Harbinger Research
Independent Investment Analysis

Investment Report

United States
Healthcare – Diagnostics Tests

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Chembio Diagnostics Inc. (CEMI–OTC:BB)

Focused on Continuing to Grow its Rapid HIV Test Kit Segment While Seeking Out New Niche Markets for Diagnostic Test Kits

Recent Price: **$0.53**

Market Data

Market Capitalization (mln)	$4.3 mln
Enterprise Value (mln)	$7.9 mln
Common Shares Out (mln)	8.15 mln
Fully Diluted Shares (mln)	24.1 mln
Float (mln)	6.14 mln
Ave. Volume (90 day, approx.)	4,250
Institutional Ownership	0.0%
Insider Ownership	20.8%
Exchange	OTC-BB

Company Overview

Chembio Diagnostics, Inc. develops and manufactures point-of-care medical diagnostic tests for the detection of infectious diseases and other conditions in humans and animals. The company's primary product offering includes three rapid test kits for the detection of HIV which are marketed abroad to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations and medical professionals. Chembio also has a rapid test for the detection of Chagas Disease and is developing a serological test for active pulmonary tuberculosis (TB) as well as dental bacteria and veterinary tuberculosis.

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Summary and Investment Opportunity

- **International sales from PEPFAR – Aided Countries Expected to be Higher with Increased Demand for HIV Tests Beginning in '05**

President's Emergency Plan For AIDS Relief (PEPFAR) is a U.S. government program established in 2004 to assist primarily African countries in combating AIDS by injecting $15 billion dollars over a 5-year period. A report produced by the Center for Strategic and International Studies notes that a substantial increase in HIV/AIDS testing is essential if the PEPFAR is to meet its goals of providing support and treatment for 2 million people over the next five years. Consequently, Chembio has initiated several strategies to meaningfully participate in the PEPFAR program as well as the UN Global Fund and other treatment and prevention programs.

- **FDA Approval of its Rapid HIV Tests Expected by the End of '05.**

Chembio has successfully manufactured and marketed its HIV rapid test products since 2001 to customers in several countries outside the United States. Subject to satisfactory completion of its manufacturing facility inspection in accordance with FDA requirements, management believes that FDA approval of its HIV rapid test kits will be achieved by the end of 2005.

- **Additional Revenue Expected from Bio-Manguinhos Agreement**

In February 2004, Chembio signed a thirteen year technology transfer and supply agreement with Bio-Manguinhos, Brazil's largest manufacturer of vaccines. Chembio recently reported that it will deliver 700,000 units by year end, compared with 450,000 in 2004; 150,000 were delivered in the second quarter. By the end of 2007 this collaboration will provide Bio-Manguinhos with a Brazilian-made HIV rapid test and Chembio, through a royalty agreement, with continued participation in one of the most significant markets over the next 10 years.

- **Developing New Diagnostic Tests that Address Niche Markets**

Part of the company's strategy is to seek out additional opportunities to develop diagnostic test kits that provide a cost effective diagnostic solution to niche markets that address a variety of neglected diseases. An example of this strategy is the company's test for Chagas Disease which is estimated to afflict 16-18 million people, resulting in 21,000 deaths annually.

Company Overview

Chembio Diagnostics, Inc. develops and manufactures point-of-care medical diagnostic tests that aid in the detection of infectious diseases and other conditions in humans and animals. The company's primary product offering includes three HIV Rapid Tests called **Sure Check™ HIV** and **HIV 1/2 Stat-Pak™ , and HIV 1/2 Stat-Pak™ Dipstick**. These rapid tests are easy-to-perform, single-use diagnostic tests that allow for visual detection of antibodies to the HIV virus, on a strip. These products are manufactured either under the label of Chembio Diagnostics or under the private labels of its distributors or their customers and are marketed abroad to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals, and retail establishments. Chembio is also developing a dual parameter HIV/ tuberculosis (TB) rapid test that the company plans to market once it establishes the clinical performance of its TB test on a stand alone basis. Additionally, Chembio has developed a rapid test for the detection of antibodies to Chagas Disease, which is a tropical disease specific to the Americas caused by pathogens that are typically transmitted to humans by triatomine insects, commonly known as assassin bugs, vinchuca or kissing bugs. Chembio is also developing a serological test for active pulmonary tuberculosis as well as products in the areas of dental bacteria, veterinary tuberculosis, and cerebral spinal fluid leak detection. Part of the company's strategy is to seek out additional opportunities to develop diagnostic test kits that provide a cost effective detection solution to niche markets that address a variety of neglected diseases.

Historically, a majority of the company's revenues were derived 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 area, Chembio chose to exit this business and pursue higher margin opportunities for diagnostic test kits. Part of Chembio's strategy in developing new test kits is to collaborate with leading companies and agencies that are best positioned to identify market needs and provide distribution within their field(s) of expertise. This approach enabled Chembio to establish its collaboration in Brazil.

In HIV and TB, the company is focused on building strategic relationships with public health agencies, non-governmental organizations and world class distribution organizations that are positioned to access these markets in the developing countries as well as the developed markets of the US, Europe and Japan. In December 2004, the company completed its U.S. clinical trials for its Sure Check™ HIV and HIV 1/2 Stat-Pak™ rapid tests with 2,700 patients at five clinical sites located throughout the U.S., which successful in achieving sensitivity and specificity rates of 99.8% and 99.9%, respectively. With the clinical trials concluded, the company submitted a Pre-Market Approval (PMA) application in February with the FDA, which the company anticipates will be approved by the end of 2005.

In Chembio's Q2-05 earnings press release, management noted that Chembio experienced a 77% and 32% increase in net sales of its HIV and Chagas rapid tests during the first half of the year. Management attributed this sales increase to greater demand for its HIV test kits in Africa, where the company is beginning to see results from its marketing efforts in this region as well as continued strategic focus on these product lines. For the balance of 2005 and into 2006, management anticipates that the company will continue to experience significant growth in demand for its HIV and Chagas Disease rapid test products, which should grow revenues and thereby permit the company to generate substantially better gross margins.

Competitive Advantages of Chembio's Rapid HIV Tests – Fast and Requires a Small Sample Size

Rapid HIV tests usually produce results in about 20-40 minutes. In contrast, the results from commonly used, laboratory-based HIV-antibody screening tests – either enzyme immune assay (EIA) or the enzyme-linked immunosorbent assay (ELISA) – are typically not available for several days. Unfortunately, a large percentage (>25%) of individuals tested in public health settings do not return or call back to get test results from laboratory-based tests. Consequently, there is an increasing need for routine rapid HIV/AIDS testing in clinical settings, where testing is becoming part of routine check-ups and doctor visits.

Management believes that its HIV test kits offer several advantages over competing products. As the table below shows, Chembio's test kits require a small sample size (3 to 5 µl blood, plasma or oral swab) and provide test results in less time (10 to 15 minuets) than its competitors. Additionally, Chembio's HIV test kits utilize lateral flow technology, and therefore require no special equipment. Furthermore, Chembio's HIV test kits are capable of being stored at least 24 months at room temperature, which an appealing feature for many customers in lesser developed countries where refrigeration may not be readily available.

Chembio's HIV Tests Versus the Competitors			
Test	**Manufacturer**	**Results Time**	**Sample Size and Type**
Sure Check™ HIV	Chembio Diagnostics, Inc	15 minutes or less	3 µl blood
HIV 1/2 Stat-Pak™	Chembio Diagnostics, Inc	10 minutes or less	5 µl blood or plasma or oral swab
OraQuick	OraSure Technologies, Inc.	20 – 40 minutes	5 µl blood or plasma or oral swab
Uni-Gold	Trinity Biotech plc	10 – 20 minutes	60 µl serum plasma or whole blood
Determine	Inverness Medical Innovations	20 minutes	50 µl blood, serum or plasma

Recent Company News

Chembio's Q3-05 Net Sales Increase 93% Over the Same Period a Year Earlier

On October 3, 2005 Chembio's management announced that it estimated the company generated approximately $850,000 in revenue during the third quarter, or a 93% increase in net sales over $440,371 during the same period a year earlier. This sales increase was largely attributable to the shipment of 220,000 HIV 1/2 Stat Pak test kits to Bio-Manguinhos, an affiliate of the Brazilian Ministry of Health (MOH).

