



CytoSorbentsTM

Working to Save Lives Through Blood Purification

CytoSorbents Corporation (NASDAQ CM: CTSO) Q2 2015 Earnings and Operating Results Conference Call August 13, 2015 @ 4:45 pm Eastern

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

Operator:

Good day, everyone and welcome to the CytoSorbents Second Quarter 2015 Financial Results Conference Call. As a reminder, today's call is being recorded and at this time I'd like to turn the conference over to our moderator, Lee Roth. Please go ahead.

Lee Roth – Moderator:

Thank you, Aaron, and good afternoon everyone. Welcome to CytoSorbents Second Quarter 2015 Operating and Financial Results Conference Call. Joining me today from the company are:

- Dr. Phillip Chan, Chief Executive Officer and President
- Kathleen Bloch, Chief Financial Officer, and
- Dr. Christian Steiner, VP of Sales and Marketing from Germany

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 August 13, 2015 and we assume no obligation to update these projections in the future as market conditions change.

During today's call, we will have an overview presentation covering the financial and operating highlights for the second quarter by Dr. Chan and Ms. Bloch. Following that presentation, we will open the line to your questions during the live Q&A session with the rest of the management team.

At this time, it's now my pleasure to turn the call over to Dr. Phillip Chan. Dr. Chan, go ahead, please.

Phillip Chan - CEO:

Thank you very much, Lee, and thank you everyone for joining the call today. It's a pleasure to be here and welcome. Following the presentation, we will have a live Q&A session and an official transcript of today's call will be available within the next week on our website at www.cytosorbents.com. For those of you who like to learn more about our flagship product, CytoSorb, I would encourage you to visit www.cytosorb.com.

Slides 3: CytoSorbents is a leader in critical care immunotherapy and we are leading the prevention or treatment of life-threatening inflammation in the ICU and cardiac surgery using CytoSorb blood purification. Rather than go through some introductory slides on what we do, I'd like to show you a video that was produced independently of us, so we had nothing really to do with this, by one of the major television studios in Germany about a patient who was treated with CytoSorb at the University of Rostock. We did, however, tag it at the end.

Slides 4: For those of you on the call today, there may be a slight wait time at the end of the video before we go back into the presentation, while others with slower internet speeds finish watching the presentation.

[VIDEO]

Great, I think we're back. I apologize if anyone had technical difficulties. There are no video controls for this particular platform, and so I think the video may have restarted for some. So I apologize for that.

But hopefully you found this video interesting, because it really speaks to the complexity of the patients that we treat and shows how CytoSorb is being used to help "regain control" of the patient.

Slides 5: As you saw from the video, CytoSorb removes the fuel to the fire of deadly inflammation. The purpose of controlling this deadly inflammation is to prevent or treat the organ failure that is caused by this inflammation, in order to improve patient outcomes and survival, while decreasing the massive costs of treating these critical illnesses. We continue to advance as one of the most promising revolutions in critical care medicine.

So with that, I'd like to turn it over to Kathy to talk about our operating and financial highlights. Kathy?

Kathleen Bloch - CFO:

Thank you, Phil, and good afternoon, everyone. For today's call, I will be providing an update regarding CytoSorbents' second quarter 2015 financial results, including product sales, as well as an update around our working capital and cash runway.

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Slide 8: Turning to our financial results for the second quarter of 2015, our CytoSorb product sales were approximately \$773,000, which is a 17% increase over second quarter 2014 product sales of approximately \$663,000. The decrease in the euro had the impact of reducing sales in the second quarter of 2015 by approximately \$147,000 or 19% of total product sales. In other words, if we eliminate the impact of the decline in the euro relative to the dollar, second quarter 2015 product sales would have been approximately \$920,000.

Our grant and other income was \$190,000 for the second quarter of 2015, as compared to approximately \$361,000 for the second quarter of 2014, as a result of the conclusion of several significant grants.

We also note that we were able to achieve gross product profit margins of approximately 63% in the second quarter of 2015, compared to 65% for the second quarter of 2014, and this was despite the drop in the euro that we experienced.

Slide 9: Next, a quick review of our six-month revenue results. Our CytoSorb product sales for the six months ended June 30, 2015, were approximately \$1.5 million, which is a 20% increase over the first half of 2014 product sales of approximately \$1.2 million. In the first half of 2015, the value of the euro averaged \$1.12 as compared to the first half of 2014 when the euro value averaged \$1.37. The decrease in the euro had the impact of reducing sales in 2015 by approximately \$259,000, or 19% of total product sales.

Trailing 12-month product revenue for the period ended June 30, 2015, was approximately \$3.4 million, as compared to approximately \$1.8 million for the 12-month period ended June 30, 2014.

Slide 10: Next, we'll look at our chart of products sales by quarter, which shows an increase in sales in Q2 2015 over the first quarter of 2015. Comparing 2015 product sales to the third and fourth quarters of 2014, the single largest factor impacting 2015 product sales is the fact that there were no new significant distributor initial orders in the first or second quarter of 2015, which is simply a matter of the timing of bringing our new distributors onboard.

In the second half of 2015, we expect to potentially benefit from initial product rollouts in France, Poland, Sweden, Norway, Denmark and Finland by Fresenius and also rollouts in Saudi Arabia as well as Australia and New Zealand. The other factors that were impacting 2015 sales include:

First, the impact of the restructuring of the sales force. The second quarter of 2015 represented the highest number of devices sold by our direct sales force in any quarter in our history, and yet we will not realize the full impact of our newly expanded sales team until into the second half of 2015.

