CEO CFO

MedaSorb CytoSorbents™

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MedaSorb Technologies Corporation In Clinical Trials With CytoSorb™ - A Promising Therapeutic Approach Addressing The Wide Open Multi-Billion Dollar Sepsis Market

Healthcare
Medical Devices
(MSBT.OB)

MedaSorb Technologies Corporation
and its operating subsidiary
CytoSorbents, Inc

7 Deer Park Drive, Suite K
Monmouth Junction, NJ 08852
Phone: 732-329-8885
www.medasorb.com
www.cytosorbents.com

Dr. Phillip Chan MD, PhD
Chief Executive Officer

BIO:
Prior to MedaSorb, Dr. Chan led healthcare life science investments as Partner for NJTC Venture Fund. He was responsible for numerous investments in therapeutics, medical devices and diagnostics. Dr. Chan also co-founded Andrew Technologies, a medical device company developing advanced surgical instruments for minimally invasive surgery. Dr. Chan is a Board-certified internal medicine physician with a strong background in clinical medicine and research. He completed his residency at Harvard Medical School at the Beth Israel Deaconess Medical Center. Dr. Chan received his MD/PhD from Yale University School of Medicine and his BS in cell and molecular biology from Cornell University.

Company Profile:
MedaSorb Technologies Corporation (OTCBB: MSBT) is a publicly-traded medical device company focused on treating human diseases through blood purification. It is currently in clinical trials with its flagship product CytoSorb™ - a patented highly porous polymer bead technology designed to reduce "cytokine storm" and treat severe sepsis, a major cause of death across the world.

MedaSorb became public June 30, 2006 through a merger transaction with Gilder Enterprises, a Nevada Corporation. MedaSorb is headquartered in Monmouth Junction, New Jersey and operates through its wholly-owned subsidiary, CytoSorbents, Inc.

Disclaimer: Any statements in this interview that are not historical fact are considered forward looking statements and are made pursuant to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Please see the Company's SEC filings for additional detail.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFOinterviews.com

CEOCFO: Dr. Chan, what is your vision at MedaSorb?
Dr. Chan: "MedaSorb Technologies Corporation is a medical device company focused on treating severe sepsis with a novel blood purification device called CytoSorb™. Severe sepsis, often called 'overwhelming infection', is very common affecting all ages, all walks of life, and all ethnicities. Unfortunately most of us know someone – a loved one, a relative, a friend, a co-worker perhaps, that developed a severe infection like pneumonia, a kidney infection, a ruptured appendix or even influenza, requiring intensive care treatment including, for example, mechanical ventilation to help them breathe, dialysis to replace failed kidneys or strong medications to support falling blood pressure. This is severe sepsis and it afflicts more than 1 million people in the US annually, 18 million people worldwide, and kills 1 in every 3 patients despite the best medical care. In fact, more people die of severe sepsis in the US than die from either heart attacks, strokes or any single form of cancer. And the numbers are growing. An aging population, an increase in antibiotic resistant bacteria, the increased use of implantable devices like artificial hips and knees, and co-morbid diseases like cancer and the diabetes epidemic are just some of the factors that put people at higher risk of infection. And all of these are driving the occurrence of sepsis. Sepsis is also one of the most difficult and expensive diseases to treat, costing our healthcare system more than an estimated $18 billion annually. Our goal at MedaSorb is to develop CytoSorb™ as a significant therapy to address this major medical need."

CEOCFO: Would you tell us about your CytoSorb™ technology and how it works?
Dr. Chan: "In order to understand how our technology works, it is important to understand what causes severe sepsis. Severe sepsis is typically caused by two processes. The first is the infection, usually bacterial or viral, that triggers the sepsis cascade and can often be treated with antibiotics or antiviral drugs. The second and often more devastating, however, is the body's abnormal immune response to the infection. In response to a mild infection, the body normally produces substances called cytokines. Cytokines are protein messengers that stimulate the immune system to fight off the infection and help regulate it. However, in severe infection, in many people, the body's immune response often goes haywire, producing massive amounts of these cytokines in something called cytokine storm. At these levels, cytokine storm causes direct cell death and organ dam-

age, ultimately leading to organ failure and in many cases death. Cytokine storm is widely accepted by the medical and research communities as the underlying cause of organ failure and a major contributor of death in severe sepsis. If you do a PubMed or literature search on 'cytokines' and 'sepsis' you will literally bring up ten thousand articles. As an example of cytokine storm, if you've ever had the flu, it's not the virus but really the body's immune response to the virus and the mini-cytokine storm that ensues that causes the fever, chills, body aches, extreme fatigue and the feeling of being extremely ill. In severe sepsis, this process is greatly magnified to where these cytokines actually cause direct toxic injury to the body, leading to organ failure and death. In sepsis due to both gram positive and gram negative bacteria, this process is very clear and widely accepted. In viral infections, such as those caused by the SARS virus or virulent strains of influenza such as avian flu or swine flu, cytokine storm has been implicated as a major contributor of complications that can lead to death. Cytokine storm can also cause the immune system to become dysfunctional, preventing the body from being able to fight infection at the worse possible time.

