



# CytoSorbents™

Working to Save Lives Through Blood Purification

**CytoSorbents Corporation (OTCBB: CTSO)**  
**2013 Earnings and Operating Results Conference Call**  
**March 31, 2014 @ 4:15 pm Eastern**

*This official company transcript has been edited for clarity and does not differ materially from the actual conference call. Slide numbers have been inserted to allow readers to follow along with the associated presentation.*

**Operator:**

Good day, ladies and gentlemen. Thank you for standing by. Welcome to the CytoSorbents® 2013 Shareholder Update Conference Call. During today's presentation, all parties will be in a listen-only mode. This conference is being recorded today, March 31, 2014.

I would now like to turn the conference over to our moderator, Ms. Donna Marincas. Please go ahead, Donna.

**Donna Marincas – Moderator:**

Thank you operator and good afternoon. Welcome to CytoSorbents 2013 Operating and Financial Results Conference Call.

**Slide 3:** With us today are:

- Dr. Phillip Chan, Chief Executive Officer and President
- Vincent Capponi, Chief Operating Officer
- Kathleen Bloch, Chief Financial Officer
- Dr. Christian Steiner, VP of Sales and Marketing from Germany and
- Chris Cramer, VP of Business Development

**Slide 2:** Before I turn the call over to Dr. Chan, I'd like to remind listeners that during the call, management's prepared remarks may contain forward-looking statements which are subject to risks and uncertainties. Management may make additional forward-looking statements in response to your questions today. Therefore, the Company claims protection under Safe Harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. Actual results may differ from results discussed today and therefore, we refer you to a more detailed discussion of these risks and uncertainties in the Company's filings with the SEC. Any projections as to the Company's future performance represented by management include estimates today as of March 31, 2014 and the Company assumes no obligation to update these projections in the future as market conditions change.

During today's conference call, we will first have an overview presentation covering the financial and operational highlights for the quarter by Dr. Chan and Ms. Bloch. We again have done our best to take everyone's submitted questions and will do our best to address them in the presentation, but also in a Q&A session with management to

follow. Thanks everyone again for participating. If we do not answer your question, we would ask you to contact the Company directly after the call today.

At this time, I would like to turn the call over to Dr. Phillip Chan. Please go ahead Dr. Chan.

**Phillip Chan - CEO:**

Thanks very much Donna and welcome everyone to our 2013 operating and financial results conference call. Thank you for taking the time to join the call today.

Since our last earnings report, there have been a lot of developments and we definitely have new shareholders online today. What I'd like to do is go over a brief summary of the company for the benefit of those new shareholders as well as for those who need an update of our story. Following that, Kathy will give a brief overview of our financial and operating progress for the quarter as well as for 2013, and I will come back on the line with an overview of the catalyst for 2014 that will help us drive growth for this year.

**Slide 4:** CytoSorbents® is an emerging leader in critical care immunotherapy. We are leading the prevention or treatment of life-threatening inflammation in the intensive care unit. When we talk about immunotherapy, broadly taken, it is the ability to manipulate the immune response to help fight disease. This is a \$100 billion revenue market. This is not a total addressable market, this is not a potential theoretical market. This is actually a market that has \$100 billion in revenues from blockbuster products focused on manipulating the immune system.

**Slide 5:** Now we all know that in order for the immune response to function normally, it has to be not too high and not too low. When the immune system is not functioning well, people are at high risk of developing infection, cancer, as well as poor healing. And on the other end of the spectrum, when the immune system is too high, patients are at high likelihood of developing things like allergy, asthma, anaphylaxis, autoimmune diseases, severe inflammation such as sepsis and SIRS, and organ failure.

Companies have worked to try to counter this by developing products, that when the immune system is too weak, will activate the immune response. Vaccines are an excellent example of that. The five top companies in the vaccine space include Sanofi, Merck, GSK, Pfizer and Novartis, and together have \$26 billion in vaccine revenue alone - it is a \$30+ billion category overall. And in the cancer immunotherapy space, \$20 billion in product revenues are generated every year with such blockbuster products such as Rituxan, Herceptin, Erbitux and others and even cancer vaccine such as Provenge and other immunotherapies such as Yervoy from Bristol-Myers Squibb.

On the high end, when we're trying to suppress the immune response, all of us have no doubt taken antihistamines for seasonal allergies, or steroids for other complications of inflammation. Blockbuster products such as Zyrtec, Claritin, Allegra, and asthma medications such as Advair and Singulair produce more than \$20 billion in revenues every single year. And in the treatment of autoimmune diseases, blockbuster products such as Enbrel from Amgen, Humira from AbbVie and Remicade from Johnson & Johnson, those three products alone have \$26 billion in worldwide revenue every year. And again, this is a \$30+ billion revenue market overall.

But where CytoSorbents fits is really in a space where we're almost by ourselves - this is in the critical care immunotherapy space where we're trying to reduce the deadly inflammation that is leading to organ failure and death in patients with diseases like sepsis, burn injury, trauma and many others. CytoSorb® is a product that is approved in all 28 countries of the European Union, and is currently commercially available in nine countries generating revenue, with 30+ post-market studies, the support of more than a 100 key opinion leaders, and little-to-no competition.

**Slide 6:** So what is the \$20 billion critical care opportunity? Unfortunately many of us on the phone today know someone who has been admitted into the intensive care unit for a life-threatening illness. In fact, millions of people are admitted to intensive care units every year in the U.S. and in the European Union with deadly inflammation caused by

inflammatory conditions such as sepsis, ARDS (acute respiratory distress syndrome), burn injury, trauma, pancreatitis, influenza, and complications of surgery. In fact, in these conditions, little exists to reduce inflammation and actively help patients get better. Rather, patients often need to be kept alive with machines called “life support”...things like mechanical ventilation and dialysis... with the hope that their bodies heal on their own over time. So without active therapies, patients linger in the ICU at cost of \$2,000 to \$3,000 a day in the United States. Despite having some of the best medical treatment in the world, here in the United States still one in every three patients often die in these life-threatening conditions. Because of this, and because of the lack of effective therapies to actively impact outcome, the U.S. alone spends almost 1% of our gross domestic product, a staggering \$80 - \$90 billion on critical care medicine every single year.

**Slide 7:** So what is driving this inflammation? Well, the inflammation is being driven by small proteins called cytokines that normally orchestrate the immune response, and normally help stimulate and regulate the immune system to control inflammation. But cytokines are very much a dual-edged sword. They are required for proper immune system function but when they are elevated they can actually cause or exacerbate diseases such as autoimmune diseases.

**Slide 8:** But when they are in vast excess, as is often found in patients with life-threatening conditions, it’s often called “cytokine storm” and that cytokine storm leads to massive uncontrolled inflammation that leads to the failure of vital organs, such as the lungs, the brain, the heart, the kidneys, the liver and many other vital organs in the body. In fact, organ failure causes nearly half of all deaths in the ICU today and little can be done to prevent or treat it.

**Slide 9:** So that is where we come in. CytoSorb® is specifically designed to remove the fuel to the fire of inflammation in the body. In fact, it represents one of the newest and most powerful immunotherapies to control inflammation. It’s approved in the European Union as the only specifically approved cytokine filter and it is clinically proven to reduce key cytokines and cytokine storm by 30% to 50% in critically-ill patients. It has a very broad indication for use, approved for use in any situation where cytokines are elevated, and it’s now been used safely in more than 1,500 human treatments with no serious device related adverse events.

**Slide 10:** The heart of our technology is what you see here in this slide. It is a highly biocompatible, porous polymer bead roughly the size of grain of salt that acts like a tiny sponge to remove harmful substances from blood and bodily fluids. The beads remove things based on size as well as surface adsorption. These beads are protected by 32 issued U.S. patents and multiple applications pending and we manufacture these beads from raw chemicals at our ISO 13485-certified facility in New Jersey. In fact these beads are one highest grade medical sorbents on the medical market today.