Secondly, the decline in the value of the euro to the dollar, which we will look at a little more closely now.

Slide 11: The impact of the decline in the euro was significant and we really see that on this next graph where we have illustrated sales in the first and second quarters of 2015, as if the euro to dollar exchange rate was unchanged from the same periods in 2014.

Eliminating this change in the exchange rate, sales would have been approximately \$816,000 for the first quarter of 2015 and \$920,000 for the second quarter of 2015, as illustrated in this graph. In fact, if we remove the impact of exchange rate fluctuations, the second quarter of 2015 would have been our second highest quarterly sales in CytoSorb's history.

Adjusted for the change in the euro, our product sales for the first half of 2015 would be \$1.7 million, which is a 41% increase in product sales as compared to the same period of the prior year, rather than the 20% increase actually reported.

Slide 12: Next, I'd like to provide some information on our working capital position and cash runway. As of June 30, 2015, we had approximately \$11.2 million in cash and short-term investments. Our gross cash burn for the second quarter of 2015 was approximately \$2.6 million. That was partially offset by the receipt of approximately \$0.5 million in cash from the exercise of warrants.

Our working capital, excluding the warrant liability, which is a non-cash item, was approximately \$11.9 million at the end of June 2015. We believe we have adequate funding to meet our objectives into 2016.

On July 23, 2015, we filed our S-3 shelf registration, which became effective on July 29. This registration gives the company the ability to raise up to \$100 million to register offerings of our common stock, preferred stock, warrants, et cetera. This shelf registration is effective for three years.

Note that the company has no immediate plans to raise capital, but we believe it is in our best interest to have the shelf available to permit us to be able to raise capital with flexibility in the future.

And just briefly looking at our capital structure, on a fully diluted basis, we currently have approximately 29 million common shares outstanding.

Slide 13: One final note, I'd also like to mention that we were recently added to the Russell Microcap Index, which will remain in place for one year and gives the company automatic inclusion into the appropriate growth and value-style indices. This is a significant corporate achievement that is expected to increase visibility and exposure of our company and our life-saving technology to the broader investment community.

Russell indices are widely used by investment managers and institutional investors for index funds and as benchmarks for active investment strategies. An inclusion in the index complements our continued institutional investor outreach.

And now I'd like to turn the call back over to Phil. Phil?

Phillip Chan - CEO:

Thank you very much, Kathy. As Kathy mentioned, if we disregard the effect of the euro, we had our second best quarter in terms of product sales in the history of our company. This was primarily driven by new orders and reorders in our direct sales territories, even with a sales force of four people. But we're looking forward to an even stronger second half. As I mentioned in the press release, there are number of potential major catalysts coming up.

Slide 14-15: First, we've strengthened the direct sales team with the addition of Steffen Martens, who is covering North East Germany, and Andreas Pendleder, who is covering Western Germany. In addition, we're working with a cardiac surgery contract sales representative and before the end of this year, we hope to increase our sales team back to nine people and add a medical science liaison, an MD intensivist who will help give lectures, educational sessions and provide support to the sales team.

Slide 16: Another major catalyst is that we're now selling in three new countries. We recently announced Saudi FDA approval and Medical Device Marketing Authorization, which enables sales in Saudi Arabia with a population of 29 million people via our partner Techno Orbits. Typically these orders are done through tenders and these tender orders can be substantial. It also potentially opens doors to the rest of the Middle East.

In addition, we signed with TekMed for Australia and New Zealand and this targets a collective population of 28 million people. CytoSorb is registered already, so sales can begin immediately.

Slide 17: In addition, Fresenius Medical Care looks to turn on in the second half of 2015. In fact, initial marketing to key opinion leaders in critical care is planned in the third quarter of 2015 in France, Sweden, Norway, Finland, Denmark and Poland, with a total collective population of about 131 million people.

CytoSorb will not only be certified on the existing Fresenius multiFiltrate machine, but will also be certified on the newly-launched multiFiltratePRO dialysis machine as pictured on the left here. Sales training and preparation of marketing literature are ongoing and suffice it to say both sides are very eager to get started.

Slide 18: But what we're doing here is sowing the seeds of growth. Listed here in these tables are the 31 countries where we have currently either direct sales or distribution through independent distributors or strategic partners. On the left-hand side are those contributing to revenue and those on the right-hand side are not yet contributing to revenue for whatever reason. The main reason is typically that they are still in the registration process.

But what you can see here is that with TekMed and Techno Orbits, we are adding 57 million people to the addressable markets that we target, with a start in this third quarter. And as I just mentioned, for Fresenius, they are also planning a start in this third quarter, and that opens up a market of approximately 131 million people.

Russia has been in registration for quite some time, but we anticipate that that registration will be completed, hopefully within the next couple of quarters. We are also actively, with our

authorized representative and distributor, working on registration in the other countries in the GCC (Gulf Cooperation Council), and in the Middle East. And last but not least, we announced also that we established distribution for CytoSorb in Israel with AlphaMedix for critical care and cardiac surgery applications and they are actively pursuing Israeli registration of CytoSorb now.

