Biomagnetics Diagnostics Corporation

Sizing the Market and Assessing New Diagnostic Technologies & Opportunities

- Biomagnetics Diagnostics Corp. (BMGP) is a California-based developer of advanced next generation medical diagnostic systems and technologies.

- The Company’s HTS-MTP diagnostic platform is unique in the industry for its use of advanced magnetics to detect actual pathogens such as a virus, bacteria or fungi, rather than just the antibodies. It can test any bodily fluid and provides qualitative and quantitative results in one diagnostic tests, saving valuable time and money.

- The Company is in advanced discussions with one of the premier U.S. government research institutions to acquire the rights for an advanced integrated optical biosensor system (IOBS) that utilizes lasers to quickly detect pathogens in human and animal blood samples.

- While the new IOBS technology will be able to diagnose a number of diseases, the Company plans to target the very large global malaria testing market in which some 3.2 billion people are at risk. Currently, there are very few reliable, field applicable diagnostic tools available. It will also target the bovine TB market, with about 1.3 billion cattle worldwide.

- The global health community desperately needs low-cost, easy-to-use, portable diagnostic tools to test for and prevent the spread of infectious diseases. Each year, between 14 million and 17 million people worldwide die from infectious diseases, most in developing countries.

- While it is very difficult to place a target valuation on a pre-revenue company, we believe the uniqueness of Biomagnetics Diagnostics’ technology and the significant market demand likely to develop upon product availability places the total potential valuation of this company in excess of $40 million, possibly higher if a major diagnostic testing company became interested in acquiring this revolutionary technology platform.

- Thus, we place the total potential market capitalization of Biomagnetics Diagnostics somewhere between $40 million and $60 million.

- This implies a target price for these shares of approximately $0.75 to $1.10 at the end of 2009 when the Company’s integrated optical biosensor system for malaria and bovine tuberculosis testing is expected to become available in the marketplace.

Please see important disclosures, including analyst certification

October 6, 2009
Biomagnetics Diagnostics Corp. ("Biomagnetics Diagnostics" or the "Company") (OTC: BMGP) is a California-based developer of medical diagnostic systems and technologies. The Company has two main technology platforms, namely, the High Throughput Screening - Magnetic Testing Platform (HTS-MTP) and an advanced Integrated Optical Biosensor System (IOBS). Biomagnetics Diagnostics’ HTS-MTP system uses advanced magnetics to detect pathogens in any body fluid. While it is still under development, the HTS-MTP system is unique in that it tests directly for the actual pathogen, such as a virus, bacteria or fungi, rather than just for the antibody produced by the human body in response to the pathogen. Also unique to the Company’s HTS-MTP system is its ability to provide both qualitative test results indicating the presence of the actual pathogen as well as quantitative information relative to viral load which then is used by healthcare professionals in order to provide the proper patient care and treatment. Given its ability to detect multiple pathogens in a single fluid sample and provide both qualitative and quantitative results, the Company’s HTS-MTP offering has the potential to significantly lower the cost of disease testing and provide test results much more quickly to medical professionals who can then immediately begin to administer the proper patient care.

The Company is also in advanced discussions with one of the premier U.S. government research institutions to acquire the rights for an advanced integrated optical biosensor technology that utilizes lasers to quickly detect pathogens in blood samples. With this technology, untrained personnel can quickly and accurately test human or animal subjects for a variety of diseases including malaria, tuberculosis, AIDS, cholera, yellow fever, H. pylori and many other viral and bacterial pathogens. This technology is very flexible in that the base unit is capable of detecting virtually any pathogen, an attribute that should enable high-scalability of this assay product across a wide range of disease testing markets. To detect for different diseases, for example, a technician need simply install a separate cartridge based on the particular type of pathogen test to be performed. In many cases, multiple pathogen tests will be able to be performed simultaneously.

Each year, between 14 million and 17 million people worldwide die from infectious diseases. Most of these deaths occur in developing countries where about one third of the population, or more than 2.0 billion people, live in poverty conditions with little or no access to health care.

While infectious diseases cause almost half of all deaths in the developing world, they have an even greater impact on productivity, economic growth and quality of life. To lessen the devastating impact of these diseases, the global health community needs low-cost, easy-to-use, portable tools to diagnose and prevent the spread of infectious diseases. By addressing infections before they spread, vaccines represent the most cost effective way of managing these diseases but, where vaccines are not available, rapid point-of-contact diagnostics are needed to help medical professionals accurately prescribe effective treatments. Moreover, when accurate diagnoses are gathered from the field, public health officials can better analyze the data and eventually better manage potential epidemics and their effects on the population.

According to the World Health Organization, some 3.2 billion people, or about half the world’s population is at risk of malaria transmission in
107 countries and territories worldwide. While there are about 350 million and 500 million new cases of malaria each year, there are very few reliable, field applicable diagnostic tools available. In the case of malaria, early detection substantially improves treatability and survivability. Tuberculosis is the second leading cause of death from infectious disease worldwide. Bovine tuberculosis is also a growing problem throughout the world with an estimated 1.3 billion cattle at risk. In the United States, the cattle industry is valued at over $60 billion annually, and the use of existing diagnostic tests currently adds another $5 to $15 on average per head to the cattle industry's costs.

Field deployable integrated optical biosensor systems, such as that which the Company is planning to introduce soon, have the potential to significantly speed-up the diagnostic testing process and meaningfully lower costs and improve lives.

Biomagnetics Diagnostics recently received a commitment of up to $1.0 million in financing from a group of investors and an anonymous philanthropic source in order to bring the integrated optical biosensor system to market, with an initial emphasis on malaria and bovine tuberculosis detection. Remaining funds will be used to develop the chemistry needed to detect other pathogens and diseases.

At the current share price of approximately $0.15, the total market capitalization of Biomagnetics Diagnostics is approximately $6.6 million, if the share count at the end of the last quarter is used in the calculation. The Company’s recent successful fund-raising efforts increase the share count to approximately 54 million shares, meaning the actual market capitalization is approximately $8.1 million.

While it is very difficult to place a target valuation on a pre-revenue company such as Biomagnetics Diagnostics, we believe the uniqueness of the Company’s technology and the significant market demand that is likely to develop upon product availability places the total potential valuation of this company in excess of $40 million, and possibly higher if a major diagnostic testing company were to become interested in acquiring this revolutionary technology platform. Thus, we would place the total potential market capitalization of Biomagnetics Diagnostics somewhere between $40 million and $60 million. This implies a price per share of approximately $0.75 to $1.10 at the end of 2009 when the integrated optical biosensor system for malaria and bovine tuberculosis testing is expected to become available in the marketplace.
INTRODUCTION TO BIOMAGNETICS DIAGNOSTICS CORPORATION

Biomagnetics Diagnostics Corp. is located in Orangeville, California. The Company develops medical diagnostic systems and technologies with a primary focus on detecting HIV, hepatitis, tuberculosis, H-pylori and malaria in addition to many other viruses, bacteria and toxins that cause diseases and other adverse medical conditions. The Company’s approach to diagnostics is unique in that its assay systems perform real-time testing to detect the presence of an actual pathogen itself, rather than just the antibodies that are produced by the body's immune system. In fact, the human body can often take up to several weeks to produce antibodies once it has been exposed to a particular pathogen. Thus, by detecting the pathogen, rather than the antibody, Biomagnetics Diagnostics’ real-time testing approach allows for much earlier detection and consequent treatment, while also delivering the test at a fraction of the typical current cost.

The HTS-MTP Platform

The first product designed by Biomagnetics Diagnostics is the Company’s High Throughput Screening - Magnetic Testing Platform or HTS-MTP. This product is designed to provide both quantitative and qualitative results in a single diagnostic test. Regarding the qualitative results, this testing system uses chemical detection to determine the presence of a particular pathogen. Relative to the quantitative aspects of the test, it is able to determine the number of specific pathogens contained within the test substance. Thus, this diagnostic platform will not only tell the medical professional that a patient has a certain condition but it will also determine the amount of pathogen contained within the patient’s body. For example, the HTS–MTP testing platform can use a single sample of body fluid to both tell the medical professional that a patient has hepatitis as well as reveal the specific viral load contained within the patient’s bloodstream. This single test approach promises to significantly lower the costs of testing and to meaningfully speed-up the amount of time it takes to produce effective test results.

Importantly, the Company’s HTS-MTP system is also unique in that it can use any type of bodily fluid as the testing medium including saliva, urine, teardrops, spinal fluid, semen and hormonal fluid, among others. No other diagnostic platform currently available on the market today allows for this single diagnostic approach.
Regarding its proprietary technology, while the HTS-MTP platform utilizes technology that is rather simple in concept, it is considered revolutionary in scope. Specifically, Biomagnetics Diagnostics’ testing product allows for the detection of pathogens by measuring the magnetic field of microparticles bonded to the pathogen via the Company’s proprietary technology. (While the full methodology by which this is accomplished is beyond the scope of this report, it is more fully explained on the Company’s website.) Specifically, as part of the Company’s proprietary technology system, primary antibodies are coated on the base of the system’s testing receptacle during the testing procedure. Additionally, secondary antibodies are coated on a magnetic particle. This arrangement enables the magnetic detection technology developed by Biomagnetics Diagnostics to measure the magnetic field of the microparticles bonded to the pathogen. The actual diagnostic process is then completed in a fraction of the time currently required by existing immunoassay tests, with what the Company claims to be near 100% accuracy. Competing tests available on the market today, which detect only the antibodies that are often produced by the body weeks after exposure to the pathogen, typically produce results in a much longer time frame.

Biomagnetics Diagnostics is currently still in the developmental stage with its HTS-MTP platform and the Company plans to introduce this technology into the testing environment during 2010. The initial markets in Mexico, Thailand and China have been identified and the management team plans to use its extensive experience of the past 20 years in dealing with key government officials in these countries to help with the successful launch of its product offering. Following initial introduction in these countries, the Company plans to introduce its diagnostic platform in the United States after conducting FDA trials.

The management team believes the primary market for its platform is public and private laboratories, in addition to blood banks. The market for blood bank testing is of particular interest to the Company due to the platform’s ability to test for up to eight viruses in a single diagnostic test. Typically, blood banks must perform separate tests in order to detect each type of pathogen. Considering U.S. blood banks screened more than 14 million units of blood each year for seven types of viruses, for a total of more than 98 million tests per year, the ability to test for all virus types in a single test would yield considerable cost savings.

The intellectual property for the HTS-MTP platform is protected by three patents that have been granted to Biomagnetics Diagnostics or have been applied for by the Company over the past few years.
The Market for the Integrated Optical Biosensor System (IOBS)

In early September 2009, Biomagnetics Diagnostics announced its entry into the Integrated Optical Biosensor System (IOBS) market. IOBS are a relatively new classification of pathogen detection equipment which utilize advanced fiber-optic-based technology to detect a wide variety of human and animal pathogens. These devices are specifically designed to be field deployable and, necessarily, “ultra-portable,” allowing for rapid detection of various viral, bacterial and fungal pathogens by relatively untrained personnel outside of a laboratory setting. The management team has indicated that the first two areas of testing that will be targeted are the field detection of malaria and bovine tuberculosis.