**Slide 11:** So the goal of CytoSorb® is really to try to prevent or treat organ failure. When patients come into the ICU either from the emergency room or from the hospital wards, they are typically highly unstable. The goal of CytoSorb therapy is to try to prevent them from spiraling down that rabbit hole of organ failure from which there is often no return. Our goal is to try to prevent them from getting so sick, to prevent organ failure from happening or to treat it, thereby hoping to improve patient outcome and survival, while decreasing the costs of ICU and patient care.

**Slide 12:** CytoSorb® truly has the potential to revolutionize critical care medicine and it is not only our belief. In fact, we now have more than \$15 million in U.S. government support from groups like DARPA, that has awarded us \$3.8 million over five years as part of their Dialysis-Like Therapeutics program to treat sepsis, the U.S. Army which has awarded us \$1.15 million in SBIR contracts for trauma and burn research, the U.S. Air Force that is funding a 30-patient human pilot study in trauma valued at about \$3 million, and a Phase I SBIR grant that we were recently awarded by the National Heart, Lung, and Blood Institute for our HemoDefend™ platform which tries to improve the quality and safety of blood transfusions. So with that, that covers the brief overview of the technology and the company.

**Slide 13:** What I’d like to do right now is, transition to the operating and financial highlights for last year.

**Slide 14:** Before I hand it over to Kathy, I think it’s very important to note that not only are we trying to address a major unmet medical need with what we believe is an exceptional product. But CytoSorb®, in fact, has an excellent business

model as well. We are addressing a huge \$20 billion worldwide critical care opportunity with a “need-to-have” type product, because we’re really dealing with the difference between life and death. We’re not talking about temporary discomfort and someone who has pain and giving them a better drug to relieve the pain. This is really talking about life or death.

We also have little or no competition. And critical care physicians understand the problem. When we go in to talk to physicians, what we say is that the product is designed to control cytokine storm, to reduce the deadly inflammatory response, in order to try to prevent or treat organ failure. They already know this is the problem. They get it. This is in all the conferences, all the literature in critical care. This is the exact problem that they face and we have a therapy that can potentially help them solve that problem. So, very little education is needed to get them to understand the product.

This is a plug-and-play, high margin disposable “razor blade in someone else’s razor business model”. We work with the standard hemodialysis machines that are found in hospitals today, so hospitals do not need to buy any new hardware. Our cartridges fit right into those machines and can be run by the existing technical staff with the existing hardware infrastructure. As to the next point, technicians already know how to use the device, and this in fact, we’ve been told, is easier to use than even standard hemodialysis, which is the most common blood purification technology in the world.

CytoSorb® is also reimbursed in Germany and Austria at more than \$500 per cartridge and depending on the application and the number of devices used, the revenue potential per patient is on the order of about \$1,000 to \$5,000 per patient. So when you talk about the United States, there are about one million patients every year with severe sepsis or septic shock. At \$5,000 a patient, which would involve usage of multiple cartridges, that’s a \$5 billion total addressable markets in the United States alone, for that one single indication.

This is an affordable and yet very profitable product with gross margins of greater than 60%, and with volume and economies of scale, we are targeting gross margins greater than 80%. Because of this, it has the ability to produce cash flow very rapidly, and we’re already using that cash flow to help offset our operating expenses. And last but not least, intensive care units are highly centralized and it is very easy for a small sales force such as ours to be able to access the market effectively.

So with that, I’d like to turn it over to Kathy to cover our 2013 revenue results.

**Kathleen Bloch - CFO:**

Thank you, Phil. Good afternoon everyone.

Right now we’re going to cover some of the company’s key financial results. And of course we encourage everyone listening to refer to our press release and our annual report on Form 10-K for more detailed information regarding our operating results.

**Slide 15:** First, a look at revenue. Our total revenues for 2013 were approximately \$2.4 million. 2013 was our first full year of product commercialization and our product sales, we’re pleased to report, were approximately \$822,000 which is a dramatic increase over 2012 product revenues of approximately \$152,000. We also note that grant revenue for 2013 was approximately \$1.6 million as compared to approximately \$1.2 million for 2012.

**Slide 16:** Next, we’ll look at the quarter-over-quarter sales results. This chart highlights the product sales of CytoSorb® for each of the last six quarters since we began commercialization of the product. First of all, note that product sales for the fourth quarter of 2013 - that’s the blue bar to the far right - are approximately \$317,000, and this represents the highest quarterly sales achieved by the company thus far. They are in fact approximately 54% higher than product sales for the third quarter ended September 30, 2013. We actually completed orders for and invoiced approximately \$351,000 in the fourth quarter of 2014. Of this amount, approximately \$37,000 could be not be recognized as revenue

until 2014 due to common carrier delays in picking up the products which is why we fell slightly short of our guidance for the fourth quarter of 2013.

**Slide 17:** And now, our guidance for the first quarter of 2014. We are expecting product sales of approximately \$530,000 - \$570,000 which is an increase of approximately 75% over the fourth quarter of 2013. This is the new record once again for quarterly sales of CytoSorb®. Note that the sales for the first quarter of 2013 were approximately \$176,000. Sales for the first quarter of 2014 are then more than triple year-over-year same quarter sales. We are also seeing more stabilized sales growth trending towards the latter half of 2013 and continuing into 2014 as the engines of our commercialization process begin to bear results. These revenue multipliers include additional direct sales resources, our 100 plus key opinion leaders, orders from existing distributors, further international expansion with new distributors in new markets, the fact that the device is being used for more applications, repeat orders from existing customers and increased adoption within the critical care departments. The majority of our orders are now repeat orders from existing customers. This is the result of our deliberate strategy of moving our focus beyond the key opinion leaders to deep within the critical care departments, promoting usage by the senior and junior doctors and the nurses and technicians who are actually treating the patients on a day to day basis. We continue to establish new customers and distributors as well, and this will also contribute to more re-orders in the future.

**Slide 18:** So, I'll just review our strategy for 2013. We were selling in Germany, Austria and Switzerland with our four person direct sales force. And this sales team successfully garnered more than a 100 key opinion leaders and we are currently working with the largest and the most important university and public hospitals in most of the major cities of Germany. You see a list of those shown here. And these institutions are the equivalent to hospitals in the United States like Mass General, Johns Hopkins, Columbia, and UCSF. We chose Germany for our direct sales efforts because it's the third largest medical device market in the world. In Germany, there are approximately 154,000 cases of sepsis and septic shock per year. At an average CytoSorb® treatment cost per patient of \$5,000, the market opportunity for Germany alone is greater than \$750 million if we were to become standard of care.

**Slide 19:** Our CE Mark gives us broad commercialization potential just about everywhere except for the United States and Japan. And so our strategy has been to complement our direct sales force with distributors in these other markets. In 2013, we signed distribution agreements with the United Kingdom, Ireland, the Netherlands, Turkey and Russia and we entered into a strategic partnership in India. We are in active discussions with other potential distributors and/or strategic partners to expand to other parts of Europe and other countries that accept the CE Mark.

**Slide 20:** Sales momentum has been very positive. This slide summarizes our trailing 12 months of CytoSorb® sales and we believe it demonstrates the successful path of our commercialization program. Note, that we have now surpassed the \$1 million mark for annual sales. In fact, our trailing 12 months sales for the first quarter ending 2014 are expected to be approximately \$1.2 million.

So while we're very pleased with the growth and sales that we've experienced so far, we caution our investors that customer education does take time, particularly in our situation where we're just beginning to acquire clinical data to support the sales efforts. In addition, registration and reimbursement can be a lengthy process and it's different in each new market that we enter. So there can be a delay between the time we have signed with a distributor, and the distributor's actual first sales of CytoSorb®.