I think it's very important to note that we are just tapping into these major markets. We expect that the third quarter of 2015 to begin to reflect the initiation of selling in new markets covering approximately 188 million people or approximately 600,000 cases of severe sepsis or septic shock per year, using a published incidence of about 300 cases per 100,000 people per year.

And given that we obtain roughly \$3,000 to \$5,000 in CytoSorb treatment revenue per patient, these new territories enable us to target a \$1.8 billion to \$3.0 billion total addressable market for sepsis alone. If we talk about critical care applications, outside of sepsis, this effectively doubles this total addressable market, and this does not even include the potential upside benefit of cardiac surgery.

Slide 19: This goes back to the slide that I presented in the last conference call, of how we look to grow our sales. It is a layering of direct sales with sales from our current distributors, with our partners like Biocon, one of the largest cardiac surgery companies in the world, as well as Fresenius, as well sales starting from the Middle East and other countries around the world. The growth is a combination of geographic expansion and organic growth, coupled with inflection points where data from studies catalyze broader adoption and advancement of CytoSorb towards standard of care therapy. You can see how the numbers could get very big, very quickly.

Slide 20: That leads nicely into an update about the cardiac surgery partner that we have been talking about. I'm pleased to say that the evaluation by our partner in France - again one of the top four cardiac surgery companies in the world - continues to go well, and although slower than anticipated, should be completed in the next several months.

Meanwhile, two randomized, controlled studies, one at the University of Hamburg-Eppendorf and the other at the Medical University of Vienna using CytoSorb intra-operatively during cardiac surgery have both completed with data expected later this year. In fact, both principal investigators will be presenting at the Second Annual International CytoSorb Users Meeting in Berlin, Germany in October.

Last but not least, CytoSorb has been used safely now in more than 300 intra-operative cardiac surgery cases to date. We believe this number likely underestimates the true number that has actually been used for cardiac surgery.

Slide 21: And that provides another nice segue into a REFRESH update. Again, this is one of the two pathways that we are taking to seek approval for CytoSorb in the United States. REFRESH stands for the REduction in FREe Hemoglobin trial. The FDA has approved our amendment to expand the trial to a 40-patient randomized controlled study at eight centers. This differs from the original approval which was for a 20-patient, three center, single arm treatment only study, where we were going to compare the results with a non-interventional trial in a larger number of centers. This one study now consolidates those two studies together.

Led by our Chief Medical Officer, Dr. Robert Bartlett, we are in the process of negotiating and finalizing clinical trial agreements and obtaining IRB approvals with eight major cardiac surgery centers in the United States. We have obtained central IRB approval which is applicable in some of the sites and we have established our data safety monitoring board with some very well-known key opinion leaders in the space of cardiac surgery and post-operative cardiac surgery care. We are on schedule to start enrollment in September 2015 with the goal of completing enrollment in either the fourth quarter of 2015 or in the first quarter of 2016.

We are also pleased to have added Steven Sisk as our Director of Clinical Operations. He was formerly at Medtronic and will oversee the day-to-day operations of the trial. He replaces Dr. Greg Di Russo who stepped down for personal reasons. This trial is expected to support the REFRESH II registration trial for CytoSorb that we hope to begin in 2016.

Slide 22: For those of you who need a reminder of what the REFRESH trial looks like, it is a 40 patient eight-center randomized controlled feasibility study using CytoSorb intra-operatively in a bypass circuit during elective, non-emergent complex cardiac surgery, lasting more than 180 minutes.

There will be two arms. One arm will be the standard of care control arm with 20 patients, versus the CytoSorb plus standard of care arm with 20 patients. Our primary endpoint is safety; our primary efficacy endpoint is the reduction in plasma free hemoglobin, with secondary endpoints that include clinical outcomes as well as biomarker reduction outcomes.

Slide 23: Now, some have asked, what is it about plasma free hemoglobin and why are you interested in reducing it during cardiac surgery? Well, patients undergoing complex cardiac surgery typically undergo cardiopulmonary bypass for long periods of time. These are surgeries where they are cutting into the heart, like multiple valve replacement surgeries, congenital defect repair, aortic reconstruction, LVAD implantation, and many others.

In these surgeries, there is typically a lot of bleeding, and hence, also a need for a lot of cardiotomy suction where they are sucking blood from the field. Blood cells under negative pressure creates hemolysis of red cells, which in turn releases a large amount of plasma free hemoglobin into the circulation.

Once the natural scavenging mechanism of the body for free hemoglobin, which includes a molecule called haptoglobin, is overwhelmed, plasma free hemoglobin can then cause its negative effects. Some of the major negative effects are because of the high affinity of plasma free hemoglobin for nitric oxide. Nitric oxide is one of the most important molecules in your body that regulate blood vessel tone. It causes blood vessels to vasodilate or expand.

So when free hemoglobin scavenges nitric oxide, blood vessels start to clamp down, leading to high levels of systemic resistance in the body as well as pulmonary hypertension. It can also cause the renal blood vessels to clamp down, causing renal ischemia and acute kidney injury, as well as causing intestinal mucosal injury, organ failure and other complications. Also, plasma free hemoglobin, because it's an iron containing protein, can also lead to the generation of oxygen radicals that can damage the cell lining of blood vessels and cause further organ damage.