Biomagnetics Diagnostics plans to bring this technology to market over the next few months via a licensing and research partnership with one of the U.S. government's premier national security research institutions. This national security research institution has spent considerable time and expense in developing this technology, having already completed the vast majority of development over two years ago. While the government laboratory has not revealed its actual costs relating to the development of this technology, the Company’s management team believes that at least $5.0 million to $15 million was spent on development.

Licensing this unique technology from the government laboratory will enable Biomagnetics Diagnostics to quickly enter the growing market for advanced biosensors that are capable of detecting and characterizing a broad range of infectious agents, including viruses, bacteria and fungi, in a given sample.

The Company also recently announced that its initial plans are to target the malaria and bovine tuberculosis testing markets with this technology. According to the World Health Organization, some 3.2 billion people, or about half the world's population is at risk of malaria transmission in 107 countries and territories worldwide. While there are about 350 million and 500 million new cases of malaria each year, there are very few reliable and field applicable diagnostic tools available. In the case of malaria, early detection substantially improves treatability and survivability. Tuberculosis is the second leading cause of death from infectious disease worldwide. Bovine tuberculosis is a growing problem throughout the world with an estimated 1.3 billion cattle at risk. In the United States, the cattle industry is valued at over
$60 billion annually and the use of existing diagnostic tests currently adds $5.0 to $15 on average per head to the cattle industry's costs. Field deployable integrated optical biosensor systems, such as those Biomagnetics Diagnostics is planning to introduce soon, have the promise of significantly speeding-up the diagnostic testing process while lower costs meaningfully and improving lives.

We are expecting the Company to sign its agreement with the government laboratory over the coming weeks as it appears advanced discussions are well underway. We believe the Company’s relationship with the government laboratory will go well beyond simple licensing as, in our opinion, it is likely that the Company will become a research partner with the government laboratory.

In late September, Biomagnetics Diagnostics announced it entered into an agreement with Bright Dairy of China, the third-largest dairy products producer and marketer in the country. Under the terms of the agreement, Bright Dairy will become the exclusive distributor in China for the Company’s portable diagnostic system and assay for bovine tuberculosis. The Chinese government and the Chinese dairy industry have implemented wide scale programs to improve the quality of dairy products, with testing for bovine tuberculosis having received significant attention. Bright Dairy in particular is stepping-up efforts to improve its raw milk production quality in the raising and breeding of its dairy herds.

We believe this relationship with Bright Dairy could develop into a significant revenue stream for the Company considering Bright Dairy and its parent company own 21 large-scale dairy farms and lease hundreds of thousands of acres of grazing lands for its other dairy cattle, in addition to purchasing raw milk from approximately 500 large-scale dairy farming cooperatives.

While we believe the market for bovine tuberculosis diagnostics presents an exciting opportunity for the Company, we believe it pales in comparison to the potential market for malaria testing. Although the process of testing for malaria seems simple to many, the actual efficacy of the malaria diagnosis is subject to many factors.

There are four main forms of the malaria parasite species and there are different stages in the life cycle of each different species. There are also many complexities among the interrelation between the levels of transmission, immunity, parasitemia and drug resistance in the sequestration of the parasites in the host’s deeper tissues. Additionally, testing is further complicated by the use of preemptive treatments. All of these issues have an effect on the successful identification and
interpretation of a diagnostic test, making the diagnosis of malaria exceedingly complex, especially in third world environments where only limited advanced laboratory equipment and technical personnel are available.

As described later in this report, the “gold standard” for malaria diagnostics is light microscopy of thick and thin stained blood smears. This involves the relatively effort-and-time-intensive process of collecting a blood smear sample, effectively staining it as part of the test process, followed by identification under a microscope. This process, which has been used for decades, produces very reliable results. There are many drawbacks, however, to this type of testing method. Most importantly perhaps, this testing methodology requires transportation of the host’s blood sample to a laboratory where well trained personnel then conduct the diagnostic tests. Additionally, the overall cost to perform this type of testing is often cost prohibitive for many people living in third world countries where malaria is most prevalent.

Various non-microscopic tests have also been developed to take malaria diagnosis out of the realm of the microscope, in an effort to reduce costs and move testing closer to the site of patient care. One of the biggest progressions has been the development of Rapid Diagnostic Tests (RDTs) which detect species specific circulating parasite antigens. (An antigen is any substance such as a toxin or enzyme that stimulates an immune response in the body, especially the production of antibodies which are infection-fighting protein molecules.) These tests are often called “dipstick tests.” Although dipstick tests may enhance diagnostic speed, microscope inspection remains mandatory in patients with suspected malaria because occasionally these dipstick tests will turn out negative in certain patients who actually have the disease.

With the high monetary costs and delays inherent with microscopic testing, and the less than acceptable result rates produced by RDTs, there is clearly an unmet demand for a new malaria testing diagnostic technology that lowers costs and is rapid, reliable and can be use by untrained personnel at the sight of patient care. We believe integrated optical biometric sensing technology, such as that Biomagnetics Diagnostics plans to soon introduce into the market, fills this need. We expect the Company to make this technology available toward the end of the fourth quarter of 2009 or during early 2010.

Furthermore, the IOBS that Biomagnetics Diagnostics plans to introduce will go beyond testing for just malaria and bovine
tuberculosis. This technology is incredibly flexible and can be used to detect virtually any pathogen whether a virus, bacteria or fungus. While additional product development will be needed in order to test for these other pathogens, we believe the capital Biomagnetics Diagnostics recently raised will likely be sufficient to begin this process.

One of the reasons we are very excited about this technology is its inherent flexibility. Specifically, we believe it will be very possible for the Company to develop a single test capable of screening for multiple pathogens simultaneously. For example, with relatively little development effort, the Company will likely be able to establish a single test that will enable a healthcare provider located at the sight of patient care to test for the three major diseases responsible for most deaths worldwide, namely AIDS, tuberculosis and malaria. The availability of this type of diagnostic capability could potentially save millions of lives each year.

We can also envision this technology eventually being made available to blood banks in Western countries. Currently, blood banks in the United States ask potential donors a series of questions before blood is actually drawn. As long as these questions are answered without raising any major health concerns, blood is then taken and later tested to determine whether the donor actually carries any major diseases. This process is very expensive and results in a considerable amount of costs due to the many separate tests that must be performed on each blood sample as well as due to the time wasted on having to draw blood that is eventually deemed tainted and ultimately discarded.

If instead, blood banks had a reliable point-of-donor-site diagnostic tool that could easily screen donors for diseases, considerable cost savings could be attained. Considering that nearly every blood bank in the United States currently operates at a significant loss each year, we believe this technology would likely be very welcome as an effective way to significantly reduce operating costs and better ensure a safe blood supply.

Recent Events

September 28, 2009 - Biomagnetics Diagnostics Receives a Financing Commitment of up to $1.0 Million to Speed Development of Malaria Testing Technology

In late September, a group of investors pledged up to $1.0 million to the Company in order to further its development of the malaria testing technology. These funds will be used to finish the development of the
chemistry portion of the technology specifically relating to malaria and bovine tuberculosis testing. Any remaining funds will then be used to finance development of other diagnostic tests, including a combined tests targeted for Western blood banks.

September 22, 2009 - Biomagnetics Diagnostics Enters into Agreement with One of China's Largest Dairies

The Company recently signed a letter of intent to provide a state-of-the-art handheld bovine TB test to the Bright Dairy of China, which is China's third largest dairy operation. Under the terms of the agreement, Bright Dairy will become the exclusive distributor for China. This is a significant event for the Company expected to generate meaningful revenues over the short term as Bright Dairy deploys the technology in order to test its herd and as its personnel distribute the product to other companies within the Chinese dairy industry.


The Company announced it is continuing its contract negotiations to acquire the rights to the Integrated Optical Biosensors System (IOBS) technology developed by one of the U.S. government's top national security research institutions. Successful conclusion of these negotiations will allow Biomagnetics Diagnostics to quickly enter the growing market for advanced biosensors capable of detecting and characterizing a broad range of infectious agents in a given sample, including viruses, bacteria and fungi. The Company announced its initial plans are to target the malaria and bovine tuberculosis testing markets.

September 14, 2009 - Biomagnetics Diagnostics Retains Emerging Growth Research, LLP for Public and Investor Relations

Valuation

As of the last quarterly report, there were approximately 44 million BMGP.PK shares. Of these, approximately 22 million are restricted and approximately an additional 10 million are owned by management team members and long-term investors who are not likely to trade the stock. This leaves an effective float in the public market of approximately 12 million shares.

Considering the current share price of approximately $0.15, the total market capitalization of Biomagnetics Diagnostics is approximately $6.6 million, if the share count at the end of the last quarter is used in the calculation.
The Company’s recent fund-raising effort raises the share count to approximately 54 million shares, meaning the actual market capitalization is approximately $8.1 million at $0.15 per share.

While it is very difficult to place a target valuation on a pre-revenue company such as Biomagnetics Diagnostics, we believe the uniqueness of the Company’s technology and the significant market demand that is likely to develop upon product availability places the total potential valuation of this Company well in excess of $40 million, and possibly higher if a major diagnostic testing company were to become interested in acquiring this revolutionary technology platform. Thus, we would place the total potential market capitalization of Biomagnetics Diagnostics somewhere between $40 million and $60 million.

This implies a price per share of approximately $0.75 to $1.10 after the advanced integrated optical biosensor technology is available on the marketplace.
MARKET OPPORTUNITY

Diagnostics Test Market

Each year, between 14 million and 17 million people worldwide die from infectious diseases. Most of these deaths from infectious diseases occur in developing countries where about one third of the population, or more than 2.0 billion people, live in poverty conditions with little or no access to health care.

While infectious diseases cause almost half of all deaths in the developing world, they have an even greater impact on productivity, economic growth and quality of life. To lessen the devastating impact of these diseases, the global health community needs low-cost, easy-to-use, portable tools to diagnose and prevent the spread of infectious diseases. By addressing infections before they spread, vaccines represent the most cost effective way of managing these diseases but, where vaccines are not available, rapid point-of-contact diagnostics are needed to help medical professionals accurately prescribe effective treatments. Moreover, when accurate diagnoses are gathered from the field, public health officials can better analyze the data and eventually better manage potential epidemics and their effects on the population.

While the right diagnostic tests have the potential to dramatically improve global health, developing and deploying these tools has been difficult given their cost, resource intensiveness (ie: use of high technology, expensive and non-portable equipment and need for trained personnel) and, in some cases, the inability to perform well in warm/hot temperature environmental conditions. These factors have limited the deployment and availability of many existing diagnostic tests, especially in the poorer regions of the globe where they are needed most. For this reason, the world desperately needs a better (cheaper, faster, easier, more robust and portable) way to test for infectious diseases, as the key to reducing the cost of long term health care is early diagnosis.