In February 2004, Chembio signed a thirteen year technology transfer and supply agreement with Bio-Manguinhos, Brazil's largest manufacturer of vaccines and an affiliated entity of the Brazilian Ministry of Health. Within approximately three years, this collaboration will provide Bio-Manguinhos with a Brazilian-made HIV rapid test and Chembio with an opportunity to meaningfully participate in this significant market over an additional ten year period. In 2004, Chembio sold 450,000 HIV test kits to Bio-Manguinhos, and expects to sell them 700,000 test kits in 2005. Year-to-date, the company has shipped 370,000 test kits to Bio-Manguinhos and management anticipates shipping an additional 330,000 HIV 1/2 Stat Pak test kits during the fourth quarter.

Chembio Opens a New Office In West Africa to Focus on Marketing HIV Rapid Test Kits

On October 4, 2005 Chembio announced that it had established a new sales office in West Africa (Abuja, Nigeria) as part of its strategy to market its rapid HIV tests to countries that are recipients of the President's Emergency Plan for AIDS Relief (PEPFAR) program funds. This marketing effort's of this office are directed by Dr. Joseph Nnorom, MD, MPH, who, until recently, was the Director of the CDC's Global Aids Program in Nigeria. Dr. Nnorom brings with him twenty years of experience in public health as a medical epidemiologist. His experience includes implementation, monitoring and evaluation of HIV/AIDS/ STI and reproductive health programs. Additionally, his program management experience in Voluntary Counseling and Testing (VCT), Prevention of Mother to Child Transmission (PMTCT), anti-retroviral therapy treatment and monitoring of AIDS infected persons is expected to be an enormous asset to the company, helping to grow Chembio's revenues throughout Africa.

Chembio's HIV 1/2 test chosen as the confirmatory test in Uganda

On September 21, 2005 Chembio announced that Uganda's Ministry of Health had officially designated Chembio's rapid HIV 1/2 Stat Pak test to be the confirmatory test in its national testing algorithm. The national testing algorithm, which appears below, is the sequential protocol of tests typically recommended by the ministries of public health to diagnose HIV/AIDS infected persons, in conjunction with the VCT (Voluntary Counseling and Testing) and PMTCT (Prevention of Mother to Child Transmission) programs. Once a patient has tested positive, the protocol in Uganda requires a second confirmatory rapid test to follow the initial screening test at the point of care, since many patients would otherwise fail to return for their confirmatory lab results.

Recommended HIV Testing Algorithms for Uganda

Testing Algorithm 1: Determine → Statpak → Unigold
Testing Algorithm 2: Tridot → Statpak → Unigold
Testing Algorithm 3: Capillus → Statpak → Determine (temporary for AIC soon to replace Determine with Unigold)

Note: Determine is manufactured by Inverness Medical Innovations (AMEX:IMI), Tridot is manufactured by Mitra & Co. (India), both the Capillus and Unigold are manufactured by Trinity Biotech plc (NASDAQ:TRIB).

The market for rapid tests is expected to increase exponentially in Uganda as public health officials are encouraging the use of rapid testing devices to diagnose HIV/AIDS infected individuals. While the screening test is used on 100% of the

people tested, the confirmatory test is used only on those who test positive. The utilization rate of confirmatory tests varies with the prevalence of the disease in screened groups. In Uganda, management currently expects that 25% to 30% of the screened population will test positive for the HIV virus. In 2004, Uganda's demand for rapid HIV tests exceeded 400,000 kits, and is expected to exceed 1.5 – 2.0 million tests kits in 2005.

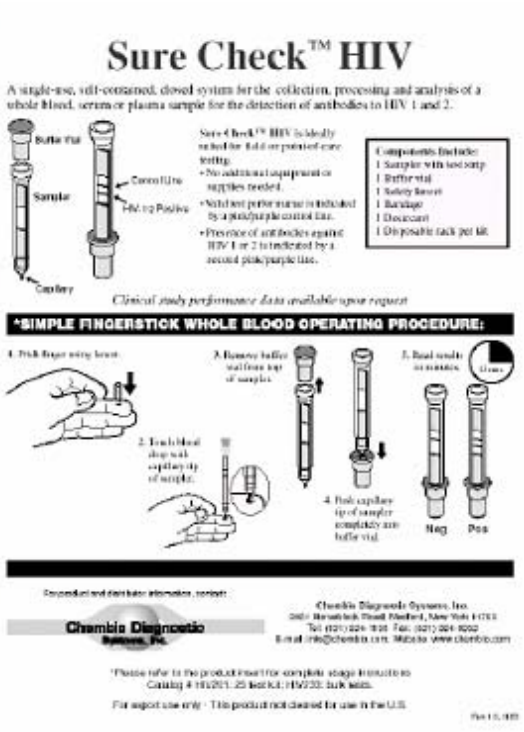
Chembio also announced that Quality Chemicals Limited (QLC) will act as its distributor in Uganda. QCL, a leading importer and distributor in the sales of medical devices and drugs, is the largest supplier of antiretroviral drugs (ARVs) to the Ugandan government.

Legal Issues Regarding Chembio's Sure Check™ HIV Test

On October 3, 2005 Chembio reported that it had received a Claim Construction Ruling and summary judgment in a case that the company initiated in 2004 against Saliva Diagnostic Systems, Inc. In these proceedings, Chembio sought a declaratory judgment that its Sure Check™ HIV barrel device does not infringe on Saliva Diagnostic's patent, or in the alternative, that Saliva's patent is invalid or unenforceable. The motions for summary judgment made by both parties were denied, opening the way to fact discovery in the case. In responding to the motion for a Claim Construction Ruling, the judge interpreted the patent in such a way that only the sampling part of the device is to exclude absorbent material, a narrower finding than what Chembio's motion had requested. The case is in a preliminary stage and this order does not address issues of patent infringement, validity or enforceability. Despite this, Saliva Diagnostic has indicated that it plans on seeking damages as well as a judgment that enjoins Chembio from selling or offering for sale its Sure Check™ HIV test kit.

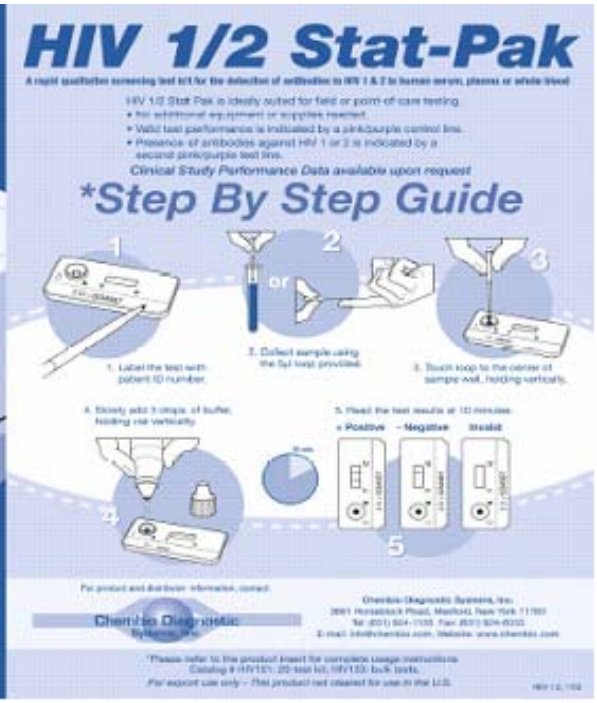
Sure Check™ HIV Test Kit

Chembio's Sure Check™ HIV rapid test eliminates the need for a separate sample collection system when used to collect finger-stick whole blood samples. Management believes that this test improves ease of use and safety.



