti-retroviral treatments are available, affordable and are being funded, so that people actually have a reason to be tested.

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[1] www.businessfightsaids.org/site/pp.asp?c=gwKXJfNVJtF&b=1008825 - Policy Documents/Facilitating Access to Testing

Because HIV medicines have become much less expensive and more widely available, unprecedented multi-billion dollar financial commitments are being allocated in each of the next few years. Some of these commitments are being made by the UNAIDS "3 by 5" initiative[2], The Global Fund[3] , and the U.S. Presidential Emergency Plan for AIDS Relief[4] , which will provide treatment to five million people, and in order to identify these five million people, rapid testing is being implemented on a very large scale. The United States is the largest donor, by far, to these programs. Each of these programs recognizes that a massive scale-up in the use of rapid HIV tests is the only way their treatment goals can hope to be achieved.

We further believe that the global demand for rapid HIV testing will increase at very high rates well beyond the next few years and for the foreseeable future. As of the end of 2004 (which is the latest data the Company has available to it), there were an estimated 40 million people infected with HIV/AIDS worldwide, of which an estimated 6 million were in need of antiretroviral therapy. The number of people in need of treatment will continue to grow as infection rates increase significantly worldwide, and there is little expectation for an effective vaccine anytime soon. As such, even with relatively low prevalence rates in Asia, UNAIDS estimates that 12 million new infections could occur in that region alone between 2005 and 2010[5] .

FDA approval for two of our rapid HIV tests is anticipated in the first half of 2006, and this will enable us to participate in the U.S. market as well, which is estimated to become at least a $50 million market during the next few years[6] . The U.S. market opportunity has been developing first in the public health and hospital emergency room segments, and as a result of increased advocacy for routine testing, will likely increase and expand use of this technology into the physician's office, prisons, and other venues. In his State of the Union Address this year, President Bush called on Congress to reform and reauthorize the Ryan White CARE Act, which among other things provides counseling and testing for those in greatest need of HIV/AIDS assistance. The President has also proposed to direct a total of more than $90 million to the purchase and distribution of rapid HIV test kits, facilitating the testing of more than 3 million additional Americans. Test kits would be distributed in areas of the country with the highest rates of newly discovered HIV cases and the highest suspected rates of undetected cases. We are also in preliminary discussions with a US marketing partner to serve these markets.

Finally, based upon recent pronouncements, we believe that the over the counter market is also likely to open up in the U.S., which would expand the U.S. market very significantly. We are already developing OTC opportunities outside the US, and we will consider adding an oral fluid feature to our product lines as such a feature may offer greater convenience provided there is equal performance when using oral fluid samples.

**Chagas Rapid Test.** Chembio had developed this test several years ago but the market for the product was not meaningful as most prevention efforts, which were minimal, were made using laboratory tests used for blood bank screening of blood. However, there has now been a greater interest in Chembio's rapid test because of an important publication that demonstrated the effectiveness of the rapid test in the screening of blood donors (as opposed to the blood in blood banks), and because it can be effectively deployed in rural populations to screen children and pregnant women. Also, studies that have been completed at multiple sites in Central and South America showing sensitivity of between 98.5% and 99.6% and specificity between 94.8% and 99.9%, shows that the test is a good alternative to standard laboratory testing methods.

**Other Products Under Development.**

Chembio is developing rapid tests for other infectious diseases, particularly rapid tests for human and veterinary tuberculosis.

Tuberculosis ("TB") is the leading killer of people who have AIDS. Chembio's TB products will leverage several years of basic NIH-funded research by Chembio's scientists in TB and, if successfully completed, will result in products applicable to both human and veterinary TB, while also leveraging a marketing and distribution capability which the Company has been developing for its HIV products.

Tuberculosis is also a problem in a number of animal species either because of potential transmission to humans, costs to agricultural production or because of the impact on the cost of the animals themselves. For example, nonhuman primates used in research or in zoos are quite costly, and whole colonies can be lost if transmission is not effectively controlled through routine and accurate diagnosis. Bovine (Cattle) TB can be transmitted from livestock or deer to humans and to other animals. Under rules established by the Animal and Plant Health Inspection Service, a state can lose the right to move cattle across state lines if TB is detected in two or more herds as has recently happened in Texas and Michigan. TB control of meat at slaughterhouses is dependent upon visual inspection. The Company believes that a rapid test could complement or supplant these visual inspections.