Market Size & Growth

The medical diagnostics industry is large and growing. The global market for diagnostics is over approximately $150 billion, with anticipated compounded annual growth of 8.0%. The global in vitro diagnostic (IVD) market in particular was over $40 billion in sales in 2008, with the U.S. IVD market sized at over $17 billion, and the global IVD market is expected to generate nearly $60 billion in 2014. The long-term growth projected for the U.S. market is between 7.0%
and 8.0% and the outlook is similar for medical product sales in Europe. In emerging nations, demand growth for medical diagnostic products is expected to reach significantly higher rates. Emerging markets will experience 10% to 20% annual growth in IVD device sales, with the purchase of U.S. made products typically representing the first choice in most areas.

This forecast for significant growth going forward is due in part to the projected rise in the 45-year-old to 75-year-old population of many countries. Other trends will also lead to rapid growth in the IVD market. With improving economic conditions, developing countries will shift their diagnostics emphasis from infectious diseases to chronic conditions, and rising incomes and living standards in developing countries throughout the world will also increase demand. In particular, China, with its recent entry into the World Trade Organization, is expected to double its use of IBD devices over the next five years.

From 2009 onwards, it is estimated that worldwide investment in IVD testing will increase due to a variety of factors including a general greater awareness of the availability of tests and their usefulness as well as the development and emergence of new, more widely applicable and accurate tests.

The Bill & Melinda Gates Foundation

The Bill & Melinda Gates Foundation is currently a donor to FIND, a product development and implementation partnership devoted to developing and implementing diagnostic tools for poverty-related diseases including malaria. The Bill & Melinda Gates Foundation has donated $30 million to help develop better diagnostics tests.

Infectious Diseases

Altogether, the cost of treatment and lost productivity associated with illness from infectious agents tops $120 billion each year in the United States alone. Globally, this figure is significantly higher as infectious diseases cost individuals, communities and nations heavy social and economic tolls. Specifically, HIV/AIDS, tuberculosis and malaria sap economic growth, reduce educational opportunities, decrease life expectancy and increase child and maternal mortality, especially in developing countries.

Early and effective diagnostic testing for each of the diseases listed below is essential for managing, treating and eliminating the human,
social and economic impact inflicted by these illnesses worldwide each year.

**Malaria**

Malaria is one of the oldest diseases known to mankind that still represents one of the greatest global threats to public health today. Malaria is a mosquito-borne disease caused by a parasite. There are four main species of mosquitoes that can cause illness in humans including fever and, in the case of certain mosquito-species, significant mortality.

**Size of the Problem**

According to the World Health Organization (WHO), at the end of 2004, some 3.2 billion people, or about half the world’s population, lived in areas at risk of malaria transmission in 107 countries and territories worldwide. The WHO estimates each year, between 350 million and 500 million new cases of malaria occur worldwide with over one million cases resulting in death, 80% to 90% of which are located in sub-Saharan Africa mostly among young children. In 2006, the WHO African Region received more than US $688 million for malaria control, which represented considerably more than for any other region in the world.

Globally, large areas of Central and South America, Hispaniola (the Caribbean island that is divided between Haiti and the Dominican Republic), Africa, South Asia, Southeast Asia, the Middle East and Oceania are considered malaria-risk areas. In the United States, about 1,300 cases of malaria are diagnosed each year, the vast majority of which are in travelers and immigrants returning from malaria-risk areas, many from sub-Saharan Africa and South Asia.

Upwards of $2.0 billion per year is spent on malaria testing considering the worldwide annual caseload. Currently, malaria is reemerging as the number-one infectious killer worldwide and its control, management and eradication are the World Health Organization’s top priority in the area of tropical diseases. Additionally, being able to properly diagnose malaria and effectively demonstrate actual parasites in the blood is also important for the rational delivery of treatment in many malaria-endemic areas, particularly as parasite resistance to cheaper anti-malarial drugs is raising the cost of anti-malarial therapies around the world.
The global distribution of malaria and its relative stages of risk and eradication are shown below.


Transmission and the Spread of Disease

People with malaria often experience fever and chills along with other flu-like symptoms. While malaria is a disease that can be treated in just 48 hours, if left untreated or if diagnosis and treatment are delayed, it can cause severe complications and even death.

Insects that feed on blood, such as the female anopheline mosquito, can distribute the diseases from one host to another. In fact, female mosquitoes are the best vectors or transmitters of disease of all insects and animals alike, as they suck and feed on blood in order to provide food for their healthy, fertile eggs. Diseases such as malaria are caused by a human parasite that she carries within her after taking blood from an infected person. The parasite will then mature while resident inside the mosquito and will be passed onto a new host when she feeds on the blood of the next human/animal source, primarily during the time between sunset and sunrise. The male insects do not transmit the disease as they feed only on plant juices.

There are four kinds of malaria parasites that can infect humans: Plasmodium falciparum; P. vivax; P. ovale; and P. malariae. If not promptly treated, infection with P. falciparum may lead to death. Although malaria can be a deadly disease, illness and death from
malaria can usually be prevented if properly diagnosed and treated. Many tropical locations provide the ideal conditions for malaria outbreaks, as the mosquito breeds in water, typically a stagnant and potentially “unclean” source, with each species having its preferred breeding grounds, feeding patterns and resting place.

Furthermore, because the malaria parasite is found in the red blood cells of an infected person, malaria can also be transmitted through blood transfusion, organ transplant or the shared use of any needles or syringes that are contaminated with infected blood. Malaria may also be transmitted from a mother to her unborn infant before or during delivery, a condition known as congenital malaria.

**Social and Economic Costs**

Malaria imposes substantial costs on individuals, governments and nations as poverty and poor health are closely intertwined. For centuries, malaria has prevented economic development in vast regions of the globe. Since many countries with malaria are already among the poorer regions of the world, the disease maintains a vicious cycle of illness and poverty.

It is estimated that malaria alone kills a million people every year and reduces GDP per capita growth rates by at least a quarter of a percentage point per year. In fact, it has been estimated that the economic growth per year of countries with intensive malaria is 1.3% lower than that of countries without malaria. With billions of dollars lost each year in low productivity due to malaria, the toll of poverty-related diseases and illness is a huge burden on developing countries and, in many cases, represents a significant obstacle to achieving economic and social progress.

Malaria continues to be an enormous social, economic and health-related problem, particularly in tropical countries. In countries with a heavy malaria burden, this disease can consume as much as 40% of public health expenditures and can account for up to half of all outpatient visits and inpatient admissions. Under these circumstances, enhanced diagnostic capabilities mean better societal health and, in turn, an overall better use of resources, higher productivity and greater opportunities for economic development.

**HIV/AIDS**

Acquired immune deficiency syndrome, also known as acquired immunodeficiency syndrome or AIDS, is a disease of the human
immune system caused by the human immunodeficiency virus (HIV). This condition (HIV) progressively reduces the effectiveness of the individual’s immune system, leaving them susceptible to opportunistic infections and tumors (AIDS).

Thus, it should be noted that HIV and AIDS are not the “same thing,” as having the HIV infection does not necessarily mean an individual has AIDS. Specifically, HIV is the virus that damages the body's immune system and leaves the body at risk for those illnesses and infections said to be AIDS defining; and acquiring one of these infections means a person is diagnosed with AIDS. A person can be infected with HIV for years without having AIDS.

HIV testing is the key to slowing the HIV epidemic. Presently, there is no known cure for the HIV infection.

Size of the Problem

AIDS is currently a global pandemic and HIV/AIDS is the leading cause of death from infectious disease worldwide. In 2007, it was estimated that over 33 million people lived with the disease worldwide (31 million adults and 2 million children) and that AIDS killed an estimated 2.1 million people, including 330,000 children. Over three-quarters of these deaths occurred in sub-Saharan Africa, retarding economic growth and destroying human capital.

With over 33 million people living with HIV, the market for HIV diagnostics is expected to undergo strong growth over the next five years. The HIV diagnostics market stands out as a highly lucrative and expanding market because diagnostics play an integral role in day-to-day disease management and are widely used in initial diagnosis as well as in determining therapeutic options and monitoring disease progression in patients. In 2002, the United States alone performed over 22 million HIV diagnostic tests.

Transmission and the Spread of Disease

AIDS is transmitted through direct contact of a mucous membrane or the bloodstream with a bodily fluid containing HIV such as blood, semen, vaginal fluid, preseminal fluid and breast milk.

Social and Economic Costs

Around half of the people globally who contract HIV become infected before they turn 25 years old and they typically die of the life-threatening illnesses called AIDS before their 35th birthday. By the
end of 2007, the epidemic had left behind 15 million AIDS orphans worldwide under the age of 18 years. These orphans are vulnerable to poverty, exploitation and becoming infected with HIV themselves. Additionally, they are often forced to leave the educational system, find work and sometimes even care for younger siblings or head a family, all of which presents an enormous social and economic cost to society, including in the form of lost productivity and unrealized future potential.

Regarding regions of the world where the HIV/AIDS crisis is most prominent, Sub-Saharan Africa is by far the worst-affected area of the AIDS epidemic. While this region has just over 10% of the world's population, it is home to 67% of all people living with HIV. An estimated 1.9 million adults and children became infected here with HIV during 2007, bringing the total number of people living with HIV/AIDS in the region to 22 million by the end of the year. Approximately 1.5 million people in Sub-Saharan Africa died of AIDS in 2007.

In the whole of Asia, about 5 million had AIDS in 2007, while an estimated 1.7 million people are living with HIV in Latin America and the Caribbean. The total number of people living in the United States with HIV/AIDS is thought to be around 1.0 million.

Regarding actual costs, in 1993, the estimated global cost of care for Stage I and Stage II HIV patients was $4.7 billion, and the cost for Stage III AIDS patients was $4.8 billion. It was predicted during that time that the global cost of caring for people with HIV/AIDS would increase more than 20% during each year over the next decade. Under these circumstances, the estimated global cost of care for HIV/AIDS reached just under $60 billion in 2003, and at this trend rate, the cost is currently about $174 billion in 2009.

Tuberculosis

Tuberculosis (abbreviated TB for tubercle bacillus or tuberculosis) is the second leading cause of death from infectious diseases worldwide, following only after HIV/AIDS. Tuberculosis is a common and often deadly infectious bacterial disease caused by mycobacteria usually affecting the lungs (pulmonary TB). TB can also affect the central nervous system, the lymphatic system, the circulatory system, the genitourinary system, the gastrointestinal system, bones, joints and even the skin.

In most people who become infected, the body's immune system is able to fight the TB bacteria and stop them from multiplying. Under these
circumstances, while the bacteria are not killed, they become inactive and are stored harmlessly in the body. This condition is known as TB infection. People with TB infection have no symptoms and cannot spread the infection to others. However, the bacteria remain alive in the body and can become active again later. On the other hand, if an infected person's immune system cannot stop the bacteria from multiplying, the bacteria eventually cause symptoms of active TB, or TB disease. To spread TB to others, a person must have TB disease.