HIV 1/2 Stat-Pak™ Test Kit

The company's HIV 1/2 Stat-Pak™ , like other competitive rapid HIV tests, requires that the finger-stick whole blood sample first be transferred to the test device. However, HIV 1/2 Stat Pak is value priced and more flexible than Sure Check™ HIV for samples of venous whole blood, plasma and serum.



Regulatory Status and Approval of its HIV Test Kits

Chembio is qualified under U.S. FDA export regulations to sell its HIV test kits to customers outside the U.S. To date the company has received approval from a number of potential importing countries, although Brazil is the only country in which it has significant sales. In December 2004 Chembio completed clinical trials for Sure Check™ HIV and HIV 1/2 Stat-Pak™ in the U.S. which consisted of 2,700 patients located at five clinical sites located throughout the U.S. On February 17, 2005 Chembio submitted a Pre-Marketing Approval application ("PMA") to the FDA for its HIV test kits. Facility inspection – which management expects to be completed during Q3-05 – is the primary remaining step that the company must complete in order to achieve FDA approval.

Chembio's HIV 1/2 Stat-Pak™ and HIV 1/2 Stat-Pak™ Dipstick products were also evaluated by the World Health Organization in 2004. In January 2005 the company received a final report confirming that these products met the performance criteria 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. The company has also received confirmation from the United States Agency for International Development that its Sure Check™ HIV and HIV 1/2 Stat-Pak™ met the criteria for being eligible for procurements pursuant to the President's Emergency Plan for AIDS Relief.

Patents

Although the company does not own any patents covering its lateral flow technology, it has obtained a non-exclusive license from Abbott Laboratories to a portfolio of its lateral flow patents. In June 2005, Chembio filed a new patent application with the United States Patent and Trademark Office for a novel method and device for rapid testing incorporating a form of lateral flow technology. Management believes that this patent application is a significant departure from conventional lateral flow product designs and that it has shown substantially improved performance compared to conventional products based upon preliminary studies that the company has conducted. Furthermore, management believes that this new patent application substantially improves the company's intellectual property portfolio by providing it with a broad proprietary platform upon which to develop future HIV, TB and other products that will address the needs of prevention efforts globally. Management also believes that this new lateral flow test may improve the sensitivity of TB serology, especially in HIV infected patients.

Company History

Chembio Diagnostic Systems Inc. was formed in 1985. Since inception, the company has been involved in developing, manufacturing, selling and distributing medical diagnostic tests, including rapid tests, for a number of diseases and for pregnancy. On May 5, 2004, Chembio Diagnostic Systems Inc. completed a merger through which it became a wholly-owned subsidiary of Chembio Diagnostics, Inc., formerly known as Trading Solutions.com, Inc.

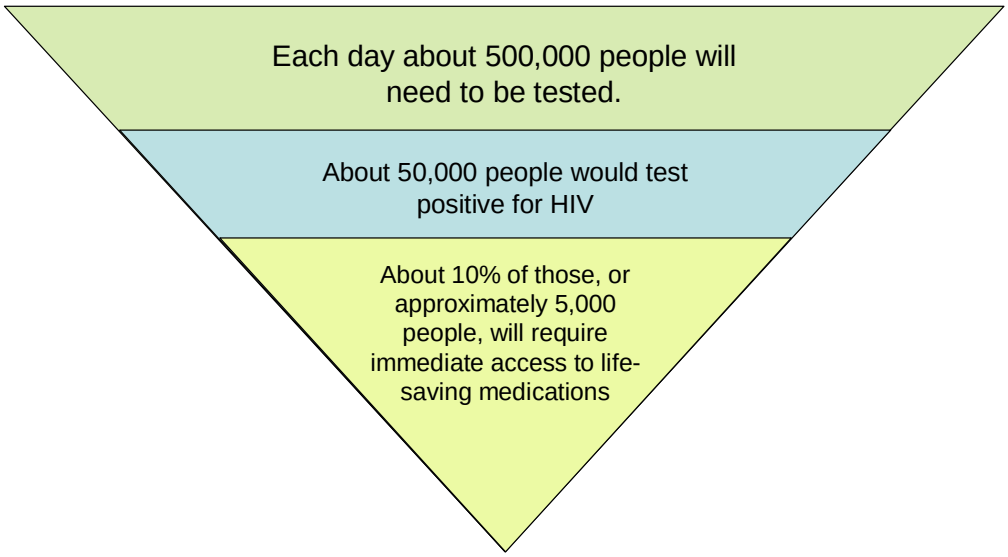
The company's administrative offices, production and research facilities are located in Medford, New York. The company leases approximately 14,000 square feet of industrial space of which approximately 2,700 square feet is used for administrative offices, 9,800 square feet for production and 1,500 square feet for R&D.

The Market for Rapid HIV Test Kits

The Market for HIV Rapid Test Products

Demand for HIV and tuberculosis rapid diagnostic tests in affected developing countries is largely dictated by the availability of donor funds such as those funds administered and distributed pursuant to the United States Presidential Emergency Plan for Aids Relief, the Joint United Nations Programme on HIV/AIDS as well as other governmental and non-governmental programs that fund testing for HIV and tuberculosis.

The World Health Organization and the Joint United Nations Programme on HIV/AIDS announced the "Three by Five" initiative



Source: Chembio Diagnostics and Harbinger Research

According to the Joint United Nations Programme on HIV/AIDS 2004 Report on the Global AIDS Epidemic, knowledge of HIV status is the gateway to AIDS treatment. This report further states that a routine offer of HIV testing by health care providers should be made to all patients in sexually transmitted disease clinics, maternal and child health clinics, and healthcare settings where HIV is prevalent. In 2003 the World Health Organization and the Joint United Nations Programme on HIV/AIDS announced the "Three by Five" initiative, with the goal of treating three million people living with HIV/AIDS by the end of 2005. As the chart above shows, according to the Global Business Coalition on HIV/AIDS, to achieve having 3 million people on treatment by 2005, each day 5,000 people would need to be brought onto treatment and kept on it. In order to achieve this, each day about 500,000 people would need to be tested. This estimate assumes that in countries with a high prevalence of HIV, about 50,000 people would test positive and that 10% of those, or approximately 5,000 people, will require immediate access to life-saving medications.

Rapid HIV tests help to address the problem that a large percentage of individuals tested in public health settings do not return or call back for test results from laboratory tests, which can take at least several days to process. Management believes that this group comprises a significant amount of all new infections. Chembio has successfully manufactured and marketed its HIV rapid test products since 2001 to customers in several countries outside the United States. Subject primarily to satisfactory completion of clinical trials and its manufacturing facility inspection in accordance with FDA requirements, management believes that FDA approval will be achieved by the end of 2005. Both of its HIV tests use a standardized test strip which the company developed by using patented materials licensed non-exclusively to us from third parties as well as its own proprietary know-how and trade secrets.

Product Features that Differentiate Chembio's Rapid HIV Test Kits

Management believes that the format of its rapid tests, which are easy-to-perform, single-use diagnostic tests for rapid, visual detection of antibodies to the HIV virus, on a strip provide the following benefits:

1. **simple** – requiring neither electricity nor expensive equipment for test execution or reading, nor skilled personnel for test interpretation,
2. **rapid** – providing a turn around time less than 15 minutes,
3. **safe** – minimizing the handling of potentially infected specimens,
4. **non-invasive** – requiring only 5 µL (a (a µL = a microliter, 1µL = 10^{-3} mL) of serum or whole blood easily obtained with a finger prick,
5. **stable** – capable of being stored at least 24 months without refrigeration,
6. **highly reproducible**, and is
7. **highly specific and highly sensitive**.