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[2] www.unaids.org/en/treat3millionby2005initiative.asp
[3] www.theglobalfund.org/en
[4] www.usaid.gov/our_work/global_health/aids/pepfar.html
[5] www.unaids.org/html/pub/global-reports/bangkok/unaidsglobalreport2004_en_html.htm
[6] Market research prepared for Chembio

Chembio has already completed development of a rapid lateral-flow test for the detection of TB in Non-Human Primates (PrimaTB STAT-PAK), and has a similar test near completion for multiple host species, including cattle, deer, elephant and other exotic wildlife. The tests can use serum, plasma, whole blood or "meat juice" samples and provide results within 20 minutes. The Company believes, subject to USDA approvals, that commercialization of these products can begin in early 2007.

**Distribution Channels & Marketing Strategy**

Approval from the FDA of our HIV rapid tests will not only permit sales in the U.S. but will also enhance marketing capability in the international markets. HIV 1/2 STAT-PAK and HIV 1/2 STAT-PAK Dipstick were recently made part of the World Health Organization (WHO) 2005 Bulk Procurement Scheme and, together with SURE CHECK HIV, the USAID blanket waiver list. These are both critically important for international sales. The WHO's endorsement is required for virtually all international procurements by governmental and non-governmental organizations. The USAID waiver allows our products to be procured with USAID and CDC (i.e., PEPFAR) funding even without FDA approval which, as mentioned above, is pending.

Our marketing strategy is to:

- Expand our international sales effort and strategic partnerships in the developing world for our global health rapid test products, particularly our HIV and Chagas Disease tests. We are actively engaged in expanding HIV test sales and marketing through our recently established East and West African offices. These offices are headed by seasoned professionals that have extensive marketing and/or public health experience in Africa and are establishing distributor relationships throughout the continent. We also have new collaborations and sales opportunities that we are pursuing in Southeast Asia, China, and South America for our HIV and/or Chagas Disease tests, as well as other new tests that we have under development.

- Launch our rapid HIV tests in the US and Europe. We anticipate FDA approval during the first half of 2006. Our products will be marketed initially in the public health and hospital markets, through our own direct sales people and/or with marketing and distribution partners with whom we are currently in discussion. Once we obtain approval we will move aggressively on approval in Europe.

- Pursue potential OTC marketing in the U.S. and internationally. There is discussion now to allow over-the-counter sale of HIV rapid tests in the U.S. as well as in other markets.

- Launch in 2006 our initial veterinary TB product, Prima TB Stat Pak(TM), within our growing line of veterinary TB tests. We anticipate USDA approval of our initial product, a nonhuman primate TB test, in late 2006. During 2007 we expect to obtain revenues from certain other veterinary TB products, at very favorable margins.

**Strategic Alliances**

Strategic alliances are a key element in Chembio's business strategy.

**Clinton Foundation HIV/AIDS Initiative** - In January we entered into an agreement with the William J. Clinton Foundation's HIV/AIDS Initiative (CHAI) to be recommended by CHAI to receive the procurements from CHAI partner countries (more than 50 countries in the developing world and also including China, Brazil and India) that choose to access CHAI's suppliers products and their preferred pricing in exchange for their sharing information with CHAI and permitting CHAI to fill gaps that will improve and scale up the country's health care delivery systems. We are one of four companies worldwide (and the only US-based manufacturer) to be recommended by CHAI for sales of HIV rapid tests. While CHAI is not a procurer of the tests per se, it is an increasingly major factor in influencing which tests are to be procured. CHAI also has major agreements with generic HIV ARV manufacturers and manufacturers of viral load and CD-4 monitoring diagnostic tests, and those agreements have been very successful models.