**Slide 21:** Now, let's take a look at our gross margins. Our gross margins of CytoSorb® for 2013 exceeded 60%. There has not been any downward pressure on average selling prices, in other words our sales prices have remained constant or have risen. As the mix between direct sales and distributor sales changes, our gross margins will vary, but no matter what the mix, we do expect gross margins to remain strong as we move forward. Higher production scales should also result in lower product cost. We are working on this and this will also improve our gross margins. And finally, it's important to note that as our product sales increase, the gross margin will provide a rich source of working capital for the company.

**Slide 22:** And let's talk about working capital for a minute. Our cash balances have hovered around \$2 million for each of the last five quarters. Then in the first quarter of 2014, our working capital position has been dramatically enhanced by the financing we just successfully completed this month, which has added approximately \$9.45 million to our working capital. That's a big difference. We're very pleased with the successful capital raise because it helps to secure CytoSorbents' future by providing the resources we need to execute on our strategic plan. First of all, it provides working capital to permit us to increase our direct sales and sales support in Germany to accelerate commercialization of CytoSorb®. Additionally, we now have an estimated approximately \$5 million of funding needed for our clinical trial for CPB in the United States. And with a continuing increase in sales, it will provide adequate working capital that is expected to carry us well beyond the first half of 2015. We also expect to benefit from our other sources of working capital, which besides product sales, include grant funding, and potential strategic partnerships.

So at this point, I would like to turn the call back to Phil, who will provide additional information related to our catalysts for 2014. Phil?

**Phillip Chan - CEO:**

**Slide 23:** Thanks very much Kathy. The financing that we just completed added almost \$10 million to our balance sheet and will go a long way in terms of catalyzing our growth for 2014. Instead of doing what we need to do, we now have the capital resources to do what we want to do, and what is right for the business in order to build shareholder value, as well as grow our business more rapidly.

**Slide 24:** As we talked about in our third quarter earnings call last year, one of the places where we are looking to spend new capital is to stimulate CytoSorb® sales. Kathy mentioned that we now have more than a 100 key opinion leaders in Germany and Austria, and our goal for this year is to leverage those key opinion leader contacts in order to be able to drive usage deep within their departments amongst the junior and senior physicians. So rather than having key opinion leaders use the therapy once or twice a month, our goal is to have these junior and senior physicians utilize and think about the therapy on a daily basis when they admit patients with the variety of illnesses such as sepsis, burn injury, trauma, pancreatitis, and many others.

In addition because of all the opportunity that we have, our goal is to significantly increase our sales team, as well as our clinical and distributor support, which I will cover on the next slide.

In addition, what we're seeing right now is that, in many of the reference hospitals we are working with today, we are in more than one intensive care unit in the hospital. We've expanded from one key opinion leader and one intensive care unit to now multiple intensive care units throughout the hospital, including, for example the medical ICU, the surgical ICU, the cardiac ICU, as well as the trauma ICU, and in many cases in the cardiac surgery departments.

Further demand for the product, we believe, will be generated by the 30+ post-market studies that will hopefully help to generate clinical data in many applications. In his remarks, Christian Steiner, our Vice President of Sales and Marketing, will discuss some of our activity in this area.

And importantly as Kathy had mentioned, our distributors represent a significant source of potential growth for the company as we expand internationally and add geographically to our business. We expect that orders from existing distributors will increase particularly as a number of them get the product registered in their countries. And as Kathy mentioned, we're looking to actively add on additional distributors for different geographic territories around the world where CE Mark approval is recognized.

**Slide 25:** In this next slide, I'd like to talk about our sales infrastructure targets for 2014. It demonstrates where the holes were in 2013 and how we're looking to fill those in 2014. In 2013, we had revenue coming from our direct sales team, distributors, as well as our strategic partner Biocon in India. In terms of direct sales, we are selling in Germany, Austria and Switzerland. We have four distributors, and Biocon was our partner that we signed on in September of last

year. We did this all with four sales reps and we added a clinical support person at the end of the year. From a manufacturing standpoint, we began ramping manufacturing as the demand for the product increased towards the second half of 2013. And from a reimbursement standpoint, we were really focused on the direct sales territories, where we have reimbursement in Germany and Austria today.

In 2014, our goal with the cash available to us now, is to continue to expand upon the strategy. Specifically, the focus is on Germany where we are looking to have a total of 10 sales reps by the end of the year. We currently have seven, as of the end of the first quarter, and will continue to push sales in Austria and Switzerland. On the distributor side, we are looking to add at least five more distributors and on the partner side, we are looking to add at least one more partner to help broaden the reach of CytoSorb® both in the European Union as well as outside the European Union.

In order to support our distributors and partners, we will be adding a distributor/partner support representative, who will help to communicate the advances and treatments that we are seeing in our direct sales territories and in other places in the world, and bring that research to treating physicians all over the world. We are also looking to expand our clinical support staff to two people, and in doing so, in order to meet the need, we are also increasing our manufacturing and quality control and quality assurance staff appropriately.

In addition, we will be spending a significant number of resources to obtain reimbursement in other countries, not only through the establishment of more clinical data, but also by having a focused effort on reimbursement in those countries.

**Slide 26:** So what we are seeing right now is market pull from two key applications of all the different applications that CytoSorb® has been used for. The two that are rising to the top are sepsis and cardiac surgery. As I mentioned before, sepsis is the overzealous immune response towards a life-threatening infection. It affects 2.5 million people in the United States and Europe annually, about 27 million people worldwide every year, and it represents, in these two territories, a \$6 - 8 billion market.

Although many of you know that there have been many failures in the sepsis space, we believe that CytoSorb® represents one of the most comprehensive treatments for sepsis because it has the ability to do many different things. Not only can it control cytokine storm, both for pro-inflammatory as well as anti-inflammatory cytokines, but because of our work with DARPA we know that CytoSorb® can remove many different bacterial toxins such as Staphylococcus aureus alpha hemolysin, that is a cause of major morbidity and tissue damage in Staph aureus and methicillin resistant Staph aureus (MRSA) infection. Through work with Dr. John Kellum at University of Pittsburgh Medical Center, we now know that we can also direct the activated immune system to go where it's supposed to go and fight the infection, and away from innocent bystander organs where these activated cells can often cause more harm than good. No other single therapy has demonstrated this broad range of activity, which is why many key opinion leaders believe that CytoSorb® could be the answer for the treatment of certain types of sepsis.

In cardiac surgery, another application, where patients undergo coronary artery bypass graft surgery or CABG surgery... for example, President Bill Clinton and David Letterman underwent CABG surgery for blocked heart arteries, or for valve surgery, or for left ventricular assist device implantation made by manufacturers like Thoratec and Heartware for the treatment of heart failure, or for valve replacement surgery, or for congenital defect repair, as well as heart lung transplant.

There are half a million cardiac surgery procedures done every year in the United States, and half a million in the European Union alone. The problem with cardiac surgery is that it can cause severe inflammation that can lead to post-operative complications such as lung failure and kidney failure. And because of this, it represents an addressable market for us of about \$500 million to \$1 billion in the U.S and Europe alone.

**Slide 27:** So, what we expect to see is a revenue multiplying effect of all these activities that we're undertaking to try to boost sales from what was approximately \$822,000 in 2013 sales, to multiples of that in 2014. I just would point out

that the number of cartridges used here are only used to graphically illustrate the multiplier effect and do not reflect revenue guidance for 2014.