PEPFAR – Helping to Create Demand for HIV/AIDS Diagnostic Test Kits

The Presidential Emergency Plan For AIDS Relief (PEPFAR) is a U.S. government fund established in 2004 to assist primarily African countries in combating AIDS by injecting $15 billion dollars over a 5-year period. Through this plan, the U.S. government will work with international, national and local leaders worldwide to promote integrated prevention, treatment and care programs, with an urgent focus on countries that are among the most afflicted by the disease. Specifically, the U.S. commitment provides the following:

- $9 billion in new resources to 15 of the most afflicted countries in the world,
- $5 billion to ongoing bilateral programs in more than 100 countries,
- An additional $1 billion pledge over the next 5 years to the Global Fund to Fight AIDS, Tuberculosis, and Malaria, and
- A commitment to amplify the worldwide response to HIV/AIDS through international partners.

The 15 countries of PEPFAR's primary focus include: Botswana, Cote d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Vietnam and Zambia. In these focus countries, PEPFAR's goal is to:

- Support treatment for 2 million HIV-infected people,
- Prevent 7 million new HIV infections, and
- Support care for 10 million people infected and affected by HIV/AIDS, including orphans and vulnerable children.

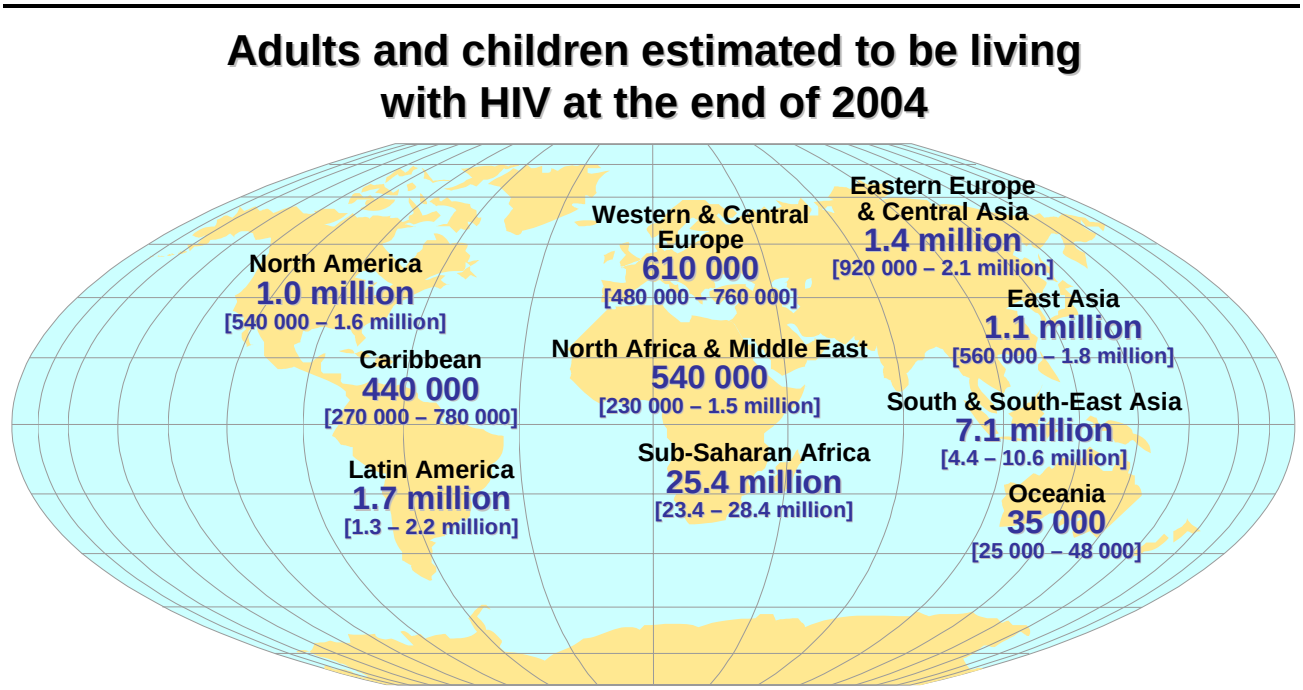
According to a document that was posted on U.S. Department of State web site (http://usinfo.state.gov/gi/Archive/2005/Feb/14-40245.html) on February 11th 2005, testing will be imperative to meeting AIDS treatment goals. In fact, this article notes that a report produced by the Center for Strategic and International Studies (CSIS) – a private, nonpartisan, nonprofit think tank – specifically calls for increased testing and counseling. Moreover, the report notes that a substantial increase in HIV/AIDS testing is essential if the PEPFAR is to meet its goals of providing support and treatment for 2 million people over the next five years. The report also states that the implementation of routine HIV/AIDS testing, or client-initiated voluntary counseling and testing, in which the testing becomes part of routine check-ups and doctor visits, could help meet testing goals. Furthermore, integrating HIV/AIDS testing into services offered by existing clinics that treat other diseases, such as tuberculosis, is another approach that should be considered. Additionally, the authors of this report estimate that that "no more than 10 percent of HIV-infected people in developing countries are aware of their infection." The report also noted the need to increase testing in all regions of the world to help prevent the continued spread of the disease by those unknowingly infected.

Chembio has already initiated several strategies to meaningfully participate in the $15 billion PEPFAR program as well as the UN Global Fund and other treatment and prevention programs. The company's participation requires that it work through U.S. and international public health agencies, non-governmental organizations, national health ministries as well as other private and public organizations that are involved with the procurement, distribution and use of diagnostic testing kits which are needed to meet these programs stated treatment and prevention goals.

The HIV/AIDS – A Pandemic Crisis

AIDS (acquired immune deficiency syndrome) was first reported in the United States in 1981 and has since become a major worldwide epidemic. AIDS is a condition that is caused by HIV (human immunodeficiency virus). By killing or damaging cells of the body's immune system, HIV progressively destroys the body's ability to fight infections. People diagnosed with AIDS may get life-threatening diseases called opportunistic infections, which are caused by microbes such as viruses or bacteria that usually do not make healthy people sick.

The Centers for Disease Control and Prevention (CDC) defines AIDS as HIV-infected people who have fewer than 200 CD4+ T cells per cubic millimeter of blood. In contrast, most healthy adults typically have CD4+ T-cell counts in excess of 1,000 per cubic millimeter of blood. Additionally, the definition includes 26 clinical conditions that affect people with advanced HIV disease. Most of these conditions are opportunistic infections that generally do not affect healthy people. In people with AIDS, these infections are often severe and sometimes fatal because their immune systems are impaired by the virus that the body cannot fight off certain bacteria, viruses, fungi, parasites, and other microbes.