**Brazilian Ministry of Health** - In addition, the Company is committed to securing alliances and technology-transfer agreements with government agencies and commercial entities. For example, Chembio signed, in early 2004, a thirteen year technology transfer, supply and license agreement with Bio-Manguinhos, an affiliate of the Brazilian Ministry of Health (MOH) and the predominant supplier for meeting public health needs in Brazil. Over a three-year period, Chembio will transfer its proprietary technology related to HIV 1/2 STAT-PAK to Bio-Manguinhos in exchange for commitments to purchase at least one million rapid tests. This purchase commitment was met during 2005, though we expect substantial additional procurements prior to the completion of the technology transfer agreement, currently anticipated for early 2007. Thereafter Bio-Manguinhos will have the right to produce its own rapid tests and Chembio will receive royalties for ten years.

**Other Partnerships in Development** - Chembio is applying its Brazilian success to other areas of the world. The Company will endeavor to partner with qualified entities that will assemble and package semi-finished tests produced by Chembio under Chembio's quality control in the U.S. These unique arrangements would create an effective public-private partnership with local governments and ensure the availability of rapid HIV tests. This will foster self-reliance in these countries, create local jobs and contribute to their economic and technological growth.

**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;
· 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 lateral flow rapid tests, particularly for HIV and tuberculosis, 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 is instrumental in our obtaining the collaborations we have and that we continue to pursue.

Prior to 2005, we had very limited experience with regard to obtaining FDA or other required regulatory approvals, and no experience with obtaining pre-marketing approval of a biologic product such as HIV. See "Governmental Regulation" for definition of pre-marketing approval. For this reason, during 2004 and 2005 we hired employees and consultants that collectively have that experience from other companies. We believe this has been critical in our progress toward obtaining these approvals during the last year and in ensuring that we manufacture our products in accordance with FDA, USDA and other regulatory requirements.

Our access to capital is much less than that of several of our competitors, and this is a competitive disadvantage. We believe however that our access to capital may increase as we get closer to FDA approval of our rapid HIV tests and/or as we complete the development of, and the requisite regulatory approvals related to, our other products, including those that we have under development. ( See Management's Discussion And Analysis Of Financial Condition And Results Of Operations - *Overview* and in particular the last paragraph)

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 complete effectively for the same individuals to the extent that a competitor uses its substantial resources to attract any such individuals. With respect to the availability of patent protection, we do not have our own portfolio of patents or the financial resources to develop and/or acquire a portfolio of patents similar to those of our larger competitors. We have been able to obtain patent protection by entering into licensing arrangements.

Competitive factors specifically related to our HIV tests are product quality, price and ease of use. Product quality for an HIV rapid test primarily means accuracy (sensitivity and specificity), early detection of cases, time elapsed between testing and confirmation of results, and product shelf life. We believe that our product offerings and business model position us well to compete effectively and win a meaningful share of this expanding market.

The leading products in the international market are UniGold(R), produced by Trinity Biotech in Ireland, and Determine(R), produced by Abbott Diagnostics in Tokyo. The Abbott Determine business was sold to Inverness Medical Innovations last year, although Abbott retained the distribution rights to the Determine product for approximately three years. Determine and UniGold have well established presences in many of the developing world markets, often as the screening and confirmatory tests, respectively. Inverness' Orgenics subsidiary in Israel has a rapid test, Double Check Gold, and this is one of the other three products recommeded by CHAI; the other two companies whose products were selected by CHAI are based in India and China, respectively, and they have not yet established apparent marketing efforts outside their countries, although they are qualified by the WHO. In the developed world, particularly the United States, our competitors are Orasure Technologies with OraQuick(R), and, to a much lesser degree Trinity with its UniGold(R) product, both of which are FDA-approved, CLIA-waived products. We do not believe Inverness plans to submit either the Determine or the Orgenics product to the FDA.

We are targeting the developing world markets that are being funded by PEPFAR and The Global Fund where Determine and UniGold are the established tests. However, neither one of those products contains a true IgG control. This means that the control line does not confirm that the test was run properly with the patient sample; it only confirms that the buffer solution was applied. Thus the appearance of the control line in these tests does not necessarily mean that the test was validly performed, so it may not be a true non-reactive or negative result, and this can lead to potential false negative results.