The reduction of cytokine storm has been the holy grail of the medical industry for the past three decades. Though many have tried, most have been unable to reduce more than a single cytokine or inflammatory mediatory or impact more than one part of the sepsis cascade. As such, most of these therapies have failed. There is so much redundancy in the immune system during severe sepsis that the removal of just one cytokine has little effect because 10 others quickly take its place. As evidence of this, there are currently no FDA approved treatments to specifically reduce cytokine storm. What is needed is a broad spectrum removal approach that can eliminate large amounts of many different cytokines simultaneously. At MedaSorb, we believe we have developed such a solution. We are pioneers in the rapid and broad removal of cytokines from blood. CytoSorb™ is a highly porous resin that acts as a state-of-the-art cytokine filter designed to reduce cytokine storm in severe sepsis. We are currently running, to our knowledge, the largest randomized, controlled trial of its kind for broad cytokine reduction. It is an up to 100-patient study in Europe involving patients with severe sepsis in the setting of respiratory failure. We treat patients very simply. Using standard hospital dialysis equipment, blood is pumped though a CytoSorb™ cartridge where the resin binds and removes cytokines and other toxins related to sepsis, and the purified blood is then put back into the body. We treat patients for 6 hours a day for 7 days, each day with a new device."

"Severe sepsis, often called 'overwhelming infection', afflicts more than 1 million people in the US annually, 18 million people worldwide, and kills 1 in every 3 patients despite the best medical care. More people die of severe sepsis in the US than die from either heart attacks, strokes or any single form of cancer. Severe sepsis is caused by two processes. The first is the infection that can often be treated with antibiotics. The second, and often more devastating, is the body's abnormal immune response to the infection and the production of massive amounts of cytokines called cytokine storm. Cytokine storm is widely accepted by the medical and research communities as the underlying cause of organ failure and a major contributor of death in severe sepsis. There are currently no FDA approved treatments to specifically reduce cytokine storm. CytoSorb™, as an efficient cytokine filter, could fill this gap and potentially represents a truly novel 'game-changing' advance in the treatment of sepsis."

- Dr. Phillip Chan MD, PhD

CEOCFO: So, a single CytoSorb™ cartridge is only used once?

Dr. Chan: "Yes and this is the basis of our strong business model. A typical patient in our trial uses seven CytoSorb™ cartridges. A similar hemoperfusion charcoal cartridge used for drug detoxification, but that cannot efficiently remove cytokines, is currently sold for $500 per device. At this price point, CytoSorb™ has exceptional profit margins with a course of treatment costing $3,500. This is very affordable for hospitals, especially since a sepsis patient costs the hospital more than $3,000 for each day they stay in the intensive care unit. If CytoSorb™ can speed recovery and get a patient out of the intensive care unit just one day faster, it could pay for itself. In addition to being a high profit margin disposable, CytoSorb™ is compatible with standard hemodialysis equipment found in any major hospital. This is very important in this cost conscious environment, since hospitals don't need to purchase any additional equipment to use our device. Also, the device can easily be run by a technician familiar with dialysis, so no significant training is needed. CytoSorb™ is very much a plug and play device and is a high margin 'razorblade' that can drive usage of other companies' 'razor' dialysis machines. We think that a number strategic partners will see the potential of our CytoSorb™ cytokine filter."

CEOCFO: How is severe sepsis currently being treated?

Dr. Chan: "Severe sepsis remains a major, unmet medical need. Currently, patients with severe sepsis are treated predominately with standard of care therapy that includes antibiotics, fluid resuscitation, and nutritional and metabolic support. When necessary, other interventions like mechanical ventilation, dialysis and vasopressors are used. Though this is considered the best care available, the mortality of severe sepsis is still roughly 30-35%. The only FDA approved product to treat sepsis is called Xigris®. This is a good drug manufactured by Eli Lilly and Company (NYSE: LLY), but has not been widely embraced by the physician community due to high cost, controversy about efficacy and when to use it as well as potentially dangerous side effects. In a multi-billion dollar market, it had less than $200 million in annual worldwide sales in 2008. We hope to demonstrate that

CytoSorb™ plus standard of care therapy is better than standard of care therapy alone."

CEOCFO: Would you tell us about your clinical trial that is being conducted in Europe?