As you can see, plasma free hemoglobin is very dangerous. In this figure, from a paper written by *Windsant et al.*, a thought leader in the adverse effects of free hemoglobin during cardiac surgery, it is clear that those patients who have relatively low levels of free hemoglobin do not develop kidney injury, while those who do develop acute kidney injury, or AKI, have exposure to much higher levels of free hemoglobin. This finding is highly statistically significant. There is actually a lot of science behind the dangers of plasma free hemoglobin. And this is what we are looking to do with CytoSorb. We are looking to scavenge and reduce free hemoglobin and other inflammatory mediators as they are being generated during the cardiac surgery procedure to try to prevent these bad things from happening.

Slide 23: We are advised by a number of key opinion leaders in the field from places like the University of Kentucky, Dr. Robert Bartlett, our Chief Medical Officer from University of Michigan, Texas Children's Hospital, Cleveland Clinic Foundation, Columbia University, the University of Pittsburgh Medical Center, and well-respected perfusionists, cardiac surgeons, and cardiac surgery intensivists in Germany and Austria.

Slide 24: The second pathway to potentially seek CytoSorb approval in the US is the Expedited Access Pathway that we have talked about before. It's essentially new guidance from the FDA that will allow potentially life-saving medical devices that address major unmet medical needs to be approved much more rapidly, in a fast-track pathway similar to the breakthrough designation pathway for drugs and biologics. For EAP designated medical devices, the FDA has given guidance that they are willing to accept lesser endpoints in registration trials that lead to the early market approval of these medical devices, in order to get the products to the market more quickly, provided that the devices are safe.

Then in the post-market period, the FDA would require the sponsor, which in this case would be us, to then commit to a post-market study that would need to prove out the much more stringent endpoints to stay on the market. We've been working very diligently on the EAP application for sepsis and expect to file it with the FDA in the coming weeks.

The application must be very thorough, including a data designation plan that details in very high detail the proposed clinical trials that are to be pursued in the pre-market as well as the post-market periods. Once we submit the FDA response, an EAP designation is expected within 30 days of submission, but it could be delayed due to questions.

EAP designation is the first step in the EAP pathway that basically allies sponsors like us with the FDA to now come up with the clinical studies that are necessary to get the product approved in the most rapid way possible and then of course the studies that are needed in the post-market period to stay on the market. We are very excited by this pathway, because we believe that CytoSorb is well-suited to this pathway given the many life-threatening diseases that we treat.

Slide 26: One of the reasons why we chose sepsis for this EAP pathway is unlike any other therapy that has been tried for the treatment of sepsis in the past, CytoSorb attacks sepsis from many different facets and attacks it very broadly. What we typically talk about is how CytoSorb reduces inflammatory cytokines to reduce the systemic inflammatory response syndrome that can cause organ failure. But it does much more than that.

In fact, we have data that it can remove immunosuppressive cytokines and re-establish immune responsiveness. This is particularly very important, because many people who develop sepsis get immune suppression and are prone to secondary infections like MRSA (methicillin resistant Staph aureus) infections or other hospital-acquired infections, catheter-related infections and other things, and wind up dying from those secondary infections. This is very important.

A third way is an underappreciated mechanism in the treatment of sepsis and this is in the removal of bacterial toxins. Through our work with DARPA and others, we have learned that CytoSorb removes many different bacterial toxins extremely efficiently. For example, we know that we can remove Staph aureus alpha-hemolysin, one of the most dangerous toxins and one of the reasons why MRSA and Staph aureus are so virulent. We can remove that with our CytoSorb device.

Also through work done by Dr. John Kellum, we now know that, in animal models, we can establish proper leukocyte trafficking to prevent cell-mediated organ injury. That means that we are able to direct cells of the immune system to where they should go to fight infection and away from innocent organs that are not affected, to try to prevent cell-mediated organ injury and organ failure.

Another area where CytoSorb has demonstrated benefit is in the improvement of hemodynamic stability. In just a few moments, I will give you several examples of that.

If you don't have a high enough blood pressure to push oxygenated blood to your vital organs, those organs will become ischemic and potentially die. This hypotension, or low blood pressure, is a problem commonly seen in septic shock, but also in shock from other critical care illnesses such as trauma, anaphylaxis, burn injury, pancreatitis, and many others.

Last but not least, another area where the device can potentially help is in the reduction of capillary leak syndrome. It is well-known that cytokines, like tumor necrosis factor, IL-1 and IL-2 can disrupt the endothelial lining of blood vessels and the cell-to-cell interactions that maintain the integrity of these blood vessels. When cytokines disrupt those intercellular connections, they become leaky, resulting in a direct pathway of fluid from the blood vessels into the surrounding tissues which is a bad thing.

When this happens in the lungs, for example, the air sacks, or alveoli, in the lungs start filling up with fluid and the patient essentially drowns from the inside out. We are finding, in a number of cases, that CytoSorb is helping reduce capillary leak syndrome.

We believe that there has been no other single therapy that has demonstrated this broad range of activity, which is one of the reasons why we are very excited about moving forward in sepsis for the EAP application.

Slide 27: One of our marketing slogans is "SIRS and SEPSIS: Regain Control" because this is what physicians are telling us that CytoSorb is helping them do. In addition to the case report study that we went over in the video, I have several case report studies that I would like to convey to you, just show you how the device is being used today.