**Slide 28:** So just to give you a little bit of color in terms of the clinical activity that we're seeing in Europe. This is the picture of the first ever CytoSorb® Users Meeting at the DIVI Conference, one of the major critical care conferences in Leipzig, Germany in December last year. Here, key opinion leaders and pioneers of CytoSorb® research came together to share their CytoSorb® clinical experiences with each other in this day-long session that we conducted in Leipzig. In fact, on YouTube and in the 2013 earnings press release we put out today, there is a link to a brand new short summary video of the DIVI Conference that I would urge you to take a look at. <http://www.youtube.com/watch?v=98FuPhlvFOY>

Not only did we see a lot of different examples of how CytoSorb® is used in sepsis, and in trauma, and in cardiovascular surgery, and other things, but I think what was remarkable about this meeting was the level of excitement of the people at the meeting, and the feeling that we were really on to something very special. In addition, as Christian will talk to you about later, we also established a CytoSorb® registry that will hopefully help categorize and catalog many different treatment cases around the world, to help clinicians learn how to treat their patients better in many different applications.

**Slide 29:** We also sponsored a research symposium at the DIVI Conference. This was an early morning conference that competed with a number of other academic conferences and lectures at DIVI. Yet, with our symposium that was specifically focused on CytoSorb® treatment, we were able to pack the room with more than 120 people from Germany and Austria who were interested to learn more about this technology.

**Slide 30:** More recently, at the International Society of Intensive Care and Emergency Medicine (ISICEM) Conference in Brussels, Belgium, we held another symposium where our speakers were some of the major key opinion leaders in sepsis research and critical care research. This includes Dr. John Kellum, on the left, from the University of Pittsburgh Medical Center, who is also the Chair of our Sepsis Advisory Board and who has done most of the preclinical animal work on our technology. Next to him, Professor Herwig Gerlach, who is the President of the German Sepsis Society. Professor Michael Quintel, from University of Goettingen who is the principal investigator of our Sepsis Dosing Study that is currently ongoing in Germany, and Professor Karl Träger, who is the Head of Critical Care in the Cardiothoracic Surgery ICU at the University of Ulm.

What we heard here in a session that attracted more than 100 participants from international countries were a very fascinating set of lectures on the basis of immune response, the pre-clinical and clinical work that has been done to date with CytoSorb®, as well as clinical applications including cardiac surgery and sepsis.

**Slide 31:** A second major catalyst for the Company is the expansion of our clinical trial capability and data generation. As a small company with limited resources, we have not previously had the ability to develop our clinical trials the way that we have wanted to in the past. But we now have so much clinical activity in Europe as well as in the United States, and with the financing that we just did, we have the ability to augment our capabilities to obtain the clinical data needed to hopefully help make CytoSorb® standard of care medicine in a number of different applications.

Because of this, we are in the process of hiring a Chief Scientific Officer, who will help manage both the U.S. as well as the European studies. Last year we announced the hiring of our Director of European Scientific Affairs, Dr. Rainer Kosanke, and we will be hiring a comparable position in the United States - a clinical trial manager to help manage a U.S. pivotal trial in cardiac surgery as well as the U.S. Air Force funded trauma pilot.

In addition, in the next month or so, we will be announcing the recruitment of a Cardiac Surgery Advisory Board, which will augment the scientific rigor of our trial design, and complement our Sepsis Advisory Board and our Trauma Advisory Boards as well. You can just see the tremendous amount of clinical activity here, and this is something that Christian will discuss in his prepared comments.



**Slide 32:** So, what I wanted to do right now is talk to you about the U.S. cardiac surgery pivotal trial. Now many of you who have followed our company in the past know that we have been pursuing sepsis as a pivotal study in the United States.

**Slide 33:** But because of the market pull that we are seeing and the market interest in cardiac surgery, there are a lot of reasons why doing a cardiac surgery trial in the United States makes a lot of sense. We believe that the path to approval in the United States is potentially faster, less expensive and most importantly, less risky than seeking approval for critical care applications such as sepsis.

Again, we are seeing significant market pull for this application. We have more than 20 heart centers in Germany and Austria who are either using or evaluating the technology. And we will see data coming in the second quarter and third quarter this year from cardiac surgery trials in Germany and in Austria. These are very large markets. There are again, a half a million cardiac surgeries in the U.S. every year, half a million in Europe and more than 1.5 million in the world, with India and China representing major areas of growth in terms of cardiac surgery. This is a potential total addressable market just in the U.S. and Europe of about \$1 billion or more.

CytoSorb®, importantly, is the only cytokine reduction technology capable of direct installment in a bypass circuit into a heart-lung machine without the need for another machine like a dialysis machine. Because of this, we have a very competitively strong position if we were to become approved as a standard of care for cardiac surgery.

In addition, there is already a market for a product called a leukoreduction filter in cardiac surgery. Companies like Terumo, Pall Medical, and Asahii, sell leukoreduction filters to try to reduce the inflammatory molecules that are often generated during cardiac surgery that we talked about before. Unfortunately, they cannot remove cytokines and free hemoglobin and other inflammatory substances directly. Rather, they are trying to reduce cytokines by removing cells that manufacture cytokines, and that really does not work. But they've created a multi-million dollar market for this concept and for these leukoreduction filters. Today, with CytoSorb® finally delivering on the promise of active cytokine reduction and free hemoglobin reduction during cardiac surgery, we could take over this market while significantly expanding the market as well.

Another reason to do this cardiac surgery trial is that the trial is expected to be much more straightforward, less expensive and less risky because, first of all, patients are much more homogenous than in a critical care application, and they can be enrolled quickly. Treatment times and follow up can be relatively short. We are also not looking for 60-day mortality, and that's another major point here. The endpoint for cardiac surgery trial will not be mortality, which is really the highest bar there is for clinical studies today. Rather, a clinical endpoint such as the incidence of respiratory failure or acute kidney injury is much easier to achieve. And I apologize for this, the formatting in this presentation somehow got messed up a little bit, but once CytoSorb® is approved in the United States, we can expand the applications in the United States through a label extension strategy, while driving usage in cardiac surgery outside the U.S. where CytoSorb® is already approved and being used in cardiac surgery today. These are just some of reasons why a U.S. cardiac surgery trial makes a lot of sense.

**Slide 34:** We are looking to use the product either intra-operatively, where it's used in a bypass circuit in a heart-lung machine to prevent post-operative complications by actively removing these inflammatory mediators DURING the surgery itself. Or the second alternative is to treat patients with CytoSorb® after the surgery is done and treat patients who develop inflammation and instability following these cardiac surgeries, which is actually relatively common. So this is something that we'll be giving more guidance to investors later this year.

**Slide 35:** From a sepsis trial, however, we absolutely believe that sepsis is one of the largest and most important markets for CytoSorb® and we are looking, rather than to duplicate efforts in the United States and in Germany, to focus our efforts in sepsis in Germany and the European markets.

**Slide 36:** What is remarkable about sepsis is that it's a very difficult disease to treat and in fact the treatment alternatives continue to shrink. At the ISICEM Conference in Brussels, what we learned is that two major trials, the early goal-directed therapy trial (ProCESS) and the endotoxin removal trial with Toraymyxin have both showed no benefit. Early goal-directed therapy was trying to use early optimization of blood pressure, hemodynamics, and oxygenation in septic patient to improve outcome. But unfortunately it was not successful and showed no benefit in mortality, reversing the findings of a landmark 2001 study. There was another study called the ABDO-MIX trial done in France, where unfortunately they also showed no benefit of endotoxin removal in septic shock patients due to organ perforation in a large scale clinical study. CytoSorb® remains one of the few promising therapies in sepsis and other applications.

**Slide 37:** So the goal for sepsis, in our minds, is that because of the lack of competitors "breathing down our necks" so to speak, we have an opportunity to continue to advance the understanding and knowledge of how to treat patients with sepsis with CytoSorb® and increase our odds of success. Again, CytoSorb® is one of the only therapies being used to treat sepsis today in Europe and elsewhere and holds promise in early studies. Our European Sepsis Trial and dosing study demonstrates that up to 24 hours of treatment is safe and that there are certain patients that seem to benefit from the therapy including those with very high cytokine levels, and those who are 65 years of age or older, the latter who make up about two-thirds of the patients hospitalized for sepsis today. And in actual clinical practice there have been many remarkable treatment successes in patients with either severe sepsis or septic shock, particularly when it's been used early.