Dr. Chan: "We are currently running an up to 100 patient, randomized, controlled human trial in Europe to treat patients with severe sepsis in the setting of respiratory failure. We have recruited 28 patients from 4 clinical sites to date and expect recruitment to accelerate now that we have a total of 12 sites. The primary endpoint of the trial is cytokine reduction. However, the secondary and tertiary endpoints include all of the things that both regulatory agencies like the FDA and clinicians are interested in, including 28-day and 60-day all-cause mortality, ventilator-free days, organ failure scores, hemodynamic stability, vasopressor use and others. We plan to finish this trial by the end of 2009 and to have data to support both strategic partnership and investor discussions. We also plan to obtain CE Mark approval in Europe in the first half of 2010 and begin commercializing and selling our device in Europe in 2010 as well."

CEOCFO: What about the safety of your device?

Dr. Chan: "Similar to antibiotics, the treatment for severe sepsis with our device is also considered short term, approximately 7 days of treatment. Because of this, short-term, rather than chronic, safety is the main issue. CytoSorb™ has passed strict FDA and medical device standards for safety and quality. For example, CytoSorb™ passed strict ISO 10993 biocompatibility standards used to evaluate 30-day implantable medical devices. These tests demonstrated that CytoSorb™ was safe on blood and blood cells and did not cause any acute or systemic toxicity in animals. In addition, the effluent of the CytoSorb™ device also passed USP particulate standards for large parenteral injections. We have also tested our device in humans in roughly 460 treatments, more than 100 of which have been in sepsis patients, and there have been no severe device related adverse events. The treatment has also been well-tolerated by patients. We don't expect there to be any long term negative effects of treatment with our device. On the contrary, we expect there to be improved long-term outcome in patients by preventing some of the horrible sequelae that happen because of severe sepsis."

CEOCFO: How do you get the medical community's attention?

Dr. Chan: "As I mentioned earlier, severe sepsis kills one in every three patients despite the best medical care. As a physician, this is a horrible statistic, yet it's even worse when a patient is dying in front of your eyes and you can't do anything about it. Sepsis is such an important and costly medical problem that if we can demonstrate that CytoSorb™ can save lives, our therapy and company will become widely known amongst not only potential investors and strategic partners, but more importantly by the physicians who will use it. We have a distinguished Critical Care Advisory Board that includes some of the top thought leaders in critical care medicine and blood purification who can speak about our technology. We also plan to publish our results and present at major annual conferences such as the International Sepsis Forum and the Congress of the Society of Critical Care Medicine. These activities will supplement interest by the popular press as well as our own PR activities."

CEOCFO: Cytosorb™ can potentially revolutionize and really impact a major problem!

Dr. Chan: "Although we are waiting for the results of our trial, we firmly believe it can. MedaSorb/CytoSorbents is a pioneer in the use of blood purification and cytokine removal to treat severe sepsis and all of us at the company are truly passionate about our mission to help these patients, as most of us have been touched by it somehow. And then you hear on the news how people we don't even know are affected. The deaths in the current swine influenza pandemic are just one example of how critically ill patients are dying from complications of infection and severe sepsis and how modern medicine is still poorly equipped to save these patients. I can't imagine what would have happened if this virus were more deadly. Already with normal seasonal influenza, 40,000 people die each year in the US. The story of Mariana Bridi da Costa, the young Brazilian model who, at age 20 earlier this year, developed a severe urinary tract infection, and had to have her hands and feet amputated before ultimately succumbing to sepsis is another tragic example. Here, the infection was recognized late but physicians knew what the bacteria was, and were giving the appropriate antibiotics to treat it, but had no way to treat the cytokine storm that contributed to her death. CytoSorb™, as an efficient cytokine filter, could fill this gap and represents, what we believe, a truly novel 'game-changing' advance in the treatment of sepsis."

CEOCFO: What is the commercialization plan?

Dr. Chan: "We plan to complete this trial by the end of 2009, obtain CE Mark approval and begin commercializing the device by 2010 in Europe through independent distributors with a particular focus on Germany where our trial is taking place. Germany is the largest medical device market in the European Union and third in the world. We are currently looking for a strategic partner to license CytoSorb™ for the sepsis application and to help market and distribute the device throughout Europe through their sales force and distribution channels, providing a more rapid revenue ramp.

CEOCFO: What is the financial picture like for MedaSorb?

Dr. Chan: "We ended the first quarter of 2009 with $2.15 million in cash and are looking at creative ways to supplement our current cash position. We want to ensure that we have enough resources to comfortably finish our trial and have time to raise additional capital and sign a strategic partner based on what we hope will be encouraging results."

CEOCFO: What about potential reimbursement, ease of use, training needed and all those little pieces that make CytoSorb™ viable for doctors to utilize?