The lack of accurate, robust and rapid diagnostics impedes tuberculosis patient management and disease control. For communities, the risk of transmission from undetected cases requires widespread access to diagnostic services and early detection. Unfortunately, diagnostic services in most places where tuberculosis is endemic fail both the individual and the community. Patients are often diagnosed after weeks to months of waiting, at substantial cost to themselves and at huge cost to society. Many patients are never diagnosed and thus contribute to the astonishing number of yearly deaths from tuberculosis worldwide.

Size of the Problem

Approximately one-third of the world’s population is afflicted with the bacillus that causes TB and thus has TB infection, but most of these infections do not lead to ill health or so-called “active” TB disease.

Nonetheless, as an airborne disease thought to have been eliminated by the 1960s, tuberculosis today kills nearly two million people worldwide every year. According to the World Health Organization, new infections of tuberculosis occur at the rate of one per second and approximately 8.8 million new cases of TB occur each year worldwide.

Analyses indicate over $1.0 billion is spent annually worldwide on TB diagnostics. One third or about $326 million of this money is spent outside of the established market economies of the world where in fact 73% of TB diagnostic testing takes place.

Transmission and the Spread of Disease

Tuberculosis is spread through the air, such as when people who have the disease cough, sneeze, spit or even sing. TB infection is transmitted by inhalation or ingestion of tubercle bacilli and manifested in fever and small lesions, usually located in the lungs but also found in various other parts of the body in acute stages of the disease. The classic symptoms of tuberculosis are a chronic cough with blood-tinged
sputum, fever, night sweats and weight loss.

Most TB infections in human beings will result in asymptomatic, latent infection and about one in ten latent infections will eventually progress to the active disease stage which, if left untreated, kills more than half of its victims.

Social and Economic Costs

Tuberculosis disproportionately affects poor people with 95% of the disease concentrated in the developing world where TB and poverty combine to perpetuate a vicious cycle. Poverty contributes to the spread of tuberculosis as people are forced to share close living quarters and are often in overall poor health. At the same time, costs associated with TB diagnosis and treatment create further financial hardship for both patients and their families, including children. Worldwide, TB creates hundreds of thousands of orphans, increases child malnutrition and forces many children to leave school in order to work or care for the family or because of the negative stigma associated with the disease.

Sub-Saharan Africa and Southeast Asia in particular bear the highest number of tuberculosis cases, accounting for one-third of the global incidence of tuberculosis. Furthermore, of the estimated 14 million people co-infected with TB/HIV, 10 million reside in Africa. Insufficient resources, neglect and challenges posed by TB/HIV co-infection have collectively contributed to a diagnostic emergency in tuberculosis, uniquely jeopardizing people with HIV.

OTHER

Hepatitis

Hepatitis (hepatitis A, B, C, D & E) is a liver disease usually caused by an acute infection of the hepatitis virus. Specifically, hepatitis is a disease characterized by inflammation of the liver that can be acute and self-limiting or chronic and degenerative. Hepatitis has a variety of different causes, including a range of viruses (ie: A, B, C, D & E).

The impact of the disease on world society is highly significant and now presents a major crisis in public health circles. More than two billion people have been infected worldwide with the hepatitis B (HBV) virus alone, one of the most prevalent forms of hepatitis, making it a serious global health problem. Approximately 360 million people suffer from chronic HBV infection and more than 520,000 die each year. In 2002, the United States alone performed an estimated 31
million diagnostic tests for Hepatitis B.

Bovine Tuberculosis

With the world cattle population estimated to be about 1.3 billion head, the threat of bovine TB in many locations around the world remains a primary driver for increased diagnostic testing.

In the United States, where the cattle industry is a $60 billion industry, use of existing diagnostic tests currently adds $5.0 to $15 on average per head to the cattle industry's costs.

Blood Banks

In the United States alone, blood banks screen 14 million units of blood annually for seven types of viruses, including HIV and hepatitis B among others, for a total of 98 million tests conducted per year. Interestingly, use of the existing equipment to screen for hepatitis B alone, for example, has added $8.00 to the cost of a unit of blood, while the use of equipment to screen for HIV has added $5.00, greatly increasing the need for a more effective, economical diagnostic solution.

DIAGNOSTIC TESTING

Importance of Testing

Infectious diseases must be recognized promptly in order to effectively treat patients in time and prevent further spread throughout the community.

When accurate diagnoses are gathered from the field, public health officials can better analyze the resulting data and eventually better manage potential epidemics and their effects on a population. Getting accurate information on the type and status of infectious diseases is particularly important in many developing regions of the world for treatment and illness containment, as access to good health care is minimal or non-existent.

While early, accurate diagnosis is essential, achieving this goal is often difficult in many poorer countries. Many areas of the world simply lack the right diagnostic tools that can be cheaply, easily and quickly deployed in “rougher” field type conditions that require more robust, portable solutions able to withstand temperatures and challenging environmental conditions. For this reason, the world desperately needs a better way to test for infectious diseases.
Next Generation of Diagnostic Tools & Methods

The history of medical diagnostics has progressed perhaps slowly but steadily over the centuries, from basing the diagnosis of diseases on the clinical or physical symptoms of a patient, to microscopic testing for pathogens to some of the more modern immunological formats used today such as rapid diagnostic testing, all of which are discussed below.

Going forward, however, as the national health care budgets of many developing nations come under increasing pressure and as global population growth explodes, particularly in many of the poorer developing regions of the globe where infectious illnesses can be rampant, the world still needs better solutions for diagnosing and containing disease. In particular, future diagnostic solutions need to enhance productivity and save critical health care resources, including both physical resources as well as human capital in the form of health care worker time and effort, as well be easy to use, fast to deploy and cost economical.

One relatively untapped technology with the potential to revolutionize the next generation of diagnostic testing is the use of magnetics and sensors/lasers to detect disease. While nearly every major pharmaceutical company in the industry plays at some level in the diagnostics market, R&D efforts have largely passed over the use of magnetics and/or laser sensors in favor of pursuing “higher technology” options. Specifically, it appears many R&D trends in the well capitalized developed world are concentrating on building technology intensive diagnostic tools such as the “lab-on-a-chip” concept, in which the process of disease testing is largely an all-in-one (ie: screening, confirmation, identification of disease type, viral load etc.) automated device. The problem with this concept is that while accurate and effective, it is very expensive and thus does not meet the needs of the developing world where high diagnostic costs are prohibitive for infectious disease testing in mass populations.

In comparison to the “lab-on-a-chip” concept, use of magnetic/laser technology in diagnostics represents a simpler, easy-to-deploy, cost effective solution that can be leveraged in design in order to be able to detect multiple diseases and/or disease in multiple patients all at once.

Biomagnetics Diagnostics Corporation’s Solution

Biomagnetics Diagnostics is focused on a new diagnostic solution that utilizes proprietary electronics and chemistry technology for the detection of disease agents by measuring and defining the magnetic
field of micro-particles bonded to the pathogen. The adverse pathogens are detected through use of specially designed magnetic resonance (MR) sensors, integrated into the Company’s exclusive patented technology, that provide high throughput screening (HTS) to detect the paramagnetic micro-spheres. To date, Biomagnetics Diagnostics has been issued two patents in this field and has filed for a third.

At present, the Company is working to develop its High Throughput Screening - Magnetic Testing Platform (HTS-MTP) designed to detect actual pathogens with near 100% accuracy from any one of a number of bodily fluid types in an approximate 72 to 96 hour time period, a fraction of the time currently required by existing immunoassay tests.

Furthermore, because this diagnostic technology has the capability to screen many more assays per hour, labs and other users will be able to perform far more tests in the same amount of time, and at significantly less cost, than would otherwise required to perform a single more traditional testing format. The Company believes this capability represents a breakthrough that could revolutionize the diagnostics industry and be of significant importance to blood banks and other testing locations around the world.

Additionally, and importantly, the Company is also currently working to develop a fully portable, durable diagnostic testing solution for application in many of the world’s more remote and environmentally challenging regions. The Company believes this testing equipment will have very wide applications and can be designed for the detection of some of the world’s most infectious and populous diseases such as malaria, bovine tuberculosis (TB) and tuberculosis in humans, among many other diseases.

Existing Diagnostic Tools & Methods

Early case detection and treatment is a major part of disease control. The diagnosis of many infectious diseases involves identification of the actual parasite/pathogen, its antigens and/or antigen-related products in the patient’s blood stream. (An antigen is any substance such as a toxin or enzyme that stimulates an immune response in the body, especially the production of antibodies which are infection-fighting protein molecules.)

While this concept seems simple in theory, actually attaining a proper diagnosis is subject to many complex and dynamic factors including: the relationship between transmission levels, immunity, the presence of actual parasites in the blood and the patient’s symptoms; drug resistance; the level of how endemic a pathogen is to a particular
Importantly, in order to be able to get a proper diagnosis in all cases, the diagnostic method used must be both accurate and available to the population at a “near-household” level. Unfortunately, many of the diagnostic tools currently available in the developing world are largely out-dated and ineffective, while solutions used in wealthier societies are either too expensive or not yet adapted for use in low-resource settings, including the issue of being lab-bound and thus not being portable. As a result, millions of people in low-resource settings still die each year from diseases that are otherwise treatable including malaria, tuberculosis (TB) and sleeping sickness, among others. The lack of appropriate diagnostic tests also leads to delayed treatment, multiple clinic visits and misdiagnosis, all of which result in escalated health and financial costs as well as the waste of valuable resources.

At present, three main diagnostic alternatives exist for the diagnosis of several prevalent global pathogens including malaria, tuberculosis, HIV/AIDS and hepatitis: Clinical or symptom-based diagnosis; microscopy or microscopic diagnosis, including the QBC test, acridine-orange staining and other test variations; and immunoassays such as rapid diagnostic test formats. Each of these is discussed below.

Clinical Diagnosis

Clinical diagnosis is based on observation of a patient's symptoms and on physical findings at examination. Unfortunately, symptom-based diagnosis is well demonstrated to have poor accuracy. Furthermore, by the time visible symptoms set in, progression of the disease is already well along in the patient, making treatment and containment much more difficult.

For this reason, the diagnosis of malaria and other diseases is largely confirmed today by the testing of a patient’s blood and/or other bodily fluids, which can be performed at either the microscopic or non-microscopic/immunoassay level via various testing methods.

Microscopy or Microscopic Diagnosis

Microscopy is the technical field of using microscopes to view samples or objects. Most specimens are treated with stains that color the pathogens, causing them to stand out against a background when viewed under a microscope.