Our goal is to ensure our pivotal sepsis study design has the best chance of success. And the many sepsis studies with CytoSorb® that are being conducted today including our dosing study will hopefully help us get there. When we are ready, we plan to conduct a study in Germany led by our major collaborators who are already part of the Sepsis Trials Network (the SepNet in Germany), which is a government funded trials consortium that conducted government funded sepsis trials in Germany.

**Slide 38:** A third major catalyst is that our bead technology enables a diverse and valuable pipeline. Chris Cramer, our Vice President of Business Development, will give you a little bit more color on this in just a little bit.

As we have discussed, CytoSorb® is CE Mark approved and is now generating revenue for critical care illnesses. We have another product called HemoDefend™, which is designed to help improve the quality and safety of the blood supply. And we have another product called ContrastSorb™ that we are developing to remove IV contrast that is given during imaging procedures and interventional radiology procedures, such as cardiac catheterizations, that can lead to kidney failure in high risk individuals. We have another product called DrugSorb™, for drug detox and drug overdose and another product called BetaSorb™ for improving dialysis. But we actually have another four to five different products that are under development that we have not yet publicly disclosed that also are very exciting products that address very large markets as well.

**Slide 39:** But more importantly, the reason why this pipeline is important is because of this slide. These are companies that are focused in our key markets that we are addressing with our pipeline - companies in the renal dialysis space, in the critical care space, in cardiac surgery space, in the blood transfusion space, as well as in the biotech and immunotherapy space. I would note here, the companies listed here are used simply as examples of companies in these respective verticals. We make no other representations to our relationship with any of these companies. But I would say that, in fact, the majority of these companies know who we are and know our technology.

And as you can see, there are companies like Haemonetics that cross over from blood transfusion to cardiac surgery. Maquet crosses over from cardiac surgery to critical care. Companies like Fresenius are on the dialysis side as well as on the blood transfusion side. You can see how CytoSorbents' technology could be very synergistic to the larger businesses of companies like these, as an example. We address so many major markets that have billion dollar revenue potential that if we are successful, we can impact the top and bottom line growth of most major multi-national corporations, which is something that you cannot normally say of technologies from small companies such as ours.

**Slide 40:** One of the partnerships that I just want to touch on, that the Chris will describe in much more detail, is our Biocon partnership. Biocon is the largest biotechnology company in India, often called the “Amgen of India”. And we have teamed with them to bring together the most comprehensive treatment for sepsis, where they are bringing critical care antibiotics that treat the primary infection, and we are treating the massive inflammatory response. Kiran Mazumdar-Shaw, Chairman and Managing Director of Biocon, who has been cited as Time Magazine’s top 100 most influential people in the world and Forbes Magazine’s 100 most powerful women in the world, mentioned us directly in their January 2014 third quarter earnings report where she said “Our recent launches of Alzumab and CytoSorb® have done extremely well, with strong uptake by both doctors and patients”. They have continued to reorder product after launching the product in September of last year.

**Slide 41:** Now another opportunity for us on the business development side is HemoDefend™. We expect there to be two major trials reporting in 2014 that may be very important to the HemoDefend™ platform. These are the RECESS trial and the ABLE trial. In the RECESS trial, they are giving old versus new blood to cardiac surgery patients. You will recognize cardiac surgery as a major market that we’re trying to address with CytoSorb® as well. There is also the ABLE trial which is giving new versus standard issue blood to critically ill patients - another one of our major target markets. If these studies demonstrate the risk of old blood, it could significantly enhance the value of the HemoDefend platform.

So again, HemoDefend™ is designed to keep new blood fresh and we are currently supported by a Phase I SBIR grant from the NHLBI, the National Heart, Lung, and Blood Institute, to remove contaminants from transfused blood products that accumulate during blood storage. These contaminants, if not removed, can potentially cause transfusion reactions and adverse events such as organ failure and death. We continue to advance the development of the HemoDefend™ platform towards commercialization, increasing its value while de-risking the asset, with the goal of out-licensing the technology to a major strategic partner.

**Slide 42:** Another major catalyst is our up-listing that we have talked about for some time. We are still targeting this for the second half of 2014 and certainly our fund raise that we just did goes a long way to getting us there. What we’re looking to do is up-list to either the New York Stock Exchange or NASDAQ. We’re targeting major operational momentum in the second half of 2014 that should help support our up-listing and post market performance after up-listing during that time. We’ve already met with the New York Stock Exchange and NASDAQ, and we’re now preparing the company for up-listing and cultivating our relationships with analysts as well as institutional investors.

**Slide 43:** And last, but not least, the final catalyst for 2014 is that CytoSorb® is being used successfully in a broad range of applications. We’ve been asked by many investors, “what are some examples of how CytoSorb® is being used today?” What I thought I’d do is take a few moments to talk to you about a handful of different applications across the board where we have been seeing positive benefits, and you will note at the bottom of every one of the slides the hospital that treated that patient.

**Slide 44:** This is a 57-year old patient that was diagnosed with gangrenous appendicitis at University of Goettingen in Germany. He had a severe deterioration of his clinical course with severe respiratory failure requiring mechanical ventilation and he was transferred to the ICU with multiple organ failure requiring intensive life support. But what was remarkable about this was really the timing of the patient’s improvement, because according to the investigator here, they did nothing else, but start our CytoSorb® therapy and within minutes, saw an immediate rapid improvement in hemodynamic stability. He was weaned off all vasopressors by Day two, he was weaned off all mechanical ventilation by Day five, he did not require dialysis therapy and did not spiral into kidney failure, and he was transferred out of the ICU to the step-down unit by Day nine. The investigator who treated this patient said “I have no other explanation except that the CytoSorb® therapy helped stabilize this patient”. Of course, I’m paraphrasing, but that was essentially what he had told us, which was quite remarkable. But with septic shock, and severe sepsis, this is what we are seeing in many different institutions across Germany, Austria, in India, in Turkey, and many other countries.

**Slide 45:** We’ve been hearing very similar type remarkable stories about how this therapy has been able to help patients. At the University Hospital in Munich, the therapy has been used many times by Head perfusionist Frank Born

intra-operatively during cardiac surgery. He relayed a case where there was a 49-year old man who developed a graft infection and sepsis, days after aortic arch replacement cardiac surgery. He went to do a “redo” operation with CytoSorb® installed in a bypass circuit in the heart-lung machine. In fact, when they opened him up they saw a lot of pus and evidence of mediastinitis in this patient who was very sick. They expected him to be highly unstable. But he was, in fact, completely stable during the operation, which was credited to the use of CytoSorb therapy. He went on to a full recovery and left the hospital after a total of 12 days without complications.

**Slide 46:** There was another treated patient at the University of Ulm by Professor Dr. Karl Träger, using CytoSorb post-operatively after cardiac surgery. An 83-year old man underwent quadruple bypass, and on day eight, he developed pneumonia with septic shock respiratory and renal failure, hence multiple organ failure. The infection was polymicrobial with bacteria in his blood. He was treated with CytoSorb and antibiotics. And you can see in the graph below, how he responded to the therapy, and how they were able to rapidly reduce his dependence on vasopressors that were used to keep his blood pressure up. They were able to remove the vasopressors and he became much more hemodynamically stable. And again, treatment led to a reduction in cytokines like interleukin-8 that we already knew we could remove. He recovered and was discharged from the ICU by Day 7 to a respiratory weaning unit.