Slide 28: In this case report on septic shock, a 72-year-old man was admitted with sepsis from a urinary tract infection. Despite appropriate broad antibiotic coverage, his condition and

hemodynamic stability rapidly deteriorated with a concurrent elevation in plasma inflammatory mediators. This is very common in sepsis. You can control or kill the bacteria, but if you don't control the immune response these patients can rapidly destabilize. Again, the control of deadly inflammation is the purpose of CytoSorb.

This patient developed full-blown multi-organ failure, septic shock, respiratory failure, coagulopathy, liver dysfunction and kidney failure and because of his kidney failure, he was placed on standard CRRT, continuous renal replacement therapy (hemofiltration), but instead of using that alone, they used it with CytoSorb. They did three CytoSorb treatments in the subsequent days. In the first and second consecutive sessions, it resulted in a significant reduction in inflammatory mediators, as well as a reduction in bilirubin, a product of the liver which can be toxic, and a marked reduction in the need for vasopressors - which are strong medicines like epinephrine to help boost the blood pressure - with a significant improvement in hemodynamics - or a stabilization of blood pressure - with reduced signs of capillary leak syndrome.

Later, the patient had a recurring second hit inflammatory episode that again destabilized him. Another session of CytoSorb was performed, following which he again rapidly stabilized. In this case, the treatment was safe and well-tolerated, helping physicians regain control of this very sick patient, who survived.

Slide 29: In a second case report study, a 45-year old man was admitted with a small bowel obstruction due to torsion. This is when the intestines twist on themselves like a sausage, causing obstruction and a disruption of the blood supply to the intestines, which can then go on to become ischemic and die.

He was immediately scheduled for surgical intervention, but unfortunately aspirated during anesthesia induction and then rapidly developed one of the most serious and fatal forms of lung failure called acute respiratory distress syndrome, or ARDS, requiring ECMO therapy, a therapy pioneered by Dr. Robert Bartlett, our Chief Medical Officer, to basically ensure that he had sufficient oxygen supply.

But he developed a massive inflammatory response with shock and capillary leak syndrome, severe whole body swelling, and multiple organ failure. CytoSorb was initiated on him which led to a very rapid decrease in IL-6 and IL-8, two major cytokines, paralleled by a marked clinical stabilization of the patient, including a significant reduction in vasopressors and a significant improvement in lung function, again reminiscent of the previous case report.

In this patient, CytoSorb again helped physicians to regain control of their patient and reduce the initially dramatic hyper-inflammatory response to help stabilize the patient hemodynamically, ultimately leading to his full recovery. CytoSorb treatment again was safe with no serious device-related adverse events noted.

Slide 30: Last but not least, another case of rhabdomyolysis. This was a 55 year old patient who was transferred from an outside hospital with sepsis from pneumonia and ARDS, but developed complications. At the outside hospital, he had developed a complication called compartment syndrome, where high pressure builds up in a muscle compartment that cannot expand. So, what happens is that the muscle tissue can't get blood supply because of the high pressures and it becomes damaged and necrotic. Once this happens, these cells release myoglobin, an oxygen-

carrying protein within the muscle cell, in a process called rhabdomyolysis. This myoglobin can crystalize in the kidney can cause kidney failure.

In addition, his inflammatory markers were extremely elevated and he also developed acute liver dysfunction. The patient underwent four consecutive CytoSorb treatments, 20 hours each, which led to a significant decrease, during the course of the treatment, of his plasma concentrations of IL-6, procalcitonin, myoglobin and others, with a simultaneous normalization of many of his laboratory parameters.

With treatment, he had a strong improvement in his clinical situation. Similar to the other cases, they were able to regain control of this patient, and help stabilize his respiratory and liver function. And in this patient, CytoSorb resulted in many improvements, not just in organ function and a reduction in inflammatory mediators, but also in the reduction of myoglobin and the treatment of rhabdomyolysis, helping to prevent kidney failure. Treatment was safe with no serious device-related adverse events. And again, this patient went on to a full recovery.

Slide 31: But there is much more to report and certainly much more than we can talk about today on this call. We'd like to get to the Q&A session. But CytoSorb is helping to save lives around the world. This is very clear. And more clinical data will be made public in October at three major upcoming events.

One of them that we are very excited about is the Second International CytoSorb Users Meeting in Berlin, Germany on October 2nd where we are expecting 100 to 150 attendees. We have three keynote speeches and probably one of the most robust lineups in terms of clinical data that we've ever had. We have a total of 17 presentations, with reports from the PIs from many of the investigator-initiated studies that are currently enrolling, including the ones that are completed at the University of Hamburg and Medical University of Vienna in cardiac surgery. We also have five to six case series. These are not just case reports, but are the hospitals' clinical experience in a series of patients in specific areas like burn injury, sepsis, post-op-cardiac surgery, lung transplant, rhabdomyolysis and others where they are going to be presenting data.

And so it's going to be very exciting. This will be followed by very extensive coverage at the ESICM, or European Society of Intensive Care Medicine, meeting in Berlin, Germany as well as the EACS meeting where we will exhibit and have clinical sessions and educational sessions as well as the EACTS, or European Association for Cardio-Thoracic Surgery, meeting in Amsterdam, in the Netherlands that same week.

We are very excited about the second half of this year. We think that the first year turned out very well, but we are looking at even better things to come in the second half. With that said, that is the end of our prepared remarks. Lee, feel free to start the Q&A session.

Lee Roth - Moderator:

Aaron, could you give the Q&A direction?