The use of microscopy to detect infectious diseases remains the most
prevalent diagnostic format today for many well known pathogens, including malaria and tuberculosis. Specifically, the peripheral smear test, also known as the smear for malarial parasite (MP) test, is the “gold-standard” for laboratory confirmation of malaria in a patient. Additionally the mainstay for tuberculosis diagnosis in disease endemic developing countries is sputum smear microscopy, first developed in the 1880s and which today remains essentially unchanged.

Microscopy can be performed quickly, but accuracy depends on the experience of the microscopist and the quality of the equipment. Regulations often limit the physician’s use of microscopy for diagnostic purposes outside a certified laboratory.

**Malaria**

For nearly one hundred years, use of a microscope to enable the direct visualization of the malaria parasite on a thick and/or thin blood smear has been the primary method for diagnosing malaria in most settings ranging from clinical laboratories to field surveys. Microscopic testing for malaria involves first collecting a blood smear sample, staining it in order to make the parasite visible to the human eye, and examining the sample via direct visualization of the patient’s red blood cells under the microscope in order to detect intracellular malarial parasites and thus the presence of disease. There are two main types of microscopic tests, the peripheral smear study for malarial parasites also known as the MP (malarial parasite) test and the Quantitative Buffy Coat (QBC) test.

As microscopy is cumbersome, expensive and not widely available, many patients are misdiagnosed, and over-treatment and mistreatment are common. In fact, in much of the world where malaria is endemic, microscopy services are simply unavailable and patients are therefore treated on the basis of clinical signs and symptoms only, resulting in over-diagnosis of malaria by as much as 40% to 90%. This situation is especially true among impoverished populations in remote rural areas, where malaria takes its heaviest toll and casualties are greatest. Over-diagnosis and over-treatment are a significant problem in that they waste precious resources, reduce confidence in health care systems and may contribute to decreased treatment/behavior compliance and the evolution of drug-resistant malaria.

**Tuberculosis**

For tuberculosis, sputum smear microscopy is the most standard diagnostic tool. However, this diagnostic method is time-consuming, tedious and dated, going back to the discovery of Mycobacterium
tuberculosis (MTB) in 1882. As an alternative to microscopy, other TB diagnostic methods include chest X-rays in order to look for cavities and abnormalities in the lungs as well as certain culture tests, neither of which represent a practical, cost effective detection method particularly in many developing countries where the disease is wide spread.

Going forward, more than one type of TB test is needed for the different levels of the health care system, namely, a point-of-care test for use at the primary health care level, such as at health posts where the majority of patients seek medical attention but where diagnosis is currently based on clinical signs and symptoms only; a test for the peripheral laboratory level, or the health center or district hospital level, as an alternative to microscopy and with a simpler technology that can detect both smear-positive and smear-negative tuberculosis; and a TB diagnostic at the district and national reference laboratory level, for use as a faster substitute to culture testing smear-negative tuberculosis, for improving antibiotic susceptibility testing and for the detection of latent infection.

The Peripheral Smear Test for Malaria

The peripheral smear test, also known as the smear for malarial parasite (MP) test, is the “gold-standard” for laboratory confirmation of malaria in a patient. Of all the malaria diagnostic tests available, the peripheral blood smear provides the most comprehensive data in a single test including: information on the particular mosquito species, newly contracted versus recurrent situations, disease severity and whether the malaria parasite is active; and the stages and density of parasitemia within a high degree of sensitivity of five to 10 parasites/µL of blood, as examined by an experienced laboratory professional. (Sensitivity is the ability of a diagnostic test to detect a person as having an illness, as an accurate positive case detection. Specificity is the ability of a diagnostic test to detect a person who does not have an illness as a negative case accurately.)

Malaria parasites can be identified by examining a drop of the patient's peripheral blood (ie: finger prick, ear lobe stab) under a microscope whereby the blood sample is spread out as a “smear” on a microscope slide. Prior to examination, the specimen is stained, most often with a Giemsa stain, in order to give to the parasites a distinctive appearance under the microscope.
The image at the right is a blood-smear stained with Giemsa, showing a white blood cell on the left-hand side and several red blood cells, two of which are infected with Plasmodium falciparum, on the right-hand side.

The test requires approximately 20 to 60 minutes to administer and complete, depending on the proximity of the associated laboratory and other factors mentioned above, and is estimated to cost between $0.12 and $0.40 per slide in endemic country locations.

While the peripheral smear test remains the standard for detecting malaria, it contains several inherent problems, as any one of several factors can have a significant bearing on the results. The efficiency of this test depends on the type and quality of the smear sample; the quality of the equipment and reagents used; the skill and expertise of the examining technician and the quality and quantity of time spent reading the smear; the level of parasitemia within the blood sample; duration of illness; and the method of examination.

Furthermore, the exacting needs of the blood smear examination are often not met in certain remote and poorer parts of the world. Under these circumstances, deficiencies with the blood smear test include: the ability to effectively detect even low levels of parasitemia; sequestering parasites of P. falciparum and past infections in aspiring blood donors; ascertaining the viability of the detected parasites; difficulties in maintaining the required technical skills in personnel; and misdiagnosis due to poor familiarity and problems in accessing and activating testing facilities in emergency situations.

Use of this method is also limited by high costs, the need for supplies and special training, and requirements for expensive equipment and laboratories.

The Quantitative Buffy Coat (QBC) Test for Malaria

The Quantitative Buffy Coat (QBC) test is a more recently developed laboratory test for the detection of malaria parasites using a capillary tube and a standard white light microscope equipped with a UV microscope adapter.

It involves taking 55 to 65 microliters of red blood cells from a peripheral blood source (ie: the patient’s finger, ear or heel) in which
the blood sample is taken in a QBC capillary tube coated with acridine orange, a fluorescent dye used to examine the sample under a UV light source, and then centrifuged. After centrifugation, one can distinguish a layer of clear fluid which is the plasma, a layer of red fluid containing most of the red blood cells, and a thin layer in between, making up less than 1% of the total volume of the blood sample; this is the buffy coat, so-called because it is usually buff in hue. The buffy coat is typically whitish in color and contains most of the sample's white blood cells and platelets. In the QBC test, the fluorescing parasites can be observed under ultraviolet light at the interface between the red blood cells and the buffy coat.

The QBC method of testing is fast, easy and reportedly more sensitive than the traditional thick smear examination, and in more than 90% of cases the specific species of parasite can also be identified. The key feature of this testing method is centrifugation which enables concentration of the red blood cells in a predictable area of the QBC tube, thereby making detection easy and fast. A negative test can be reported within one minute and positive result within several minutes.

While studies comparing the QBC with the peripheral smear have found the QBC test is as sensitive as the MP smear test, identification of the mosquito species and quantification of parasitemia are more difficult with the QBC technique. Therefore, in spite of the speed and simplicity of the QBC technique, it cannot be considered an acceptable alternative to Giemsa-stained thick film (GTF) tests under routine clinical laboratory situations. It should also be noted that the diagnostic accuracy of both the peripheral smear and QBC microscopy tests relies heavily on the quality of the blood smear and experience of laboratory personnel.

Sputum Smear Microscopy for Tuberculosis

The sputum smear microscopy method involves collecting three sputum samples from the patient over at least a two day period. Samples are then stained with a dye and washed with acid. This dye adheres to mycobacteria such as TB and other "acid-fast bacilli" (AFB) and remains visible under the microscope even after an acid wash. In order to detect the elusive acid-fast TB bacterium, laboratory workers must examine each slide using 100 different microscopic fields over a ten minute period. An individual is recorded as a smear-positive case of pulmonary tuberculosis when technicians detect AFB in two of three samples collected.

Aside from being a cumbersome testing methodology, smear
microscopy testing for tuberculosis frequently yields false negatives and is further limited by its singular focus on TB in the lung, the most infectious form of the disease. Evidence suggests that only 40% to 60% of pulmonary TB cases are acid-fast bacilli (AFB) positive by sputum smear microscopy. Smear positive cases exemplify typical pulmonary TB, which causes cavitary lesions visible in chest X-rays. In the remaining half of all cases evaluated using smear microscopy, however, TB is present in the lungs despite negative results on sputum samples, resulting in false-negative test results.

Additionally, TB can manifest as extra pulmonary disease, involving the lymph nodes, bones, joints or central nervous system tissue. HIV infection can complicate interpretation of these diagnostics as well. Studies from certain regions including southeast Asia indicate that up to two thirds of HIV-associated TB cases are either sputum smear negative or extra-pulmonary. (HIV-positive people are less likely to have abundant bacilli in their sputum, possibly leading to a false negative on smear microscopy, and often have extra-pulmonary TB disease.) Thus, even where available, sputum smear microscopy is inadequate for capturing the majority of HIV/AIDS-related TB cases. Furthermore, this testing method cannot detect TB in children who constitute a significant one-sixth of the global burden of tuberculosis and are generally under-diagnosed and under-treated.

**Immunoassays (Non-Microscopic Diagnostic Tests)**

Significant advances have been made in immunoassay diagnostics, which represent an important attempt to take the diagnosis of malaria, TB and other rampant diseases out of the realm of the microscope. Immunoassays are chemical tests used to detect or quantify a specific substance, the analyte, in a blood or body fluid sample using an immunological reaction.

As a side note, the term analyte is a very broad description of molecules that are indicative of various states, such as infection, pregnancy and high cholesterol, among others. There are two primary types of analytes, namely antibodies and antigens. Antibodies are a specific class of molecules that are created by a person’s immune system in response to an infection. Thus, antibody diagnostic tests are useful for diagnosing infectious diseases as they detect a patient’s immune response (in the form of antibodies) resulting from infection. The term antigen, on the other hand, is a general term that is applied to analytes that are not antibodies, that is, analytes other than antibodies. Therefore, antigen diagnostics detect biomarkers that are not related to
a patient’s immune response. Antigen detection tests are useful for diagnosing infectious diseases as well as various other states that do not elicit an immune response such as high cholesterol or drug use. The diagnostic procedure is generally the same regardless of whether antigens or antibodies are detected by the test format.

Immunoassays are highly sensitive and specific, where their high specificity results from the use of antibodies and purified antigens as reagents. Immunoassays measure the formation of antibody-antigen complexes and detect them via an indicator reaction. High sensitivity is achieved by using an indicator system (e.g., enzyme label) that results in amplification of the measured product. Immunoassays may be qualitative (positive or negative for a particular disease) or quantitative (amount measured, or an indicator of the disease’s progression or stage).

Examples of some of the most widely used immunoassays for diagnosing multiple disease types include rapid diagnostic tests (RDT) such as the dipstick test; Polymerase Chain Reaction assays; the enzyme-linked immunosorbent assays (ELISA); and the Western blot test, among others.

Rapid Diagnostic Tests (RDT)

Using microscopy to test for diseases is technically demanding, and extending high-quality microscopy services to remote field sites where they are needed most has been difficult. For this reason, rapid diagnostic tests developed within the past decade offer a useful alternative to microscopy in making a rapid, accurate diagnosis of diseases like malaria, HIV, hepatitis B and syphilis to name a few, in low-resource endemic areas where reliable microscopic diagnosis is simply not available. RDTs are currently being used in some clinical settings and programs around the world.