Source: Joint United Nations Program on HIV/AIDS, "AIDS Epidemic Update 2004"

Global Facts and Figures

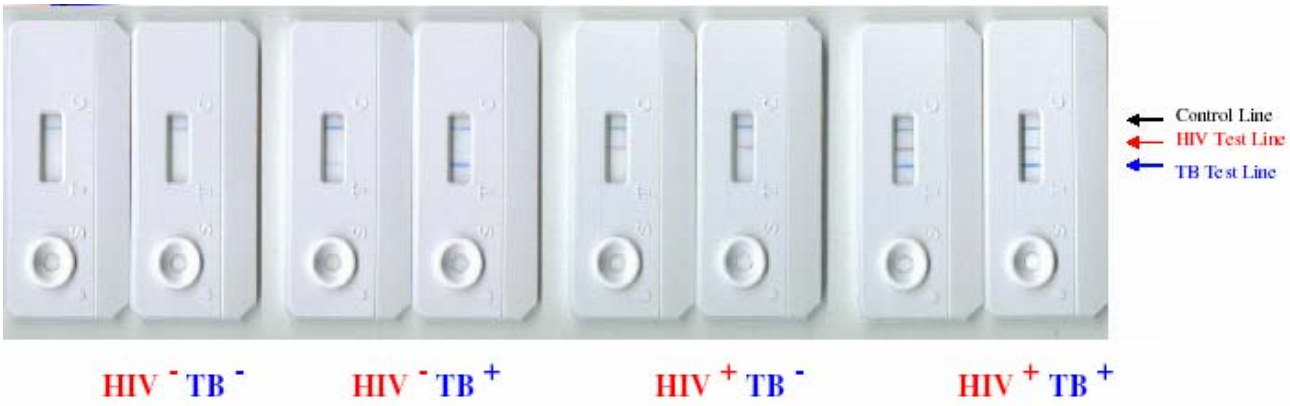
- Nearly 40 million people are now living with HIV/AIDS worldwide, roughly 95% of them in developing countries. Sub-Saharan Africa alone is home to some 25 million with HIV/AIDS, roughly 63% of the world total. AIDS is also impacting other regions. Asia how has over 7 million people with HIV/AIDS, and that number is growing rapidly.
- AIDS now kills many times more Africans yearly than war, with an African dying of AIDS every 14 seconds. Deaths resulting from AIDS in sub-Saharan Africa will soon surpass the 20 million people in Europe who died in the plague of 1347. AIDS is expected to slash overall economic activity in Africa by 25%.
- Globally, about 4.5 million children under the age of 15 have been infected since the start of the epidemic, a large proportion of them girls. In 2003 630,000 children were newly infected with HIV. Globally, a child dies of AIDS almost every minute. That's 1,342 every day.
- Some 12 million African children have lost one or both parents to AIDS, and the number of AIDS orphans worldwide could reach 40 million by the year 2010.

- Globally, 13,150 people become infected with HIV every day. In 2003, 4.8 million people were newly infected. The epidemic continues to devastate sub-Saharan Africa and is also spreading rapidly in the Caribbean, Eastern Europe, and many parts of Asia.
- Continued gender discrimination creates life-threatening dangers for women around the world. Indeed, few diseases are as rooted in gender inequality as HIV/AIDS. In sub-Saharan Africa, close to 60% of all adults with AIDS are women, and 75% of all young people aged 15 to 24 with HIV/AIDS are female. More than 6,000 women were newly infected with HIV everyday in 2003.
- Approximately 30% to 40% of people in the United States infected with HIV are also infected with hepatitis C. HCV is a leading cause of death in patients with HIV.

Source: StopGlobalAIDS.org and WebMD.com

Tuberculosis Rapid Tests

Also according to the Joint United Nations Programme on HIV/AIDS 2004 Report on the Global AIDS Epidemic, in many countries where AIDS has hit hardest, tuberculosis is the leading cause of death in people living with HIV. In HIV positive patients, the reliability of existing diagnostic methods is reduced. The Joint United Nations Programme on HIV/AIDS report states that intensifying tuberculosis case-finding in HIV testing and counseling centers and in other HIV service outlets is essential. However, detection of antibodies to active pulmonary tuberculosis in blood samples has never been achieved to a level of accuracy for this diagnostic method to be used effectively in countries with prevalence of this disease. Chembio's efforts have been focused on establishing clinical data that demonstrates that its test can detect a statistically meaningful number of patients that are not detected from the standard sputum smear method. The company also intends to develop a dual parameter HIV/TB test (shown below) using its colored latex technology once it has established the clinical performance of its TB test on a stand alone basis.



Management believes that Chembio is in a leadership position as it relates to its rapid tuberculosis test even though the product is still under evaluation and not ready for marketing. Management is not aware of any rapid whole blood test either on the market or under development 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, which they believe their test will be capable of doing when it is fully developed and evaluated. Furthermore, management is also not aware of any rapid whole blood test capable of detecting active pulmonary tuberculosis in non-human primates and/or other animals for which Chembio is developing rapid tuberculosis tests.

CHAGAS RAPID TEST

Chembio also offers a rapid test for the detection of antibodies to Chagas Disease, which was developed in collaboration with a consortium of researchers in Latin America. Chagas Disease is found only in Latin America and is named after Carlos Chagas, a Brazilian doctor who first described the disease about 100 years ago. Chagas is transmitted by a parasitic pathogen which may be found in cracks and crevices of poor-quality houses in rural areas. It can also be transmitted through blood transfusion or congenitally from an infected mother to the fetus. The worldwide prevalence of Chagas Disease is estimated to be 16-18 million cases, with an estimated 300,000 new cases diagnosed each year, resulting in 21,000 deaths annually. Furthermore, it is estimated that 25% to 30% of those persons infected will progress to irreversible cardiac, esophageal and colonic pathology, causing considerable morbidity and mortality. However, if detected early, there is an effective therapy that typically involves two drugs – nifurtimox and benznidozol – that are

capable of curing at least 50% of recent infections. Consequently, early detection through testing can have a significant impact on the patient outcome and healthcare costs.

Chembio developed a test for Chagas Disease several years ago. Unfortunately, the market for the product, at that time, was not meaningful because most prevention efforts were focused on using laboratory tests used for blood bank screening. However, today there is greater interest in Chembio's rapid test because of a publication that demonstrated the effectiveness of the rapid test not only for screening blood entering a blood bank, but also for screening individual blood donors as well as the general screening of rural populations. Furthermore, several studies have been completed at multiple sites throughout Central and South America showing Chembio's test offers a sensitivity between 98.5% and 99.6% and a specificity between 94.8% and 99.9%, making this test a good alternative to traditional laboratory testing methods. The Chagas Rapid Test provides an excellent example of one type of market where Chembio is attempting to focus its resources. Management believes that there are significant additional opportunities to develop diagnostic kits for niche markets that address a variety of neglected diseases.

Other Products Under Development

Chembio has a number of other products under development with partners that address the areas of dental bacteria, veterinary tuberculosis, and cerebral spinal fluid leak detection. Each of these diagnostic tests is intended to leverage the company's core competency – which is in the development and manufacture of lateral flow rapid diagnostic tests – and diversifying the company's addressable markets beyond HIV, human tuberculosis and Chagas Disease. Because Chembio does not necessarily have an expertise in assessing the markets in each of these new product undertakings it has chosen to partner with other companies that have specific experience within each of these new product fields.

Dental Bacteria Test

In the dental bacteria test area, Chembio has a contract with Ivoclar-Vivadent, Schaan, Liechtenstein to develop a rapid test that can detect different levels of bacteria found in saliva samples that are associated with tooth decay. The test utilizes intellectual property developed at the University of California Los Angeles Dental School for which Ivoclar-Vivadent is the exclusive licensee. Chembio's has a contract with Ivoclar-Vivadent for a three-phase development program which the company is being compensated a total of $180,000.

Chembio is currently in Phase II (Optimization of Test) of the Project Plan and anticipates moving into Phase 3 (Scale-Up of Production and Validation) by the end of 2005. However, the company has experienced difficulties with the sensitivity and specificity of the lateral flow test system related to one of the monoclonal antibodies. Consequently, Chembio is currently investigating strategies in order to overcome this technical problem and is considering another detection system, which could be applied instead of the lateral flow system. Such a system could be based on antibodies labeled with fluorescence markers. However, a correspondent reader would be required for an analysis of the risk of caries (dental decay). If the development program results in a completed product in accordance with Ivoclar-Vivadent's specifications, the company will become the exclusive manufacturer and Ivoclar-Vivadent will have exclusive marketing and distribution rights. At this time, management is not able to determine how long it will take to develop the product or obtain regulatory approvals in the US, Europe, Japan and other potential markets.