Dr. Chan: "We are running our trial in Germany. In terms of reimbursement, the hospital system in Germany works on a fixed DRG or 'diagnosis related group' payment system, similar to the United States. For a given in-patient diagnosis, hospitals receive a fixed payment. If patients stay longer than expected, hospitals bear the cost. If patients get better more

quickly, the hospital earns a profit on those patients. Sepsis is one of those illnesses that hospitals routinely lose money on because the treatment is so expensive and the outcome is so variable. We believe if we can get patients off of the ventilator sooner, out of the intensive care unit faster or otherwise get patients better more quickly, hospitals will embrace our technology.

In terms of ease of use, our trial sites have mentioned that CytoSorb™ is much easier to use than dialysis, the most widely used blood purification technology. Very little training is necessary since it uses standard dialysis equipment and a technician can easily run the treatment. We call it 'plug and play'. Yet CytoSorb™ is state-of-the-art technology. It is extremely efficient at removing cytokines and has massive capacity. For example, in comparison with a standard hemodialyzer that has the surface area of roughly two to three square meters, or about the size of your kitchen table, on which to bind cytokines, a single CytoSorb™ cartridge has the surface area of seven football fields. This is one of our major competitive advantages and is a major reason why we have the potential to impact cytokine storm when others cannot. Another major advantage is that whole blood can be treated with our hemocompatible resin directly, while other technologies need to separate blood first. This makes treatment elegantly simple. CytoSorb™ also has great logistics. Because it contains no biologics, cells or antibodies, it can be stored at room temperature on a shelf until needed. We currently have three years of shelf-life stability. This, by the way, adds to the profitability of our device. One of the reasons that antibodies or cell-based therapies are so expensive is that they degrade and expire and then have to be remanufactured. We don't have that problem. We manufacture CytoSorb™ at our manufacturing facilities in New Jersey under strict, highly reproducible and well-documented standards."

CEOCFO: In closing, address potential investors; what makes MedaSorb stand out?

Dr. Chan: "First, our CytoSorb™ approach is based on excellent science, the reduction of cytokine storm, widely accepted as the root cause of organ failure and often death in sepsis. No therapies have been approved to specifically treat cytokine storm because previous technologies have been inadequate. MedaSorb/CytoSorbents is a pioneer in cytokine removal from blood and CytoSorb™ represents a superior solution that has the potential to finally impact cytokine storm. We have strong, peer-reviewed, published, pre-clinical data that demonstrates this approach works to improve survival in animals. The technology is broadly patented with 26 issued patents and multiple applications pending. And the technology and manufacturing process has been the beneficiary of approximately $65 million in invested capital. Secondly, we address an estimated $6 to 8 billion

dollar market in the US and Europe alone. This is an underserved market with relatively few competitors compared to other medical fields. Even a small commercial success could result in a great investment. Third, as a critical care therapy that treats a costly, major unmet medical need, CytoSorb™ has the ability to command premium pricing. Coupled with our low manufacturing cost, and the fact that we are a plug and play, high margin 'razorblade' disposable that works in others' 'razors', we have an extremely profitable business model. Fourth, we believe there is strong overall near and long-term potential for investors based on a number of targeted milestones. The first is the successful completion of our European sepsis trial, anticipated by the end of 2009, which could be an inflection point for our business. The second is our efforts in business development. We believe we have a compelling technology and business model that are valuable to a number of companies, many of whom we have been and are currently talking to. Historically in the medical device and pharmaceutical industries, the value of a strategic partner has been to provide credibility and third-party validation of the technology, provide capital to offset financial needs, provide co-development funding to carry out clinical studies, and to drive sales through their established sales and distribution channels. Another milestone would be CE Mark approval and initial European commercial sales of CytoSorb™ that is anticipated in 2010. This would transform the company from a pre-revenue development-stage company to a commercial revenue-stage company with a significantly different risk profile. We also plan to leverage our FDA Investigational Device Exemption protocol approval obtained in 2007 to run a larger pivotal trial in the US. We hope to start such a study in late 2010. Next, CytoSorb™ is based on a broad polymer platform technology and is only one of a number of different resins that we have developed for a variety of clinical applications. We actually have a number of proof-of-concept studies for many of these applications that we are actively looking to out-license to potential partners. This represents a potential near-term revenue stream for MedaSorb. Also, our technology has a potential role in both military and homeland security applications, something that we are actively pursuing. Finally, we believe we have a strong story that will hopefully continue to get even better. As such, we will continue to work to create greater awareness of our company and its prospects in the investment community – an initiative that should benefit all shareholders. Our goal is to build a successful, highly profitable and lasting business that can help save the lives of many people across the world with sepsis."