Most rapid diagnostic tests work by capturing analytes on a solid surface and then attaching molecules to them that allow for detection by the naked human eye.
A few basic test formats and technologies offered by manufacturers are shown below.

RDTs for Malaria Testing

Regarding the diagnosis of malaria for example, most RDTs are lateral flow immunochromatographic antigen-detection kits that rely on the capture of dye-labeled antibodies found within a blood sample. These dye-labeled antibodies then produce a visible band on a strip of nitrocellulose in order to detect species-specific antigens derived from malaria parasites. These tests typically come in a dipstick, strip, card, pad or cassette format and most often provide results within two to 15 minutes.

An example of an RDT test is shown below.

Assay Kit for the Detection & Identification of Malaria Infections
Before malaria RDTs can be widely adopted, several issues need to be addressed including improving accuracy, lowering costs and ensuring adequate performance under adverse field conditions.

Challenges with RDTs include the fact that while the identification of the color change on the test strips may look like a simple task, the correct interpretation of the results requires health workers to have knowledge of actual disease dynamics and the possible errors that can result from using an RDT. Although RDTs have been reported to be useful and easy tools for field surveys in remote forests and villages, some studies have found that deficient experience and an insufficient level of field staff training can adversely influence the sensitivity and specificity of these tests, leading to questionable results or failure to correctly interpret the results, thus causing an increase in the number of incorrect malaria diagnoses. For this reason, good health worker training and monitoring must be in place when using RDTs, particularly at the village level where limited supervision and inadequate training can lead to problems.

While the cost of a rapid diagnostic test typically ranges from $1.20 to $13.50 per test, this expense has been considered a major obstacle for the large scale deployment of RDTs in field studies. Given the alternatives, however, health ministries around the world are currently purchasing RDTs in large numbers, with over 50 million tests being distributed per year.

Rapid diagnostic tests of similar design exist for a number of different pathogens such as hepatitis B, HIV and syphilis. In most cases, RDT testing for these diseases can be confined to centralized clinics, as these diseases progress less rapidly than malaria and diagnosis within the first few days of symptoms is less important for controlling morbidity and transmission. RDTs designed for malaria testing, on the other hand, need to be more robust for immediate field deployment, and hence quality assurance is more difficult for malaria RDTs than it is for those RDTs used to diagnose other diseases.

One main problem with using RDTs in remote clinics or in the hands of village volunteers is that many RDTs incur heat-damaged during transit, as they are susceptible to degradation upon exposure to warm temperatures commonly found in the tropical regions of malaria-endemic countries. Thus, the accuracy of RDTs should be regularly monitored for quality control and a cool “temperature chain” should be put in place for the shipping and storage of RDT test kits before dissemination to remote field sites.

The performance of RDTs, and hence the effective diagnosis and
treatment of malaria, is influenced by multiple factors including: the type of test; condition of the RDT, including storage conditions; quality of manufacture and variations in test strip batches; the species type and level of parasites in the blood; the target antigen and the capture antibody; cross-reactions with other malaria species and with auto-antibodies; and prior treatment, among others. Furthermore, the correct interpretation by the reader of the color changes used to identify malaria infection in RDTs is influenced by the level of personnel training, the type of examination instructions given to medical personnel, the technique and care used in performing the test and, in the case of self-use, the state of the patient.

While immunochromatographic tests for the detection of malaria antigens have opened a new and exciting avenue in malaria diagnosis, their role in the management and control of malaria appears to be limited at present. It is still recommended that all RDTs be followed-up with microscopy to confirm the results and if positive, to quantify the proportion of red blood cells that are infected.

**Rapid Diagnostic Tests for HIV**

HIV diagnostic testing also needs to be able to be performed outside of the laboratory in a more rapid and affordable manner. For this reason, traditional sophisticated HIV testing methods such as the enzyme-linked immunosorbent assay (ELISA) had to be redeveloped into a format that has the specifications required for out-of-laboratory test settings. Today, RDTs are a major diagnostic method for the detection of HIV/AIDS as they do not require laboratory facilities or highly trained staff and thus are very suitable for deployment in resource-poor countries.

To this end, lateral-flow tests utilize a one-step method in which the patient’s blood specimen is combined with a signal reagent and migrates through a special membrane. A positive reaction is shown as a visible line on the membrane. Most tests take less than 15 minutes. Additionally, flow-through cassettes or membrane immunoconcentration devices can capture and detect HIV antibodies in a specimen flowing through a porous membrane. Here, a visible dot or line forms on the membrane when HIV antibodies are present. Finally, solid-phase tests include the dipstick “comb” assay. This assay uses a solid plastic matrix to which an HIV antigen is fixed. When HIV antibodies are present, a spot or dot will be visible when processed with a signal reagent.
Rapid Diagnostic Tests for Hepatitis

Detection of hepatitis B surface antigen (HbsAg) identifies individuals infected with the hepatitis B virus. Quantitative enzyme immunoassay (EIA) methods are still considered to be the most sensitive tests for the disease and are widely used at well-equipped reference centers or central blood banks. Over the last few years RDT, such as lateral flow tests, have also made great strides in advancing ease of use and access to high quality hepatitis B diagnostics.

Comparison of Microscopy and Rapid Diagnostic Tests

RDTs are designed mainly for use in disease endemic areas beyond the reach of good quality microscopy as they do not require a laboratory, electricity or any special equipment. Compared to microscopy, one of the benefits of RDTs is that these tests can be performed by individuals with relatively minimal training.

Overall, the appropriateness of using either microscopy or RDTs will depend on the resources in the area of intended use and the number of potential cases, as microscopy takes hours or days to administer while RDTs typically take only minutes.

A summary comparison of the two testing methods is outlined in the table below.

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<th>Microscopy</th>
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<td>Depends on other duties of microscopist, relative accuracy, effect on treatment costs, effects on mortality and other diseases, number of cases requiring diagnosis</td>
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Polymerase Chain Reaction Assays (a form of molecular diagnosis)

Molecular biology diagnosis represents another testing method, as parasite nucleic acids can be detected using a polymerase chain reaction (PCR). In molecular biology, the polymerase chain reaction (PCR) is a technique for making multiple copies of a gene by amplifying a single or a few copies of a piece of DNA across several orders of magnitude,
generating thousands to millions of copies of a particular DNA sequence, allowing for detection and identification of gene sequences using visual techniques based on size and charge (+ or -) of the piece of DNA. The whole process of extracting genetic material and testing it with a PCR test is referred to as nucleic acid-amplification testing (NAT).

This method relies on thermal cycling, consisting of cycles of repeated heating and cooling of the reaction for DNA melting and enzymatic replication of the DNA. Primers, or short DNA fragments, containing sequences complementary to the target region, along with a DNA polymerase after which the PCR method is named, are key components that enable selective and repeated amplification.

The sensitivity, efficacy and speed of this method are unparalleled for the amplification and detection of exquisitely minute quantities of nucleic acids. Drawbacks to this method are its time and resource intensiveness.

PCR tests are used in HIV diagnoses to detect the genetic material of HIV itself, and these tests can identify HIV in the blood within two or three weeks of infection.

Diagnostic equipment used in PCR testing is shown below.

While this technique is more accurate than microscopy, it is expensive and requires a specialized laboratory. Going forward, it is anticipated that technical advances will likely result in field-operated PCR machines.

Enzyme-Linked Immunosorbent Assay (ELISA)

Enzyme-linked immunosorbent assay (ELISA) is a biochemical technique used mainly in immunology to detect the presence of an antibody or an antigen in a sample.

In ELISA diagnostics, a sample of an unknown amount of antigen is affixed to a surface and immobilized on a solid support, usually a polystyrene microtiter plate. Next, a specific antibody is washed over the surface and binds to form a complex with the antigen. This
antibody is linked to an enzyme and, in the final step of the process, a substance is added that the enzyme can convert into some detectable signal, such as a visible fluorescent signal. Thus, in the case of fluorescence ELISA for example, any antigen/antibody complexes will fluoresce when light of the appropriate wavelength is shone upon the sample, and the amount of antigen in the sample can be inferred through the magnitude of the fluorescence.

Examples of ELISA machines are shown below.

Since the mid-1980s, HIV diagnosis has been based on laboratory detection of circulating antibodies against HIV. Typically, one screening test was employed and then followed by a confirmatory test if the initial test yielded a positive result. The ELISA format was the first and most widely used screening test for HIV, with a confirmatory test utilizing a western blot or immuno-fluorescent assay (IFA).

Although these tests were highly accurate and economical, unmet needs in the diagnosis of HIV still remained, as this diagnostic process involved an invasive blood draw and the sample was sent to a centralized referral lab where they had to be batched for analysis, usually by highly skilled personnel. As a result, there was a significant wait time for results that led to an increase in anxiety for patients as well as significant loss of time before follow-up results became available, thereby delaying treatment and disease containment. For this reason, rapid diagnostic tests have become the most widely used HIV tests today.

**Western Blot Assays**

Western Blot assays are one of the oldest but most accurate confirmatory antibody tests. Western blotting is an immunoblotting technique used to separate proteins by molecular weight and identify and locate these proteins based on their ability to bind to specific antibodies. Immunoblotting techniques rely on the specificity of binding between a molecule of interest and a probe to allow detection of the molecule of interest in a mixture of many other similar molecules. In Western blotting, the molecule of interest is a protein
and the probe is typically an antibody raised against that particular protein.

The Western blot test involves several technical steps including transferring the proteins (originally in a gel) to a thin membrane using electrophoresis; treating the membrane with three different solutions for blocking and adding particular antibodies; and the final step of visualization, in which the membrane is washed in a solution that reacts (with the secondary antibody) to show where the protein of interest, if present, is bound to the membrane.

After completion of these steps, the membrane may be inspected to determine if the protein of interest is present by looking for dark bands at the appropriate position relative to the molecular weight markers and positive controls.

The graphics below depict the final diagnostic stage of the Western blot test.

Disadvantages of the Western Blot are that it is complex to administer, requires well trained staff to execute and interpret and may produce indeterminate results if a person has a transitory infection with another virus.

**Other**

**Culture Test for Tuberculosis**

Culture samples test infected tissue or fluid from an individual and then culture the bacteria/virus/organism in a test tube or dish. After being cultured, the type of pathogen can then be identified by microscopy, colony morphology and/or biochemical tests of pathogen growth.

Culture tests diagnose tuberculosis with far greater efficiency, accuracy
and sensitivity than the standard TB diagnostic of smear microscopy, even among HIV-infected people. Another clear advantage to culturing TB is that the results will also provide a drug susceptibility profile of the bacilli, enabling the detection of drug resistant TB.