**Slide 47:** We had another patient at Bergmannstrost Halle in Germany. This was a severe burn injury patient. He was in his mid-20s and suffered severe burn injury on more than 60% of his total body surface area, and also severe smoke inhalation injury. His predicted mortality was 45% to 50%. The overall mortality today in burn injury is typically on the order of 5-10% at the best burn centers, but because of the extent of his severe injury, his expected mortality was very high. He was admitted to the ICU with multiple organ failure. CytoSorb® was used continuously with renal support over eight days, changing the cartridge each day, and he was weaned off vasopressors within four days. He had significant improvement in kidney and lung function. And what they noted was that his wound healing was much faster than they had anticipated and that he currently has a good prognosis for recovery. This is a just a recent case.

**Slide 48:** Another case was a case of trauma and rhabdomyolysis at the University Hospital of Hamburg- Eppendorf, one of the biggest hospitals in Germany. A 25-year old man who was involved in a high speed motor vehicle accident suffered severe polytrauma, including internal bleeding requiring massive transfusion - head trauma, a broken leg, chest wall injuries and others. He was admitted to the ICU for decompression of his brain due to high intracranial pressure, but developed massive tissue injury that resulted in rhabdomyolysis, which is the release of myoglobin from crushed muscle that can lead to kidney failure. In treating with CytoSorb® plus continuous renal replacement therapy, they were able to reduce myoglobin very rapidly. You can see here in the picture, how the device was used in the hemodialysis machine, and then how, with the institution of our therapy, they were able to drop myoglobin levels very quickly. Removal of myoglobin is the subject of our U.S trauma trial here in the United States. Standard continuous renal replacement therapy does not effectively remove myoglobin. The magnitude of removal was attributed to our CytoSorb® therapy.

**Slide 49:** Yet another example was at University Hamburg, Eppendorf. This was a patient who overdosed on 30 grams of Tylenol. More than 12 grams is often considered highly fatal because of liver failure. Despite developing multi-organ failure, he was then treated with CytoSorb® and he survived, which was quite remarkable.

**Slide 50:** And then, last but not least, this was a case that was reported by Mr. Frank Born at University of Munich Grosshadern. He reported on a case where you can see CytoSorb® in the upper right-hand picture being used with an ECMO machine, or Extracorporeal Membrane Oxygenation Machine. This is often used to help stabilize and oxygenate patients when respiratory failure is so severe that their lungs no longer function despite pumping in highly oxygenated air into their lungs. CytoSorb was used with ECMO to transport and stabilize a 50-year old man who had a massive heart attack in Kuwait and transfer him 7 hours to Berlin. Ultimately this was a dramatic success. He was so unstable before transport, but they started him on the therapy for 2 hours where he became much more stable, and then they transported him for 7 hours on a plane without incident, and then actually used the therapy during cardiac surgery effectively and this patient did well.

So, these are just examples of how CytoSorb® is being used in the market today, hopefully giving you just a sampling of how dramatic some of these cases have been and why we have so much key opinion leader support and why our sales are beginning to reflect that.

**Slide 51:** In summary, CytoSorbents® is leading the way to prevent or treat life-threatening inflammation in the ICU. It is approved in the EU and generating international revenue. We are just touching the surface of a massive \$20 billion market opportunity addressing the critical unmet medical need of organ failure, with validation of the company and technology on many fronts including the U.S Government and key opinion leaders, with a unique and highly profitable product with little to no competition. We have a very experienced and responsible management team and there are many catalysts that we expect to see over the next 6 to 9 months including revenue growth, potential strategic partnerships, clinical data, up-listing, new product development and institutional ownership that can hopefully help propel this company to even greater heights.

So, with that I'd like to turn it back over to the moderator and open up the question and answer session with prepared remarks from our management team. Moderator?

## Question and Answer Session

### Donna Marincas - Moderator:

Thank you Dr. Chan. Over the past several weeks, we have been collecting a number of questions from investors. I think one of the most common questions relates to sales of CytoSorb.

**Q: Christian, sales seem to be trending upward. Can you comment on your progress with direct sales in Germany?**

A: Christian Steiner: Yes, thank you Donna and good evening to everybody. First of all, because of the high level of interest that we have seen in cardiac surgery for the last 12 months, we have intentionally modified our sales efforts to dedicate more resources towards this clinical application. Cardiac surgery has a number of very attractive characteristics as it relates to CytoSorb® therapy. In addition to what Phil mentioned in his presentation, relative to critically ill patients, cardiac surgery patients are much more homogenous, leading to more predictable and repeatable outcomes after surgery. For example, doctors know exactly what insult will happen, and when it happens. We have also seen that clinical data can be generated much faster and are more predictive compared to data generated in critical illnesses. Furthermore, the group of target customers is relatively small and well-defined including approximately 100 cardiac surgery centers in the German-speaking countries. In addition, the awareness of cardiovascular diseases and related surgery in the public is much higher compared to sepsis. Given that cardiac surgery generates significant profits for hospitals, allocation of resources and purchases by the hospital also favors this specialty.

There are approximately a half a million cardiac surgeries performed in the European Union each year. Based on statistics from the German Society of Thoracic and Cardiovascular surgery, in 2012 there were approximately 100,000 cardiac surgeries in Germany alone. This represents a German market opportunity of approximately \$100 million if CytoSorb® became standard of care. In addition to being a very profitable market for us, it will help to build a bridge to many other possible indications of the technology. Our existing sales force is spending a significant amount of effort on this in the near term. For example in 2013, we had 8-10 cardiac surgery centers, while already in 2014, we are now working with 22 cardiac surgery sites. The first cardiac surgery congress we attended – the Annual Meeting of the German Society for Cardiothoracic Surgery – has brought us remarkable attention from this community.

I have invested a great deal of time in carefully expanding our direct sales force in Germany. As planned and communicated during the previous conference call, we have increased the number of direct sales reps from 4 to 7

between then and the beginning of March. This was essential to adequately cover most of the major German-speaking territories. Two out of the three sales reps that we added have an excellent network in cardiac surgery, which has been helpful to the entire team. The third person is an outstanding salesperson I have worked with in the past. We can already see some effect of these hires, but the full impact will be visible within the next 3-6 months. We are targeting a total of 10 sales reps at the end of this year. We will also strengthen our international distributor business with adequate personnel over the coming two quarters.

During the last call I announced that we would host our first users meeting during the National Intensive Care Conference (DIVI) in December. As we touched upon earlier, we heard very exciting data from clinical cases and studies from about 15 clinical sites. This was the first time key opinion leaders have publicly presented their experiences to their colleagues outside of their own hospitals, both during the users meeting and also at the DIVI conference itself. What was exciting for us was the energy and enthusiasm in the room. We heard many influential people talk about how positively they view the CytoSorb therapy, and how it may possibly change medicine. We have prepared a short video of some of the testimonials that will be available on our website shortly.

In February, at the other important National Symposium on Critical Care Medicine held in Bremen, Germany, several key speakers highlighted CytoSorb therapy as the only promising adjunctive therapy at the moment. Competitive methods have been rated as “not working”.

So the awareness in Germany about our CytoSorb® therapy is significantly rising and interestingly users are spreading the word about their positive experiences. The team and also myself experienced several occasions – including telephone calls late in the night – where the treating doctors said: “What is this amazing cartridge... We just rescued a patient we never thought he would survive.” Obviously we also have patients who do not respond to the therapy...these are patients where the therapy was used too late, but these other positive situations when doctors could really turn around and rescue patients are really astonishing and give us the additional determination to continue our work. Phil has already given you just a handful of the many examples of how CytoSorb has been used recently to help doctors regain control of their patients and help them to survive. Back to you Donna.