Veterinary Tuberculosis

Chembio has developed a rapid diagnostic test for the detection of antibodies to active pulmonary tuberculosis in non-human primate whole blood samples. Chembio has completed this development with Sequella Corporation (Rockville, MD) and has entered into an agreement with Sequella whereby Chembio will have exclusive worldwide marketing and manufacturing rights for the product. In March 2005, the company submitted to United States Department of Agriculture for regulatory approval of this product in the U.S. Other veterinary applications for this technology are under active consideration.

Cerebral Spinal Fluid (CSF) Leak Rapid Test

Chembio is also working to develop a rapid test to detect Cerebral Spinal Fluid (CSF) Leak. The State University of New York at Stony Brook (SUNY) is developing antibodies against this marker and has applied for a patent for the antibodies and the test. Chembio has an exclusive option to license the technology once the patent is issued.

Industry Overview

The diagnostics industry is a multi-billion dollar international industry that is intensely competitive. Important competitive factors for diagnostic products typically include product quality, price, ease of use, customer service, and reputation. A few large corporations produce a wide variety of diagnostic tests and other medical devices and equipment. A larger number of mid-size companies generally compete only in the diagnostic industry, and a significant number of small companies produce only a few diagnostic products. As a result, the diagnostic test industry is highly fragmented and segmented. Industry competition tends to be 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 regulatory approvals,
- The ability to manufacture products that meet applicable FDA requirements (i.e., good manufacturing practices),
- Access to adequate capital,
- The ability to attract and retain qualified personnel, and
- The availability of patent protection.

The future market for diagnostic tests is expected to be characterized by consolidation, greater cost consciousness, and tighter reimbursement policies. Furthermore, purchasers of diagnostic products are expected to place increased emphasis on lowering costs, reducing inventory levels, automation, service, and volume discounts. The increased complexity of the market is expected to force many competitors to enter into joint ventures or license certain products or technologies.

Significant competitors in the HIV rapid diagnostic test market include, ***OraSure Technologies***, ***Inverness Medical*** (through its acquisition of the rapid HIV test product line of Abbott Diagnostics) , and ***Trinity Biotech*** all of which sell lateral flow rapid tests. The Inverness product line, which was purchased from Abbott Laboratories, is made in Japan and will likely not be submitted for U.S. FDA approval. There are also a number of other HIV tests that are significantly more complex to administer, require substantial laboratory infrastructure, and require a much longer time to determine the result.

Competing SIMPLE and/or RAPID HIV TEST KITS

Rapid HIV tests are simple to use and require little or no specialized equipment. They make it possible to provide test results at the time the test is done. There are currently three rapid HIV tests are approved by the U.S. Food and Drug Administration (FDA) and commercially available for use in the United States which include: OraQuick Rapid HIV-1/2 Antibody Test, Reveal G2 Rapid HIV-1 Antibody Test, and Uni-Gold Recombigen HIV Test.

Primary Competitors

OraSure Technologies Inc. (NASDAQ:OSUR) – OraSure Technologies develops, manufactures and markets oral fluid specimen collection devices using proprietary oral fluid technologies, diagnostic products including immunoassays and other in vitro diagnostic tests, and other medical devices. These products are sold in the United States as well as internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities. OraSure Technologies' rapid HIV test is the OraQuick® ADVANCE™ Rapid HIV-1/2 Antibody Test, which was the first FDA approved, CLIA waived, rapid point-of-care test that can detect antibodies to both HIV-1 and HIV-2 with greater than 99% accuracy in as little as 20 minutes, using an oral fluid, finger-stick or venipuncture whole blood, or plasma samples.

Trinity Biotech plc (NASDAQ:TRIB) – Trinity Biotech specializes in the development, manufacture and marketing of diagnostic products for the point-of-care and clinical laboratory segments of the diagnostic market. The company's broad line of test kits is used to detect infectious diseases, sexually transmitted diseases, blood coagulation disorders, and autoimmune diseases.

Trinity Biotech has developed a range of membrane and latex based rapid assays to cater for near patient and over-the-counter markets. The Uni-Gold™ range employs gold particle technology for the detection of a number of parameters, including HIV. Tests for HIV are also available in the SeroCard™ and Capillus™ format. SeroCard™ offers a self-encased flow-through device with colorimetric read, whereas Capillus™ utilizes latex agglutination enhanced by capillary slide technology.

Inverness Medical Innovations, Inc. (AMEX:IMI) – Inverness Medical engages in the development, manufacture, and marketing of vitro diagnostic products for the over-the-counter pregnancy and fertility/ovulation test market, as well as the professional rapid diagnostic test market worldwide. As a result of its June 2005 acquisition of the *Determine* line of products (from Abbott Laboratories), Inverness has acquired the HIV rapid test with the largest market share in the developing world.

Management

Lawrence A. Siebert – President and Director

Mr. Siebert has been Chairman of Chembio Diagnostic Systems Inc. for approximately 12 years and its President since May 2002. Mr. Siebert's background is in private equity and venture capital investing. From 1982 to 1991, Mr. Siebert was associated with Stanwich Partners, Inc, which during that period invested in middle market manufacturing and distribution companies. From 1992 to 1999, Mr. Siebert was an investment consultant and business broker with Siebert Capital Corp. and Siebert Associates LLC, and was a principal investor in a privately held test and measurement company which was sold in 2002. Mr. Siebert received a JD from Case Western Reserve University School of Law in 1981 and a BA with Distinction in Economics from the University of Connecticut in 1978.

Richard J. Larkin , Chief Financial Officer

Mr. Larkin oversees our financial activities and information systems. Mr. Larkin has been the Chief Financial Officer of Chembio Diagnostic Systems Inc. since September 2003. Prior to joining Chembio Diagnostic Systems Inc., Mr. Larkin served as CFO at Visual Technology Group from May 2000 to September 2003, and also led their consultancy program that provided hands-on expertise in all aspects of financial service, including the initial assessment of client financial reporting requirements within an Enterprise Resource Planning (Manufacturing) environment through training and implementation. Prior to joining VTG, he served as CFO at Protex International Corporation from May 1987 to January 2000. Mr. Larkin holds a BBA in Accounting from Dowling College and is a member of the American Institute of Certified Public Accountants.

Avi Pelossof – VP of Sales, Marketing and Business Development

Mr. Pelossof joined Chembio Diagnostic Systems Inc. in 1996 and has been responsible for developing Chembio Diagnostic System's marketing strategy and collaborations. From 1991 to 1996, he was Managing Director and co-founder of The IMS Group, Inc., which provided strategic marketing advisory services to companies involved in Latin American markets including Chembio Diagnostics, Inc. Prior to IMS he was a Citibank Vice President in the International Corporate Finance Group focused on Latin America. Mr. Pelossof received his MBA in finance and international business from New York University in 1986 and a BA with Distinction in economics from the University of Michigan in 1984.

Javan Esfandiari – VP of Director of Research & Development

In 1993 Mr. Esfandiari co-founded, and became a co-owner of Sinovus Biotech AB where he served as Director of Research and Development concerning lateral flow technology until Chembio Diagnostic Systems Inc. acquired Sinovus Biotech AB in 2000. From 1993 to 1997, Mr. Esfandiari was Director of Research and Development with On-Site Biotech/National Veterinary Institute, Uppsala, Sweden, which was working in collaboration with Sinovus Biotech AB on development of veterinary lateral flow technology. Mr. Esfandiari received his B.Sc. in Clinical Chemistry and his M. Sc. in Molecular Biology from Lund University, Sweden.