The disadvantage is that cultures are time-consuming, requiring four to eight weeks to develop, an unacceptably long time window for co-infected TB/HIV patients who may die waiting. Faster tests that use liquid media can grow the culture in as short a period as 12 days. Nonetheless, while such culture-based diagnostics are a vast improvement over smear microscopy in terms of accuracy, their utility is currently limited due to the length of time they take to complete and the amount of resources they require. Culture testing is expensive, technically demanding and less widely available in resource-poor settings where they are needed most.

Liver Biopsy for Hepatitis

A liver biopsy is one of the main and most accurate diagnostic procedures that can determine what is wrong with the liver and how badly it has been damaged, including hepatitis diagnoses. While accurate and informative, this method is clearly invasive, costly and impractical for many patients and diagnostic settings.

Flow Cytometry

Flow cytometry is a technique for counting and examining microscopic particles, such as cells and chromosomes, by suspending them in a stream of fluid and passing them by an electronic detection apparatus. Flow cytometry is routinely used in the diagnosis of health disorders, especially blood diseases and blood cancers.

Flow cytometry and automated hematology analyzers have also been found to be useful in diagnosing malaria during routine blood counts. In cases where malaria is present, abnormal cell clusters and small particles with DNA fluorescence, probably free malarial parasites, have been seen on automated hematology analyzers and it is suggested that malaria can be suspected based on the scatter plots produced on the analyzer.
THE COMPANY

Founded in March 1997 as a Nevada corporation, Biomagnetics Diagnostics Corporation is an advanced medical device and biotechnology company located in Orangevale, California. Specifically, the Company develops proprietary chemistry and electronics technology for the creation of advanced, next generation diagnostic tools based on magnetic and sensor technologies to detect most types of disease pathogens. The Company believes its diagnostic products are superior to many currently existing options in that it provides several advantages including cost effective, faster, real-time delivery of near 100% accurate results; the ability to diagnose using any one of several body fluids; and a diagnosis of the actual pathogen as well as the viral load, all in one test.

In fact, a major advantage of Biomagnetics Diagnostics’ proprietary diagnostic solution is its ability to provide real-time early detection of actual disease pathogens, which stands in contrast to currently available testing solutions that are able to detect only disease antibodies. Furthermore, the Company is working to establish its identity as a leading edge developer of high technology immuno-diagnostics by developing disease agnostic platforms in which the same instrumentation can be applied to the detection and diagnosis of several different disease types.

Biomagnetics Diagnostics’ first actual product set includes the development of its revolutionary, patented High Throughput Screening Magnetic Testing Platform (HTS-MTP) and immunoassay diagnostics system and testing kit for detecting multiple diseases including HIV, hepatitis, H-Pylori, HPV and tuberculosis in addition to many other viruses, bacteriums and toxins. The Company’s products are designed to address large market opportunities for which it believes current therapies are inadequate or non-existent.

Patent Portfolio

Biomagnetics Diagnostics, through its wholly owned subsidiary Biospectrum Technologies, holds patents on technologies that it believes can potentially revolutionize the biotechnology, stem cell and genetic engineering industries. The Company is developing an ongoing strategic portfolio of patented technologies and intellectual property that it believes will give it a strong competitive position in a diverse range of bacterial and viral diagnostic systems and pathogen
immunoassays.

To date, Biomagnetics Diagnostics has been issued two patents, one in July 2003 and another in May 2006, both in the area of System and Method for Biochemical Assay. Specifically, the Company’s patent portfolio currently includes patents for its High Throughput Screening - Magnetic Testing Platform (HTS-MTP) diagnostic system and immunoassay technologies and patent rights related to a system for detecting any pathogen. The Company believes these patents will enable it to develop a broad spectrum of applications going forward in both the testing and diagnosis fields. The Company also filed for a third patent for a new diagnostic system designed for multi-analytic testing for blood banks titled System and Method for Detecting Specific Binding Reactions Using Magnetic Labels.

Product Offering

Portable Diagnostic Products

Importantly, the Company is currently working with a premier U.S. government national security research institution to develop a fully portable, durable, reagentless optical biosensor diagnostic testing solution for application in many developing regions of the world where the ability to quickly, accurately, cost effectively and easily diagnose infectious diseases in large populations at the remote village level is critical.

The hardware aspect of this testing equipment will be fully portable, hand-held and battery operated, such that access to an electricity source will not be necessary in order to run the diagnostic equipment. Thus, medical professionals and field workers will be able to transport the hardware to any remote location where they can simply insert the inexpensive, disposable cartridges (testing assays/removable trays), take a bodily fluid sample and run the test and within minutes learn the results on site. The equipment will also be designed with a memory chip for data and storage retrieval so that test results can be saved and later be download to a computer (ie: back at the central laboratory location). Other advantages to this diagnostic testing equipment are that it will be simple to use, sensitive and specific as a “single step” solution.

The Company believes this testing equipment will have wide global field applications and can be designed to be disease agnostic for the detection of some of the world’s most infectious and rampant diseases such as malaria, bovine tuberculosis (TB) and tuberculosis in humans,
among other illnesses. Going forward, as a disease agnostic device, it is also intended for use in detecting cancers and other human ailments.

One of the first intended uses Biomagnetics Diagnostics will pursue is the market for malaria, one of the most widespread diseases in developing regions which currently lack a portable, point-of-care, cost effective and reliable diagnostic solution. Additionally, the Company intends to immediately pursue the bovine tuberculosis (TB) market in China, where the Chinese government recently mandated that the country’s stock of 11 million dairy cattle be tested at least once a year for the disease. Going forward, the Company anticipates this diagnostic test will be able to be designed for the testing of tuberculosis, hepatitis and many other infection and non-infectious illnesses.

**High Throughput Screening - Magnetic Testing Platform (HTS-MTP)**

As part of its goal to bring new, next generation technology to the diagnostics market, the Company is committed to developing testing equipment that exceeds existing standards for immunoassays by providing:

- Cost savings, speed and accuracy
- Qualitative (yes/no) results
- Quantitative (viral load) results
- A confirmatory assay for the same price as a screening assay
- No technical background requirements for health workers and test administrators
- Solutions that are virtually maintenance free

The first product offering Biomagnetics Diagnostics will bring to market is the Company’s state of the art High Throughput Screening - Magnetic Testing Platform (HTS-MTP) designed for use by public and private laboratories and blood banks. This diagnostic system is developed to detect target viruses and other antigens in 72 to 96 hours, a fraction of the time currently required by existing immunoassay tests.

It will offer customers a confirmatory test with near 100% accuracy at the same price competitors charge for a screening test, which provides far less accuracy. The Company’s technology makes this possible because, unlike other antibody detecting tests available today, Biomagnetics Diagnostics’ HTS-MTP system is designed to detect the presence of the actual virus, not just the antibodies produced by the
human body in reaction to the virus, which itself is a biological process that can take anywhere from weeks to months for antibodies to appear. Thus, Biomagnetics Diagnostics’ solution allows for much earlier, real-time disease detection and treatment. Importantly, the HTS-MTP solution is designed to detect both bacterial and viral pathogens, as well as drugs of abuse, using a wide range of body fluid samples including blood, serum, saliva, urine, hormonal or even spinal fluid. No single available diagnostic tool offers the ability to test any one of these fluids in the diagnosis of disease and other target agents.

Mechanics of the Proprietary HTS-MTP Diagnostic System

Biomagnetics Diagnostics’ principal product, its HTS-MTP system, consists of a new diagnostic solution that utilizes proprietary electronics and chemistry technology for the detection of a target pathogen (virus or bacteria) by measuring the magnetic field of micro-particles bonded to the pathogen. Specifically, the Company’s diagnostic system is a proprietary immunoassay test designed to detect target pathogens by measuring and defining the magnetic field of a single paramagnetic micro-sphere, which is coated with specific antibodies and attached/bonded to each pathogen molecule.

Logistically, the hardware component of the HTS-MTP system can be broadly likened to a “computer printer-and-paper type concept” in which multiple units of paper are continuously sold by the manufacturer/or another supplier over the lifetime of the printer. In this hypothetical example, the permanent hardware component of the HTS-MTP system is analogous to the approximate size and shape of a desktop printer, with the automated mechanics for testing located inside the “box.” Here, the automated mechanics are designed to extract the necessary chemicals (target antigen, fluorescence chemicals, and paramagnetic particles) from separate vials set within a removable tray, and dispense and combine them within available testing receptacles/wells located alongside these vials, also within the removable tray. Again, in this hypothetical example, the testing tray can be likened to the paper inserted into a desktop printer in that it is removable, disposable and designed to be replaced following use. This removable chemistry tray component of the Company’s HTS-MTP diagnostic system will be patented and designed to work only with Biomagnetics Diagnostics’ hardware equipment.

Regarding the Company’s proprietary chemistry technology involved in this process, the testing receptacles or wells located inside the
removable tray are coated with immobile primary antibodies that have
an affinity for attracting and binding with the disease antigen in
question. Thus, the ability to detect and distinguish between different
diseases is built into the proprietary chemistry of the Company’s
diagnostic test. Next, the bodily fluid sample containing the target
antigen is removed from the vial and dispensed into the testing well
where it is drawn/attracted to the bottom of the well by the primary
antibody. Next, a fluorescence chemical is dispensed into the well to
help detect the actual disease antigen, followed by a secondary
antibody with attached paramagnetic particles designed for a specific
disease that will also help detect and confirm the actual presence of
antigens in the sample. This entire process works as a chemical
reaction in diagnosing a particular disease from a sample of bodily
fluid.

The image below depicts an electronic microscope view of primary
antibodies coated on the base of a testing receptacle, secondary
antibodies coated on a magnetic particle, and the virus sandwiched in
between. This is one of the steps of the Company’s highly innovative
HTS-MTP device.

Once all the necessary chemicals (target antigen, fluorescence
chemicals and paramagnetic particles) have been combined in the tray,
a magnetic read of the mixture is taken, followed by a fluorescence
read, in order to determine the presence or absence of pathogens and
identify the associated disease and viral load. (A visual product
demonstration can be viewed on the Company’s website at
http://www.biomagneticsbmgp.com.)

Regarding the Company’s proprietary electronics technology involved
in this process, the adverse pathogens are detected through use of
specially designed magnetic resonance (MR) sensors, integrated into
the hardware component of the Company's exclusive patented
technology, that provide high throughput screening (HTS) in order to
detect the paramagnetic micro-spheres, each of which have a small
magnetic field around them that can be measured with the MR sensor.
The intensity of the magnetic field determines the test’s quantitative
results. As mentioned, these paramagnetic micro-spheres are coated
with specific antibodies that will bind to any antigen or other specified
target molecule within the bodily fluid sample. Finally, following the
magnetic read, a chemiluminescence read is performed to confirm and
backup the diagnostic results of the magnetic read. A software program
then automatically reads and displays the results in a format that can be
digitally saved.
With this technology, the Company’s diagnostic test has the capability to screen many more assays per hour, depending on the number of wells built into the removable testing tray, at a fraction of the cost in comparison to current technologies. This feature will enable a lab to perform far more tests in the same amount of time it would otherwise require to perform a single more traditional testing format. This aspect represents a breakthrough that could revolutionize the diagnostics industry and be of significant importance to blood banks and other testing locations around the world. In this regard, the Company’s HTS-MTP system achieves economies of scale in that the bodily fluid sample of many patients can be screened all at once for a disease, depending on the number of vials and testing wells built into the removable tray. Initial immunoassays will be developed to target the HIV and Hepatitis B viruses and HPV and H-pylori.