Operator:

Absolutely, and if you would like to ask a question at this time, please signal by pressing star one on your telephone key pad. If you are using a speakerphone be sure your mute function is turned off to allow your signal to reach our equipment; and that is star one to ask a question at this time.

And we'll take our first question from Jonathan Aschoff with Brean Capital.

Q&A Session:

Jonathan Aschoff - Brean Capital

After 2015, when you have brought on the two extra sales people and the medical science liaison, will that be enough for your current direct sales territory? Where else and when are you considering additional direct sales, and how many more people do you think you will need for that?

Phillip Chan - Chief Executive Officer and President

When you talk to major device companies in Germany, they typically have on the order of about 10 to 12 salespeople for the entire country. So as a small company, having nine people, hopefully by the end of the year, we'll be right up there with these major device companies. So we feel comfortable that we will have enough people to cover our direct territories well.

And as you know, we have a mixed revenue model with both direct sales as well as sales through both partners and distributors. We felt at the beginning and we continue to feel this, that Germany, Austria and Switzerland represent a great market for us to target directly with our sales force and allows us to have our own destiny in our own hands. Again, Germany is a multi-billion dollar market in critical care. For sepsis it is a \$1 billion to \$1.5 billion market alone. So if we are successful nowhere else in the world, we could do very well by just being successful in Germany.

That being said, because we are a small company, we cannot afford to have a direct sales force all over the world and that's one of the reasons why we are leveraging the sales and marketing distribution network of our partners as well as our independent distributors in other countries. This is the strategy going forward. We are not looking to open up new territories for direct sales, but it will be a blend between direct sales in Austria, Germany and Switzerland and indirect sales in the rest of the world.

Jonathan Aschoff - Brean Capital

Given the importance of the REFRESH Trial as the start of the US approval process for CytoSorb and the clear value inflection point that US approval could have that we are all looking forward to, what could delay the start of the REFRESH beyond September?

Phillip Chan - Chief Executive Officer and President

Right now, we feel very good about where we are. Clearly, legal negotiations of contracts and IRB approvals with universities can take some time and could delay our start. But I think we are in very good shape here, and are pleased to have brought on Steven Sisk, our Director of Clinical Operations who has been with us for a whole two weeks, but has really taken up the reins and will be a major positive for us for the REFRESH trial. We feel very confident about starting the trial in September. Now, not necessarily all sites will start at the same time, but the way that we are progressing, they should all come on very shortly one after another.

[Jonathan Aschoff](#) - Brean Capital

May I have the cost for both of these REFRESH trials?

[Phillip Chan](#) - Chief Executive Officer and President

The current REFRESH trial that we are looking to do here with 40 patients is under \$2 million. The REFRESH II trial that we are looking to start in 2016 will be on the order of about \$8 million to \$10 million.

Operator

And we will go next to R. K. Ramakanth with HC Wainwright.

[R. K. Ramakanth Swayampakula](#) - HC Wainwright

In terms of the sales of \$773,000 that you reported today, could you help us understand what part of it comes from [inaudible] and from India, which seem to be two major geographies at this point?

[Phillip Chan](#) - Chief Executive Officer and President

We have not broken out the direct sales versus distributor sales in the past. Right now, these are very lumpy, and can vary quarter to quarter. What I can say is, and what I mentioned in the prepared remarks is that the strength this quarter was in direct sales. Despite having a small sales force of only four people, we were able to achieve our second strongest quarter in our history in terms of product sales.

But going forward, we expect that India will be a very important player. They have already sent us their plans for the clinical trials that they will be funding and are currently expanding in Sri Lanka and also throughout all of India with their direct sales force. So we expect that India will become – it already is an important partner, but Biocon will become an even more important partner going forward.

As Kathy mentioned, in the past couple of quarter, we did not have the benefit of initial orders from new distributors, but we continue to have negotiations with independent distributors as well as strategic partners and look to help boost the distributor and partner side going forward.

[R. K. Ramakanth Swayampakula](#) - HC Wainwright

You said with four sales folks, you are doing quite well and that you should get to this sales team of nine in the second half. How directly coordinated will that be or how long will it take for the new folks to come in and learn the business before you can actually get to see the full potential of having the full team together?

[Phillip Chan](#) - Chief Executive Officer and President

Normally what we've seen in the past is that it takes salespeople roughly 3 to 6 months to get started; but I think the two sales people that we just added in July and August are well-known to our team. They have worked together before and are veterans in critical care medicine. They have established key opinion leader networks, are very smart guys, and have come up to speed very quickly. We've also been preparing them ahead of time with materials and other things to help get them up to speed quickly. So we think that they will be productive very soon.

And I think that it's important to reiterate what we have talked about previously - the potential value of a single hospital customer. Based on the incidence of sepsis and other critical care illnesses in a hospital, if CytoSorb became standard of care for sepsis or for other critical care illnesses, each hospital could potentially be a revenue opportunity of \$1 million to \$2 million per hospital.

There are more than 400 hospitals in Germany that are 400 beds or more. In fact, there are 2,100 acute care hospitals throughout the country. So you could see how the numbers could get very big, very quickly and how hospitals within each of the individual salespeople's territories can become much bigger contributors to our revenue than what we are even seeing now. For example, in the future, one hospital could exceed our entire revenue for this quarter. So I think that there is still a lot more productivity that we expect out of our sales people, and there is still a lot more that they can do individually. We also expect the new sales people to come online very quickly.