Orasure has been focusing on building its brand and market share in the US market, and successfully so; its developing world sales are not significant as we believe its product is not suitable and not cost competitive to participate in the international market. Orasure has been successful in bringing attention to the need and availability of rapid HIV testing in the United States. Its main advantage is the fact that its test can be used with oral fluid samples, though its FDA approved sensitivity is 99.3% with these samples. OraQuick is not approved for use with serum samples which may limit its marketability in certain settings.

Chembio's HIV products' shelf life is 24 months, which is double that of UniGold and four times that of Orasure's product. We expect that our products will be approved by the FDA for finger-stick whole blood, venous whole blood, serum, and plasma. Our Sure Check format is extremely convenient, easier to use than OraQuick on finger-stick whole blood sample, much more cost competitive, and provides a safe, closed system. We believe that having high level executives in the field in East and West Africa that are engaged with public health officials, NGOs, and other organizations provides us with a competitive advantage. None of the competitors to the best of our knowledge has actually done a technology transfer which we can now replicate in markets of our choosing.

We believe that Chembio is in a leadership position as it relates to our rapid tuberculosis test even though the product is still under evaluation and not ready for marketing. We are not aware of any rapid whole blood test that has the sensitivity and specificity levels necessary to replace or complement the current sputum smear microscopy method being employed in the high incidence tuberculosis countries; and this is what we believe our rapid tuberculosis test, when fully developed and evaluated, will be able to do. We are also not aware of any rapid whole blood test to detect active pulmonary tuberculosis in non-human primates and/or other animals for which Chembio is developing rapid tuberculosis tests.

**Research and Development**

We are focusing our research and development efforts on new rapid tests that will leverage our expertise and sales channels. Our research and development activities have been in three disease areas: HIV, Human and Veterinary Tuberculosis, and Neglected Diseases such as Chagas Disease **(See section entitled *General*)**.

**HIV (See section entitled *General*)**
Our HIV development efforts are on developing different specialty next generation rapid tests such as tests for accurately screening newborns and confirmatory tests. Prototypes have been developed using our patent-pending

lateral flow technology (See *Intellectual Property).*

**Tuberculosis**

Our tuberculosis rapid tests for humans are being designed to significantly increase the accuracy of existing tuberculosis screening methods and technologies. Our initial tuberculosis test was developed pursuant to Phase I and II Small Business Innovative Research grants from the National Institute of Health from 1998 until 2002, and our current test, TB STAT-PAK II, was completed in 2003. This test was evaluated by the World Health Organization in 2005 alongside more than fifteen other tests from various manufacturers, and although it was among the best performers, its sensitivity and specificity were not high enough as compared to the benchmarks employed to result in a recommendation by the WHO to switch from the current methodologies to our test or to any of the other tests in this evaluation.

In addition to our research and development efforts for tuberculosis tests for humans, we have developed a test for detecting active pulmonary tuberculosis in non-human primates (monkeys). We submitted this product for approval to the United States Department of Agriculture during the first quarter of 2005, and we expect to obtain approval of this product during the latter part of 2006. We are also engaged in collaborations related to the detection of active pulmonary tuberculosis in other animals as we can leverage our current technology for additional species. We do not anticipate any material revenues from these efforts during 2006.

During 2005 and 2004, $1,364,898 and $1,508,849, respectively, was spent on research and development activities. A significant portion of these expenditures have been on our human and non-human primate tuberculosis product development efforts.

**Employees**

At December 31, 2005, we employed 64 people, including 62 full-time employees. In May 2004, we entered into employment agreements with Lawrence Siebert, President and Chairman, Avi Pelossof, VP Sales, Marketing and Business Development, and Javan Esfandiari, Director of research and development.

**Governmental Regulation**

The Company's existing and proposed diagnostic products are regulated by the U.S. Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), certain state and local agencies, and/or comparable regulatory bodies in other countries. This regulation governs 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., CLIA regulations (for medical devices). Both before and after approval or clearance, failure to comply with the FDA's requirements can lead to significant penalties.

Most of the Company's diagnostic products are regulated as medical devices, and some are regulated as biologics. 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 d