Rick Bruce, VP and Director of Operations

Mr. Bruce has been Director of Operations since April 2000. In this capacity, he directs our production, maintenance, inventory, shipping and receiving, and warehouse operations. Prior to joining Chembio Diagnostic Systems Inc. he held director level positions at American Home Products from 1984 to 1993. From 1998 to 2000, he held a management position at V.I. Technologies. From 1993 to 1998, he held various management positions at Biomerieux. Mr. Bruce has over 25 years of operations management experience with Fortune 500 companies in the field of in-vitro diagnostics and blood fractionation. Mr. Bruce received his BS in Management from National Louis University in 1997.

Tom Ippolito – VP of Regulatory Affairs, QA and QC
Mr. Ippolito joined Chembio in June 2005. His background includes over twenty years of in-vitro diagnostics for infectious diseases, protein therapeutics, vaccines experience in R&D, Process Development, Regulatory Affairs and Quality Management. During that time he has held vice-president level positions at Biospecific Technologies, Corp., director level positions in Quality Assurance, Quality Control, Process Development and Regulatory Affairs at United Biomedical, Inc. He is a guest instructor (since 2003) for "drug development process" and "FDA regulations" for the BioScience Certificate program at the State University of Stony Brook.

Les Stutzman – VP of Marketing
Mr. Stutzman recently joined Chembio to lead the Tuberculosis (TB) diagnostic business development program. Mr. Stutzman was previously with TREK Diagnostic Systems, Cleveland, Ohio, where he served as the Global Director of Marketing since 2002. In that capacity he managed the company's $30 million global microbiology business, directed 3 new product introductions, established a new market strategy and product positioning launch plans, and directed early stage development market requirement specifications. Prior to joining TREK he spent twenty years with Biomerieux (formerly Organon Teknika Corp.) in Durham, North Carolina. From 1998 to 2002, Mr. Stutzman served as the Global Director for Microbiology & Business Development. In that position, Mr. Stutzman managed the global clinical microbiology market valued at $125 million with over 6,000 units placed, analyzed and evaluated new business opportunities, prepared and priced proposals, negotiated multinational contracts, presented to scientific and business personnel, organized clinical trials, and coordinated global interactions. A licensed Medical Technologist, Mr. Stutzman has a Master of Business Administration from Duke University and a Master of Science in Clinical Microbiology from Wagner College.

Board of Directors

Alan Carus – Director
Mr. Carus was elected to Chembio's Board of Directors on April 15, 2005. Mr. Carus is a co-founder of LARC Strategic Concepts LLC, a consulting firm dedicated to guiding emerging companies to next stage development. Prior to co-founding LARC Strategic Concepts LLC, Mr. Carus was Senior Vice President of Maritime Overseas Corporation ("MOC") and a senior executive of Overseas Shipholding Group, Inc. ("OSG") from 1981 to 1998, when he retired. MOC was managing agent for OSG, one of the world's largest ship-owners. Mr. Carus was a member of OSG's senior management committee and had senior responsibility in areas relating to administration, accounting, tax, finance, budgets, long-range projections, and human resources. He was involved in numerous acquisitions, debt and equity offerings, complex transaction structuring, and was active in the management of OSG's major investments in the cruise industry and other development stage companies. From 1964 to 1981, Mr. Carus was with Ernst & Young (including predecessors), the last seven years as a partner. Mr. Carus has a B.B.A. from the Baruch School of Business of the City College of New York.

Gary Meller MD, MBA – Director
Dr. Meller was elected to Chembio's Board of Directors on March 15, 2005. Dr. Meller has been the president of CommSense Inc., a healthcare business development company, since 2001. CommSense Inc. works with clients in Europe, Asia, North America, and the Middle East on medical information technology, medical records, pharmaceutical product development and financing, health services operations and strategy, and new product and new market development. From 1999 until 2001 Dr. Meller was the executive vice president, North America, of NextEd Ltd., a leading internet educational services company in the Asia Pacific region. Dr. Meller also is a member of the Advisory Board of Crestview Capital Master LLC, which was the lead investor in our series B preferred stock private placement. Dr. Meller a graduate of the University of New Mexico School of Medicine and has an MBA from the Harvard Business School.

Gerald A. Eppner – Director
Mr. Eppner was elected to Chembio's Board of Directors on March 15, 2005. Mr. Eppner is a partner at Cadwalader, Wickersham & Taft, a law firm based in New York City, New York. Mr. Eppner has experience in domestic and international corporate and securities law matters. Mr. Eppner has been in private practice in New York City since 1966. For more than five years prior to 1966, Mr. Eppner was an employee of certain agencies and departments of the United States government.

Recent Financial Results

For the second quarter ending June 30, 2005, Chembio reported that total revenue – which includes net sales of products as well as license revenue, research grants and development income – increased to $814,307, compared with $746,954 in the same period a year earlier. More specifically, net sales of HIV and Chagas rapid tests increased by $220,398 or 77% for the quarter, and $150,330 or 32% for the six months compared to 2004. Management attributes its sales increase to the company's strategic focus on these product lines as well as to increased sales to Africa where the company is beginning to see results from its marketing efforts in the region. Chembio also reported that it has:

(1) approximately $500,000 of HIV product orders in hand for delivery in the third quarter, which should result in further revenue gains as compared to the second quarter of 2005 and the third quarter of 2004;
(2) made substantial progress toward FDA approval of its HIV rapid tests based upon communications it has had with the agency during this latest quarter, and;
(3) developed prototypes of its patent pending lateral flow rapid test platform that it believes will provide it with proprietary intellectual property to develop a pipeline of new products.

Gross profit for the second quarter was $269,309, resulting in a gross margin of 29.7%, declining 2.6% year-over-year and 6.8% sequentially. However, for the balance of 2005 and into 2006, management anticipates that the company will continue to experience significant growth in demand for its HIV and Chagas Disease rapid test products and that its backlog and additional orders, if realized, should grow revenues and thereby permit the company to generate a substantially better gross margin.

Research and development expenses for the second quarter were $426,782, or 47.1% of sales. As a percent of sales, R&D expenses increased 1.4% sequentially and 9.4% year-over-year. Included in R&D were expenses for Clinical & Regulatory Affairs which totaled $170,376 during the quarter, a decrease of $46,194 compared to the same period a year earlier. Selling, general and administrative expense for the quarter was $729,435, or 80.5% of sales. As a percent of sales, SG&A expenses increased 4.6% sequentially and 2.8% year-over-year. This increase was primarily attributable to the company intensifying its sales and marketing efforts in Africa.

Overall, Chembio generated a net loss of $875,142 and $1,495,127 for the three and six month periods as compared with a net loss of $717,345 and $1,147,189 for the comparable periods in 2004. The net loss attributable to common stockholders for the three and six month periods was $1,087,203 (or $0.15/share) and $4,588,067 ($0.64/share) compared with a net loss of $1,035,421 ($0.18/share) and $1,465,265 ($0.27/share) for the comparable periods in 2004. The table below shows Chembio's historical income statement results for the period FY-03 through Q2-05.

CHEMBIO DIAGNOSTICS, INC.