[R. K. Ramakanth Swayampakula](#) - HC Wainwright

So with the sales folks that have been with you for a while, what is stopping you or what is stopping your sales force from getting to the point where you are maximizing sales in these hospitals?

[Phillip Chan](#) - Chief Executive Officer and President

I think Christian can comment on this as well, but I think what we're seeing in the marketplace is that there is a tremendous amount of enthusiasm in the marketplace amongst physicians. I think that is very clear. We are with the major key opinion leaders in critical care medicine in Germany, Austria and Switzerland and in fact in many countries around the world. I think that enthusiasm is really key to our visibility and our confidence going forward that this is a real business that will be successful.

I think sometimes where we get stuck is in reimbursement, so we are spending a lot of resources in achieving reimbursement in different countries. We are working heavily on targeting the hospital administration also. Sometimes the hospital administration will say, "Well, that's fine that you want this product, but show me the data, show me something that says that this is helping save lives, improve outcomes, and reducing costs?"

So we are very focused on generating that data. As I've talked to you already, there are going to be many case series that will be presented with a lot of data in many different areas in both cardiac surgery and critical care that will help address that concern. So I think that's one of the areas that we are heavily focused on and trying to fix.

But I think the message to hospital administrators is this. CytoSorb is not just another loss item on their P&L (profit and loss statement). CytoSorb is one of those therapies that has the ability to change the potential economics in that hospital, because it's addressing such a big issue. If you read the literature and you talk to hospital administrators, somewhere on the order of 10% to 20% of a hospital's operating expenses are due to critical care medicine. One of the reasons why critical care medicine is so expensive is that hospitals lack effective therapies to help prevent or treat organ failure and to help these patients get better. This is why these patients stay in the ICU at a cost of \$2,000 to \$3,000 a day. It's because they are stuck on a life-support machine because their organs don't work. For example, they are stuck on mechanical ventilation because their

lungs don't work, or they are stuck on dialysis because their kidneys don't work. This is where the costs are for a hospital and where hospitals are losing billions of dollars both here in the United States as well as abroad.

This is the message that we need to get to these hospital administrators that says this product, CytoSorb, has the ability to change the economics of your hospital and reduce significant costs in your hospital. That's really where we are trying to go. If we can get there, that will open up a significant bottleneck in the sales process. Christian, I don't know if you wanted to comment on anything I said.

[Christian Steiner](#) - Vice President of Sales and Marketing

It's a complex situation when you introduce a new therapy like this. Because it is a paradigm shift in treatment and thinking that we are bringing to the hospitals, it can be a difficult task to work on. As an example, outside of the medical field, think about how many people own a premium product like a Tesla motorcar, I would guess very few of you. Despite the compelling message and idea that everyone can normally understand, that driving an electric car is good for the environment, the adoption is slower than you would expect. So the same is true in our situation. So although we have many people working with us on CytoSorb, they are obviously caught in a situation where they have to care about the cost, they have to care about the risk, and the data we have at the moment is limited. So the decision process in the hospital is very difficult and a lot of stakeholders have to be convinced. I think that is describing best why it takes its time.

[R. K. Ramakanth Swayampakula](#) - HC Wainwright

One last thing, with most of your revenue being Euro-based, and with the dollar strengthening all the time, have you ever considered shifting some of your manufacturing to Europe, either directly or through contract manufacturing, so that it can help your contribution margin?

[Phillip Chan](#) - Chief Executive Officer and President

So let me say a few words and then turn it over to Kathy to talk about how we are hedging our currency risk currently. There is a lot of know-how that goes into our technology. We have 32 issued US patents, with multiple applications pending worldwide. And it's very important for us to maintain that know-how and those trade secrets in terms of manufacturing, to keep our competitive edge.

In the meantime, we continue to innovate beyond what even CytoSorb is, to come up with the next generation technologies to move forward. So in order to best control that, it is in our best interest to maintain US manufacturing which also allows us very strict control over the quality of our product, which is very strong. From that standpoint, talking about the Euro and the dollar let me turn it over to Kathy for some of her comments.

[Kathleen Bloch](#) - Chief Financial Officer

We have a couple of naturally built in hedges with regard to the Euro. One is that probably approximately half of our sales are in dollars. We are selling to a number of the countries that are outside of the US, and some of the larger relationships, those sales are in dollars. And although we don't see it in the revenue number which is what we are all focused on right now, we still have substantial costs in Germany to support our sales and marketing team as well as clinical studies. These costs are being paid in dollars, which are coming down as the euro comes down. Of course, since we are focusing on the revenue line, we don't really see that benefit coming through.

Operator

And we will go next to Andrew D'Silva with Merriman Capital.

[Andrew D'Silva](#) - Merriman Capital

I just have a couple of quick questions. A lot of them have already been answered. First off, as far as Germany goes, or with some of the hospitals that you've had time to really have some historic data, how sticky is CytoSorb with doctors that are already utilizing it in various therapies? [Edited] Meaning, after a physician has utilized the product one time, do you have any data that they are coming back and utilizing it over and over again?

[Phillip Chan](#) - Chief Executive Officer and President

Christian, this would be a good one for you to comment on.