**Q: That’s very helpful Christian. As Kathy mentioned, distributors and international expansion are another major source of revenue growth. How are distributors contributing to sales results? And what is your overall outlook for 2014?**

A: Christian Steiner: Yes thank you. The growth of our international business outside Germany is going to be a major topic for this year. As Kathy mentioned, CE Mark approval allows CytoSorb to be sold in all 28 countries of the European Union and allows us to expand CytoSorb distribution well beyond Europe. We have been pleased with the reception of the technology in general, but particularly in many countries outside of Western Europe. Physicians in these other countries are very progressive and eager to use new technologies, particularly blood purification. The challenges in these markets are similar everywhere: product registration, adoption, and reimbursement. This is one of the reasons we will be adding a specific distributor support person this year. In 2013, the majority of sales were from our direct territories, particularly Germany and Austria. However, as we sign more distributors, and as existing distributors gain product registration in their countries, I expect that distributor revenue will become a very significant portion of overall CytoSorb revenues in the future.

In terms of the outlook for 2014, we just had another strong quarter of revenue growth, benefiting from strong market demand. We will, of course, continue to work to expand usage and adoption in our direct and distributor territories. Back to you Donna.

**Q: Christian, during the week of March 19<sup>th</sup>, CytoSorbents participated in the 34<sup>th</sup> International Symposium on Intensive Care and Emergency Medicine congress in Brussels and hosted a scientific symposium entitled “SIRS and SEPSIS – New Therapy with CytoSorb®”. Please tell us about that.**

A: Christian Steiner : Thank you Donna. So Phil mentioned this already. The CytoSorbents Scientific Symposium at the Brussels ISICEM conference – the biggest Intensive Care Medicine Congress of the world – was really a great success, drawing an estimated 6,000 attendees. The line-up of our speakers itself was remarkable.

- Professor Herwig Gerlach is the President of the German Sepsis Society and Member of the Surviving Sepsis Guideline Committee
- Professor John Kellum is one of the top 5 leading intensive care nephrologists in the world and has done most of the preclinical work with CytoSorb up to this time
- Professor Michael Quintel is one of the leading intensivists in Germany, the Past President of the DIVI (German Interdisciplinary Society for Intensive Care and Emergency Medicine), and leads the Department of Anesthesiology and Intensive Care Medicine of University of Goettingen, which has the most experience of using CytoSorb® Therapy in patients suffering from septic shock
- Professor Karl Träger is one of the most experienced users of CytoSorb therapy in cardiac surgery patients.

Not many companies can easily have such excellent speakers to present. This, I feel, reflects our excellent network and also the belief these thought leaders have in the product and in us. The presentations covered a wide range of material, from the basics of the immune response in sepsis, to the pre-clinical and clinical data, and then to different applications in sepsis and cardiac surgery. We had approximately 100 people at the symposium and obtained a lot of good feedback. We are working on a summary of the talks for the near future.

**Q: Okay Christian. Can you bring us up to date regarding the investor-initiated studies underway?**

A: Christian Steiner: Yes, of course. I only can repeat myself by saying that a sound body of clinical (published) evidence is essential for the next phases of commercialization of our CytoSorb therapy. As Phil outlined in the presentation, with the additional funding that we have received, we will continue to be focused on 5 key areas to generate the necessary data that we need to make CytoSorb standard of care in the hospital:

- Published case reports and case series
- The International CytoSorb® Registry
- A mosaic of investigator initiated clinical projects and trials
- Multicenter trials including pivotal studies
- Additional studies to investigate important side topics, such as use in children, antibiotic removal, and other studies.

These levels are not necessarily sequential, but will be worked on in parallel.

Case reports are a low level grade of evidence but help tremendously because they are real world examples of how the therapy was used successfully by others, along with the parameters of treatment. They remove the inertia and encourage others to try the therapy in similar situations. Along these lines, there will be two data sets published on peri- and postoperative CytoSorb® applications in cardiac surgery patients this year – the first is expected in April.

The next evidence layer, the International CytoSorb® Registry, should be online by the end of Q2 this year. It took massive efforts to set up this high quality medical registry, which also fulfills FDA requirements and is led by the world renowned sepsis researcher Professor Brunkhorst and his Study Center at the University of Jena. This will give us the opportunity to very quickly collect data from nearly all treated patients on an international basis. Also we will have the ability to embed randomized studies into this registry.

We are also spending significant resources to help coordinate and support the more than 30 investigator initiated studies that are either being planned or are currently enrolling patients in a wide range of applications for CytoSorb. This includes 11 studies in the peri-operative application of CytoSorb in cardiac surgery patients, of which two

randomized controlled studies will be finishing recruitment in Q2 and Q3 of this year. There are four studies evaluating the therapy in the postoperative treatment of SIRS, and two studies in connection with ECMO. In the field of severe sepsis/septic shock and lung injury we are currently working on 6 studies (one expected to be finished by Q3/4), 5 in liver disease, 3 in trauma/burn injury, and 1 in severe acute pancreatitis.

Phil already discussed our plans to conduct pivotal trials in cardiac surgery in the United States, as well as sepsis studies in Germany. These are the two areas where we have the most clinical experience to date.

Finally, we continue to invest resources to improve technical support to our customers, and are evaluating many aspects of treatment including the length and timing of treatment, removal of additional antibiotics, as well as the potential treatment of children.

Again, just to keep expectations in the appropriate range: This is a huge amount of work that is both currently underway and needing to be done. For some studies, it took over a year to prepare the protocol, obtain funding, complete the ethics application, and finally to receive ethics approval. Also patient recruitment is dependent on many factors such as availability of patients, investigators/study nurses being available when the patient comes in, getting informed consent, etc. So we are sowing the seeds to get all the things we need, but as with everything it needs the adequate time for the studies to develop before we can bring in the crop.

At the end of the day we are seeking at least one clinical publication coming out per month. This will catalyze the awareness and the development of the therapy introduction tremendously. Thank you Donna.

**Q: Thanks very much Christian. Another topic on many people's minds is the Air Force Rhabdomyolysis trial and various grant programs such as DARPA. Dr. Chan discussed it briefly, but Vince, could you please elaborate a little regarding the progress in these programs?**

A: Vince Capponi: Thanks Donna. As Phil mentioned the Air Force Rhabdomyolysis trial has begun. We were approved last year in July but we experienced delays in the clinic as a result of the sequestration that occurred in 2013. With these governmental delays behind us we are up and running. In addition, we have decided to add a second site to increase the rate of enrollment and we are in the process of doing this now. We will bring this site on in the coming months as soon as contract requirements and IRB approvals have been completed.

Regarding grants, I'm happy to say we've recently returned from the annual DARPA principal investigator meeting, where we presented our progress for Year 2. We have made good progress against our milestones taking down nearly \$ 1.1 million in DARPA grant funding and approximately \$300K in other grant funding for 2013. Our progress in the program continues and we have supplied a small quantity of devices for testing by Battelle Memorial Institute, the systems integrator. We are encouraged by DARPA's continued interest in the CytoSorb technology and look forward to providing second and third generation bead technology to address toxins in addition to cytokines.

Beyond DARPA we have completed the Phase I SBIR for Burn and Trauma and received an additional Phase I grant from NHLBI for the HemoDefend in-line filter and beads in a bag. We continue to look toward new grant opportunities as a way of securing non-dilutive funding to advance the research for the CytoSorbents platform. Donna?

**Q: Have the increases in sales impacted production? And, do we have sufficient capacity for the near future at our existing facility?**

A: Vince Capponi: OK, great question. Our quarter over quarter growth continues to gain momentum with an average increase in excess of 50%. But with this increased growth comes the need to increase production to assure product



availability for our customers. As such, we are adding additional production staff to increase our output to address the growing demand for CytoSorb.

Regarding plant capacity, we believe we have sufficient capacity to meet our needs through 2015. However, from a manufacturing perspective, our need to consider a new facility is not far off, given the lead time to bring a new plant on line. We have begun engineering layouts to model various plant capacities and cost scenarios to better prepare for future growth. A question that often comes up is why not out source? This is a good question and simply, it revolves around the need to maximize production flexibility, control quality, and know-how. Regarding flexibility, by controlling production we control the schedule, if we outsource we are at the mercy of lead times and production scheduling associated with a contract manufacturer. In other words, we are not the only customers that contract manufacturer has, and we will have to get into queue. Product quality is critical to our success, production in our direct control allows us to focus on quality and ensure the expectations of our customers are met. Know how in a highly technical business such as this is a critical part of our success. If we begin outsourcing our products we must also outsource our know-how making it difficult to control trade secrets. For these reasons we have decided to keep the manufacturing of CytoSorb in-house but will continue to consider outsourcing as an option to meet additional capacity requirements as the business continues to grow.