Income Statement

(in millions of $, except per claim data)

- Fiscal Year Ending December 31th -

	2003	Q1-04	Q2-04	Q3-04	Q4-04	2004	Q1-05	Q2-05
REVENUES:								
Net sales	2,542,621	$ 493,970	746,954	440,371	1,561,818	2,749,143	346,125	814,307
License revenue	-	-	-	-	-	-	250,000	-
Research grants and development income	275,730	91,342	248,121	125,875	91,451	556,789	135,760	91,382
TOTAL REVENUES	2,818,351	585,312	995,075	566,246	1,159,299	3,305,932	731,885	905,689
Cost of sales	2,153,454	465,402	673,616	674,402	672,173	2,485,593	464,550	636,380
GROSS PROFIT	664,897	119,910	321,459	(108,156)	487,126	820,339	267,335	269,309
Gross Margin	23.6%	20.5%	32.3%	-19.1%	42.0%	24.8%	36.5%	29.7%
OPERATING COSTS:								
Research and development expenses	313,891	138,329	377,473	396,836	520,765	1,433,403	334,750	426,782
Selling, general and administrative expenses	1,202,185	355,723	773,624	543,097	817,854	2,490,298	556,061	729,435
TOTAL OPERATING COSTS	1,516,076	494,052	1,151,097	939,933	1,338,619	3,923,701	890,811	1,156,217
(LOSS) FROM OPERATIONS	(851,179)	(374,142)	(829,638)	(1,048,089)	(851,493)	(3,103,362)	(623,476)	(886,908)
OTHER INCOME (EXPENSES):								
Forgiveness of debt	-	-	209,372	-	-	209,372	-	-
Loss on retirement of fixed assets	-	-	-	-	(22,469)	(22,469)	-	-
Interest income	7	97	2,601	3,479	1,949	8,126	9,468	15,613
Interest (expense)	(208,532)	(55,843)	(99,680)	(13,819)	(21,216)	(190,558)	(5,978)	(4,247)
Other	-	-	-	-	-	-	-	400
(LOSS) BEFORE INCOME TAXES	(1,059,704)	(429,888)	(717,345)	(1,058,429)	(893,229)	(3,098,891)	(619,986)	(875,142)
Income taxes	-	-	-	-	-	-	-	-
NET LOSS	(1,059,704)	(429,888)	(717,345)	(1,058,429)	(893,229)	(3,098,891)	(619,986)	(875,142)
Dividends payable to preferred stockholders	-	-	56,810	91,694	91,497	240,001	182,178	212,061
Dividend accreted to preferred stock for associated costs and a beneficial conversion feature	-	-	261,266	-	1,441,806	1,703,072	2,698,701	-
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	(1,059,704)	(429,888)	(1,035,421)	(1,150,123)	(2,426,532)	(5,041,964)	(3,500,865)	(1,087,203)
Basic and diluted (loss) per share	($0.22)	($0.09)	($0.18)	($0.18)	($0.40)	($0.85)	($0.50)	($0.15)
Weighted number of shares outstanding, basic and diluted	4,919,191	4,957,340	5,881,972	6,417,908	6,609,856	5,966,769	6,945,849	7,413,129
Balance Sheet Data:								
Total Assets	1,086,745	N/A	2,746,276	1,778,844	1,426,449	1,426,449	5,135,090	4,212,648
Average Total Assets	N/A	N/A	N/A	2,262,560	1,602,647	1,256,597	3,280,770	4,673,869
Common Equity	(2,457,441)	N/A	(1,469,190)	(2,619,313)	(2,950,994)	(2,950,994)	(2,174,629)	2,783,617
Average Common Equity	N/A	N/A	N/A	(2,044,252)	(2,785,154)	(2,704,218)	(2,562,812)	304,494
Du Pont Analysis:								
Net Margin = Net Income / Sales	-37.6%	-73.4%	-72.1%	-186.9%	-77.0%	-93.7%	-84.7%	-96.6%
Asset Turnover = Sales / Average Total Assets	N/A	N/A	N/A	0.25	0.72	2.63	0.22	0.19
Financial Leverage = Avg. Total Assets / Avg. Common Eqty.	N/A	N/A	N/A	(1.11)	(0.58)	(0.46)	(1.28)	15.35
Return on Assets = Net Income / Average Total Assets	N/A	N/A	N/A	-46.8%	-55.7%	-247%	-18.9%	-18.7%
Return on Equity = Net Income / Average Common Equity	N/A	N/A	N/A	N/A	N/A	N/A	N/A	-287.4%

Conclusion

Chembio has successfully manufactured and marketed its HIV rapid test products since 2001 to customers in several countries outside the United States. Furthermore, management anticipates receiving FDA approval to market its HIV rapid test kits in the U.S. by the end of 2005, which management believes will enhance the company's international efforts as well as facilitating its U.S. marketing strategy. Furthermore, Chembio continues to focus its international marketing efforts on participating in international donor-funded programs, particularly the United States Presidential Emergency Plan for AIDS Relief, as well as in programs for Chagas disease.

The company has recently experienced a significant increase in its revenues that management attributes to greater demand for its HIV test kits in Africa, where the company is beginning to see results from its marketing efforts in this region. Perhaps most notably, for the balance of 2005 and into 2006, management anticipates that the company will continue to experience significant demand for its HIV and Chagas Disease rapid test products, which should permit the company to generate substantially improved gross margins. The chart below shows some of the metrics that investors may use to assist them in determining an appropriate valuation. Management must now demonstrate their ability to improve gross margins and leverage its operating expenses so as to produce positive and growing earnings over a sustained period of time.

Industry Comparable Financial Data

(in $ millions, except per share data)

							----- Trailing Twelve Months (TTM) -----					
Name	Ticker	Price (10/7/05)	Market Cap	Sales TTM	P/S	Enterprise Value	EBITDA	EV/EBITDA	ROE	ROA	2006 EPS Estimate	Forward P/E
OraSure Technologies Inc.	OSUR	$9.16	$414.8	$61.6	6.7x	$346.6	$5.2	66.5x	3.2%	1.9%	$0.22	41.6x
Trinity Biotech plc	TRIB	$6.99	$100.9	$87.4	1.2x	$106.3	$11.0	9.7x	2.9%	2.2%	$0.50	14.0x
Chembio Diagnostics Inc.	**CEMI.OB**	**$0.60**	**$4.9**	**$3.6**	**1.3x**	**$7.9**	**-$3.3**	**-2.4x**	**-61.3%**	**-180.8%**	**N/A**	**N/A**

Data Source: Capital IQ

Although, the company's focus is on the rapid HIV test market, this is only one part of its overall growth strategy. The company also intends to continue pursuing growth opportunities by developing additional diagnostic test kits that provide a cost effective detection solution to niche markets that address a variety of neglected diseases. As we have seen, some of these potential opportunities include test kits for HIV/TB, dental bacteria, veterinary tuberculosis, and cerebral spinal fluid leak detection. At about $0.60 per share, investors may simply choose to view an investment in Chembio as an option that has no expiration date. If management is successful in continuing to grow demand for its rapid HIV test kits, is able to further build out its portfolio of other diagnostic test kits that address niche markets and can generate positive earnings, share price appreciation will likely follow.

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Associate, Business Development

Analyst Highlight

Michael A. Bain, CFA, Director of Research and Senior Research Analyst
Healthcare and Special Situations
Mr. Bain has experience conducting both sellside and buyside equity research, primarily in the healthcare, industrial equipment and transportation sectors. Most recently, Mr. Bain worked as an equity analyst for Institutional Research Consultants, where he provided customized research services to institutional investors. Prior to that, Mr. Bain worked on the sellside for Raymond James, where his research focused on companies that provide transportation and logistics services. Mr. Bain entered the securities industry in 1996, when he joined NatWest Securities. At that time, he conducted research primarily on manufacturers of cardiovascular medical devices and industrial equipment. That office was subsequently acquired by HSBC Securities in 1998, and his coverage universe was broadened to include manufacturers of disposable medical supplies. Prior to entering the securities business Mr. Bain served as a Commercial Property Analyst for USAA and as an independent consultant.

Mr. Bain holds a Bachelor of Arts degree with a major in economics and a Master of Business Administration degree with a concentration in finance both from the University of Florida. Additionally, he is a CFA Charterholder and a member of the CFA Institute.

Equity Research Team

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David Parr, CFA *Special Situations*	Andrew S. Hua, CFA *Technology – Asian Focus*
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