Viral Load

While today's immunoassays detect only a disease’s specific antibodies, or the blood proteins produced in response to counteracting foreign substances such as viruses and bacteria, and not the actual antigen (virus or bacteria) itself, they also do not evaluate viral load. In fact, most tests conducted in the United States are screening assays that are limited to the detection of antibodies, in the case of testing for HIV, only after a minimum infection time of two to six weeks, as it can take up to three months for the body to build up enough antibodies to be detectable, and thus they are used largely for disease detection purposes only. In fact, the Western Blot Test is the most widely used confirmatory test and it is based on the detection of antibodies only.

The Company’s HTS-MTP is the only single test solution designed to detect both the actual virus presence in bodily fluid (chemical identification of the elements present in a substance) as well as the specific viral load count (number of specific elements in a substance), all done economically in a matter of minutes. It is also virtually maintenance free.

Market Applications

Initial immunoassays for the Company’s High Throughput Screening - Magnetic Testing Platform (HTS-MTP) will be developed to target the HIV and Hepatitis B viruses and HPV and H-pylori, with other disease applications to follow.
HIV

The diagnostic process for HIV involves a screening test with wholesale costs ranging from $1.50 to $5.00, a confirmatory test costing between $25.0 and $35.0 and a viral load test with an expense of $50.0 to $80.0, all for a total cost of upwards of $120.00. This cost compares to that of the Company’s HTS-MTP diagnostic test which provides all three tests at a price point of just $2.50.

Blood Banks

In the United States alone, blood banks screen 14 million units of blood annually for seven types of viruses, including HIV and hepatitis B among others, for a total of 98 million tests conducted per year. Interestingly, use of existing diagnostic equipment to screen for hepatitis B alone, for example, has added $8.0 to the cost of a unit of blood, while the use of equipment to screen for HIV has added $5.0. Biomagnetics Diagnostics’ HTS-MTP is developing a diagnostic system that can test for all seven viruses currently being screened for in each unit of blood, in a single assay, thus greatly reducing the cost to blood banks of analyze incoming blood.
COMPETITION

State of the Competitive Playing Field

The diagnostics industry is competitive and certain factors increase the competitive challenges, particularly for smaller, innovative companies. Specific factors known to influence the level of competition within the diagnostics industry include actual and perceived uncertainties, risks and benefits inherent in pursuing certain regulatory requirements (i.e., 510[k], PMA and ASR registration) and reimbursement pathways for similar products in the market place, where such options exist. In some instances, familiarity with these processes, access to capital and lack of transparent guidance in emerging areas of technology may result in an uneven playing field for competing companies.

Additionally, the customer base of the industry has undergone changes that affect purchasing power and demand for diagnostics. Laboratory customers, for example, have undergone consolidation and are more likely now than in the past to be members of group purchasing organizations (GPO’s), which tend to establish contracts with larger diagnostic companies in order to reduce administrative costs. This situation makes it easier for a lab to purchase from a larger provider than from a smaller one.

Another factor affecting competition in the diagnostics industry is its heavy reliance on patents. Due to the highly technical and research-intensive nature of the industry, patents offer protection for companies that undertake risky R&D efforts in order to ensure that they benefit exclusively from the success of their efforts for the life of the patent (typically around 20 years). Without the prospect of patent protection, there would be little incentive for diagnostic firms to undertake R&D projects at considerable expense and risk to their shareholders. Importantly, Biomagnetics Diagnostics Corp. has been issued two patents on its first diagnostic system.

Competitors in the Diagnostic Testing Industry

Competitors in the diagnostic testing market include every major pharmaceutical company that possesses capital availability, existing distribution channels and technical and personnel resources. The field of rapid diagnostic test makers for malaria alone has grown from a single manufacturer 15 years ago to include over 50 manufacturers of such tests today. Regarding tuberculosis, the lack of commercial
interest in TB diagnostics is discordant with the need for such tests, defined both by the size of the global TB epidemic and the inadequacy of the available test methods.

Some of the industry’s foremost players and a few of the main diagnostic markets in which they participate are listed below:

- **Abbott Laboratories** (NYSE: ABT) – Hepatitis, AIDS tests.
- **Johnson & Johnson** (NYSE: JNJ) - Diagnostic testing and blood screening products; in vitro diagnostic oncology products for physicians (Veridex, LLC, a J&J company); HIV-1 drug resistance testing (Virco, a J&J company).
- **Quest Diagnostics** (NYSE: DGX) – Hepatitis, HIV and other sexually transmitted diseases.
- **Roche Holding AG** (VTX: ROG.VX) - In-vitro diagnostics for a wide range of disease screening and diagnosis in laboratories, at the point of care, and for patient self-management. Diagnostics for diseases include anaemia, cancer, cardiovascular disease, central nervous system disorders, chlamydia, diabetes, gonorrhea, tuberculosis and others.
- **Siemens Healthcare Diagnostics** (NYSE: SI) - Infectious disease immunoassay and molecular testing for diagnosing hepatitis and HIV.

**Next Generation Diagnostic Technologies**

While technology in all diagnostic formats, from microscopy to immunological assays and others, advances each year, one general trend among many of the larger, well capitalized competitors is the goal of developing the self-contained “lab-on-a-chip” diagnostic tool. While this format is very accurate, it is nonetheless cost prohibitive for mass deployment among large global populations and in terms of the numerous disease possibilities that exist and need to be tested.

As a competitor in the diagnostics field, Biomagnetics Diagnostics Corporation believes simpler, cost effective, easy-to-use and quick-to-deploy solutions, such as the use of magnetics and laser/sensor technology, are the best answer for foreseeable future in which health care budgets are increasingly constrained in the developed world and infectious diseases present a growing problem for the developing world where diagnostic tools should also be both portable and durable.
GLOSSARY of TERMS

**Analyte** - An analyte is a substance or chemical constituent that is determined in an analytical procedure. There are two primary types of analytes, namely antibodies and antigens.

**Antibody** – An antibody is a protein (immunoglobulin) produced by B-lymphocytes (immune cells) in response to stimulation by an antigen.

Our bodies fight off an infection by producing antibodies. Antibodies are infection-fighting protein molecules normally present in the blood or secretory fluids that are produced in response to an antigen or foreign object (ie: toxins or pathogenic microorganisms, including bacteria or viruses). Antibodies tag, neutralize and help destroy antigens, thus producing an immune response. An antibody reacts specifically with the antigen that triggered its formation and its function is to inactivate the antigen.

**Antigen** - Any substance, such as a toxin or enzyme, that stimulates an immune response in the body, especially an immune response that stimulates the production of antibodies.

**Buffy Coat** - Following gradient centrifuging, the buffy coat is the fraction of an anticoagulated blood sample that contains most of the white blood cells and platelets.

**Chemiluminescence** - Chemiluminescence is the emission of light, with limited emission of heat (luminescence), as the result of a chemical reaction.

**Immunoassay** - An immunoassay is a biochemical test that measures the concentration of a substance in a biological liquid, typically blood, serum or urine. Identification of a substance, especially a protein, by its action as an antigen.

**Immunology** - Immunology is a broad branch of biomedical science that covers the study of all aspects of the immune system in all organisms. It deals with, among other things, the physiological functioning of the immune system in states of both health and disease; malfunctions of the immune system in immunological disorders (ie: autoimmune diseases, hypersensitivities, immune deficiency, transplant rejection); and the physical, chemical and physiological characteristics of the components of the immune system in vitro, in situ and in vivo.

**Microscopy** - The technical field of using microscopes to view samples or objects.
Parasitemia – Parasitemia is the quantitative content of parasites in the blood. It is used as a measurement of parasite load in the organism and as an indication of the degree of an active parasitic infection. Systematic measurement of parasitemia is often important in many phases of disease assessment including diagnosis and follow-up therapy, particularly during the chronic phase when reaching a cure depends on ascertaining a parasitemia level of zero.

Pathogen – A pathogen is any disease-producing agent, especially a virus, bacterium or other microorganism.

Parasitological examination - Includes examination of feces for protozoa, worm eggs or larvae and for tapeworm segments; skin scrapings for arthropod parasites; blood samples for protozoa; microfilariae; for plasma pepsinogen levels; and examination of gross specimens.

Reagent - A reagent is any substance used in a chemical reaction. It usually implies a chemical that is added in order to bring about the chemical change. For example, hydrochloric acid is the chemical reagent that would cause calcium carbonate to release carbon dioxide.

Sensitivity - Sensitivity is the ability of a diagnostic test to detect a person having an illness, as a positive case accurately.

Specificity - Specificity is the ability of a diagnostic test to detect a person who does not have an illness as a negative case accurately.

Vector - Traditionally in medicine, a vector is an organism that does not cause disease itself but which spreads infection by conveying pathogens from one host to another.
**Analyst and Other Important Disclosures**

Analyst Certification - I, Joseph Noel, hereby certify

(1) that the views expressed in this research Company report accurately reflect my personal views about any or all of the subject securities or issuers referred to in this Company report and

(2) no part of my compensation was, is, or will be directly or indirectly related to the specific recommendations or views expressed in this Company report.

**Analyst:**

Joseph Noel is a 29-year veteran investment and technology industries. Joe was recently a senior analyst at Pacific Growth Equities, LLC, where he tracked the communications equipment/services and advanced industrial sectors. Prior to Pacific Growth, he covered both the telecommunications equipment and services industries at Hambrecht & Quist and was employed by Gartner/Dataquest as a communications industry analyst. Before becoming an analyst, Mr. Noel received solid industry experience at a number of telecommunications carriers, including MCI, where he was responsible for the frame relay product marketing launch; and British Telecom, where he was involved in strategic planning for the Company’s Internet access service. He was also employed by various Bell Operating Companies in both marketing and technical roles for nearly ten years. Mr. Noel received his MBA in finance from Wake Forest University, and holds a BS in business and economics. A four-time Wall Street Journal All-Star Analyst, Joe specializes in emerging growth companies in the communications, Internet and advanced industrial equipment sectors.

The coverage analyst uses a relative rating system in which stocks are rated as: BUY, SELL or HOLD.

**Stock Ratings:**

BUY - the stock is expected to outperform the unweighted expected total return of the sector over a 12-month investment horizon.

SELL - the stock is expected to under perform the unweighted expected total return of the sector over a-12 month time horizon

HOLD - the stock is expected to perform in line with the unweighted expected total return of the sector over a 12-month investment horizon.

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