**Q: Has the Company made any progress in advancing the development of its HemoDefend product?**

A: Vince Capponi: HemoDefend will fit nicely as an additional product line to be sold by our direct sales force into the ICU along with CytoSorb. Chris will speak to partnering opportunities in a moment, but we will likely seek a strategic partner for a larger roll-out of this product outside of Germany.

Regarding development efforts for HemoDefend, we've included resources for development in our 2014 budget and have begun more rigorous engineering efforts. Our intent is to develop a first generation, first in-class free hemoglobin filter for use with high risk patients requiring a blood transfusion. At this point we have developed prototypes and shown proof of concept with the technology. We cannot predict the final end date in having an approved product, but we have made good progress in identifying key project milestones and critical path items for us to begin refining our development timeline. Donna.

**Q: Thank you very much Vince. Let's move to Business Development. Chris, On the last call you talked about the Biocon partnership and described how it will work. With the partnership now up and running, can you describe how things are going so far and what we might expect for the remainder of 2014?**

A: Chris Cramer: Thanks Donna. Our partnership with Biocon is going very well. In fact, many of our investors have noticed the positive remarks issued in their recent quarterly report. Earlier in the year, Phil and I met with Kiran Shaw, Biocon's Chairman & Managing Director. After speaking with her, it is clear to us that Biocon understands the CytoSorb value proposition and is putting the necessary resources into making our partnership successful.

While Biocon is still in the beginning stages of launching CytoSorb, market demand has been favorable. Initial field marketing and sales efforts have commenced in several major cities. Through the "Surviving Sepsis" campaign, Biocon has been able to highlight the theme of prevention of sepsis and saving patient lives. Interest levels continue to rise among key opinion leader physicians and the success stories so far have been instrumental for other intensivists to initiate treatment. More recently, user meetings have helped spur usage of the device and have raised interest levels to create a protocol on sepsis management and the role of CytoSorb. In addition, physicians are proactively reaching out to Biocon to learn more about CytoSorb and many have expressed interest in trying it in their hospital. As a result, I am pleased to report that Biocon has already exceeded its first year sales projections within the first six months.

The remainder of 2014 is shaping up to be very busy with several Biocon-led formal, targeted marketing and outreach programs aimed at developing key opinion leader support for CytoSorb, increasing product awareness, collecting usage and case study data, and driving physician adoption. Biocon has announced they will create a separate dedicated sales

and marketing team to ensure adequate attention is given to creating awareness of CytoSorb and educating physicians on the usage of CytoSorb. In addition, Biocon is developing a patient registry and evaluating different case studies for developing manuscripts. We will continue to support Biocon by sharing data from our various studies and conducting refresher training throughout the year.

Overall, we are very pleased with the Biocon partnership and look forward to continued success. We believe this partnership has the potential to change the treatment of critical care illnesses such as sepsis, and are confident that our work will lay the groundwork for an expanded partnership in the future.

**Q: Can you please comment on the progress towards establishing new strategic partnerships for CytoSorb and describe where things stand relative to the partnership discussions you described on our last earnings call?**

A: Chris Cramer: Sure. As I mentioned on our last earnings call, we have identified a key group of potential industry partners where we believe CytoSorb is a strong fit from both the commercial and strategic perspectives. These partners have been prioritized for their ability to globally develop the market and maximize the potential opportunity for CytoSorb. Over the last quarter, and throughout the remainder of the year, our BD efforts have and will focus on developing relationships with these key players.

In short, we continue to see strong interest in CytoSorb from major strategic players. Conferences such as the German Cardiovascular Surgery, European Association for Cardio-Thoracic Surgery (EACTS), International Symposium on Intensive Care and Emergency Medicine (ISICEM), the JP Morgan Healthcare conference, and others have given us an opportunity to showcase CytoSorb and meet with virtually all of our target partners.

I'm pleased to report that we continue to make good progress in establishing relationships with senior business leaders and advancing partnership discussions in both critical care and cardiac surgery organizations.

While deals with large, corporate partners can take some time to develop for many reasons – some outside of our control – it is most important that they recognize the value proposition of our products and potential role in their future strategy. I am pleased to say that partners are indeed responding very favorably to our message and our partnership discussions are definitely moving in the right direction.

I am very encouraged by our progress to date and remain confident about the strategic partnership potential for CytoSorb and our other products. The Business Development team will be very active throughout the remainder of 2014 in participating in industry conferences and advancing our strategic partnership objectives. We hope to have more positive news to discuss on future earnings calls.

**Q: How about progress on strategic partnerships for CytoSorbents' development programs like HemoDefend?**

A: Chris Cramer: To remind everyone, HemoDefend is our advanced development program for improving the safety and quality of transfused blood. As Phil mentioned earlier, HemoDefend has the potential to reduce a broad range of transfusion reactions by removing various substances such as free hemoglobin, bioactive lipids, antibodies, and other contaminants commonly found in stored blood. HemoDefend is a multi-faceted platform technology with multiple potential opportunities in purifying blood components such as packed red blood cells, platelets, and plasma in various clinical settings including blood collection, processing, storage, and point of care transfusion setting. The first generation HemoDefend inline filter will target hospital based customers for use in high risk transfusion patients.

Our goal is to identify a partner to help fund and commercialize the HemoDefend platform. To that end, we have been very active at conferences like the American Association for Blood Banking (AABB), International Society of Blood

Transfusion (ISBT), and many others. Much like CytoSorb, the value proposition for HemoDefend has been positively received by potential strategic partners in the blood management space.

In addition to our BD efforts, we are taking steps to de-risk HemoDefend thereby making it easier and more attractive for a large strategic partner to potentially enter into an agreement. For example, we have made strides in advancing the product design based on expert user input, we continue to expand data on our removal capabilities through research collaborations with groups such as the NHLBI / NIH, and we have confirmed the likely regulatory path for the first generation HemoDefend inline filter in both the US and EU. All of these are significant accomplishments which further help to increase the value of the HemoDefend platform and improve our ability to establish a strategic partnership.

Finally, as Phil mentioned in his presentation, we are monitoring several important clinical studies which we believe could provide an additional positive tailwind to our partnering efforts. Most notably, the Red Cell Storage Duration Study (RECESS) and Age of Blood Evaluation Study (ABLE) trials. Both studies are exploring the hypothesis that old blood is bad blood. If they are positive, it could accelerate the need for blood purification solutions such as HemoDefend.

In summary, we continue to make good progress on developing and de-risking HemoDefend. While investments like this take time, we are confident that they will ultimately help increase the value of the platform and advance discussions with potential strategic partners. Overall I am optimistic about the opportunities that lie ahead of us for HemoDefend.

**Moderator: Thank you, Chris. Well, we seem to have covered what were the major questions. Dr. Chan, any closing remarks?**

**Dr. Phillip Chan:**

Yes, Donna. Thank you very much everyone for submitting questions and participating in the call. If you have any additional questions, feel free to forward them to the Company at [avogel@cytosorbents.com](mailto:avogel@cytosorbents.com) and we will try to address them in our next update. With that, thank you everyone and have a great evening.

**Operator:** Ladies and gentlemen, this concludes the CytoSorbents 2013 Shareholder Update Conference Call. If you would like to listen to a replay of today's conference call, please dial 877-870-5176 and international dialers can call 858-384-5517. Thank you for your participation and you may now disconnect.