[Christian Steiner](#) - Vice President of Sales and Marketing

[Edited] If you look at our business, the whole business is based on repeat orders by physicians. At the moment, the data we can present is limited and so all the business we are doing at the moment is based on their experience. Our goal for every potential new customer is to teach them how best to use CytoSorb so that they have positive experiences that will lead to repeat usage. We have improved our recommendations regarding patient selection, how to treat, when to treat, and how often to treat, so that treatment is more and more successful. We are getting better at it, so that we are absolutely seeing reorders.

[Andrew D'Silva](#) - Merriman Capital

So reuse amongst doctors that have initially used the product is increasing, that's the situation?

[Christian Steiner](#) - Vice President of Sales and Marketing

Absolutely.

[Phillip Chan](#) - Chief Executive Officer and President

I would just add to that. The majority of our orders are reorders. One of the interesting things that we are seeing right now is that smaller hospitals that surround the big regional tertiary care hospitals, are hearing from their colleagues in the larger hospitals about how CytoSorb is being used and the successes that they have had. They are ordering now as well.

So we are actually getting a very nice mix now of both reorders from existing customers as well as new customers as well. Those new user accounts are typically small and are just using the product initially, but as they grow, those accounts could become more significant as well. So I think there is a very nice ecosystem that we are seeing based upon the successes that clinicians are having with CytoSorb in the market today.

[Andrew D'Silva](#) - Merriman Capital

My next question is around your sales process and trying to get a little bit more insight into what to expect out of some of the new markets like Australia and Saudi Arabia. First off, have sales begun there and then if so, are there any notable hospitals that are looking to utilize your product or are utilizing your product? And if not, what is the step to get in the door with them so that they are aware of the potential that it offers?

[Phillip Chan](#) - Chief Executive Officer and President

I think when we choose distributors and when we choose strategic partners, we are very careful in trying to find players that have existing thought leader networks in critical care or cardiac surgery. At this stage, these relationships are critical in introducing new products. That has been a requirement of all the distributors that we have. What we've seen is that they will take the product to their closest customers, to their main customers, to the important key opinion leaders at major hospitals, and will start with them first and then grow from there.

Now, unlike when we started off in Germany and really had no clinical experience, I think as we move forward with new territories, new distributors, and new partners, we have a much broader base of clinical understanding and clinical knowledge and clinical data to help support those launches in those countries. So, I think that what we will see from these new territories that are coming online is that they will kick off more quickly, benefiting from the data that is being generated elsewhere in the world both in the past and currently.

[Andrew D'Silva](#) - Merriman Capital

And then as far as Biocon and India goes, couple of quarters ago they were really increasing their investment in getting the name out of CytoSorb, has there been an update in some of their efforts and has that translated to any increased use?

[Phillip Chan](#) - Chief Executive Officer and President

What we've seen from Biocon is that Biocon is very excited about the product. I think what they are trying to do is to teach the market to use CytoSorb earlier during critical illnesses. In India, the affordability of imported medical therapies and devices is a challenge due their high price. So to come in with a premium product like ours, which is not being discounted by the way in India, there is that economic issue.

But I think what Biocon has been seeing is that when they get doctors to use it earlier as it is being used in other parts of the world, like Germany, Austria, Turkey, Netherlands et cetera, they are seeing much higher rates of success where they're getting more comfortable in recommending the therapy earlier and recommending the therapy to a patient's family earlier.

So I think things continue to develop at Biocon, they continue to put forth a lot of resources towards this. We just had a call with them very recently, everybody is very excited, and the team over there is very excited about what they are seeing in the marketplace. So again, as I mentioned to R.K., we expect that India will become a significant player, it is already, but will become an even more significant player in the future.

[Andrew D'Silva](#) - Merriman Capital

Just a last question, using Germany as a proxy, what do you see as the major catalyst that will make CytoSorb a product that is currently utilized from time to time in one hospital, to where it is standard of care in a whole region? If you were to put a timeline window on how long it would take, could you explain that and quantify that for me?

[Phillip Chan](#) - Chief Executive Officer and President

What we know is that there is nothing other than supportive care medicine to help patients who are critically-ill. That means for the markets we serve, including patients with severe sepsis and septic shock, trauma, burn injury, pancreatitis, severe liver disease, acute respiratory distress syndrome, complications of cardiac surgery, post-operative inflammation and many, many

others, there is little that can be done to actively help these patients. So the bar is actually relatively low in terms of trying to become standard of care in these areas.

Clearly, you need data and you need clinical experience, and importantly, what we have found, and what we will hopefully see in these case series during our International Users Meeting is that people have seen it work with their own eyes. They have been refining how to treat, when to treat, and who to treat with people with specific illnesses. Many have been having increasing success as they revise their treatment protocols and in several specific applications, CytoSorb is becoming standard of care at specific hospitals without it ever having gone through a multiple site randomized controlled trial for that indication.

For example, we have a couple of hospitals right now that have had so many experiences with rhabdomyolysis - that is one of the case report studies that we talked about before - where it's been used very effectively that they are telling us that they are using it on all of their rhabdomyolysis patients. We have some applications in cardiac surgery, for example, where the device is helping stabilize patients intra-operatively in certain types of surgeries and again, they are telling us that they are using it now on all those cases in cardiac surgery as well.

It is interesting that we are seeing this grassroots standard of care movement with CytoSorb therapy. Clearly, we look to accelerate and augment that with company-sponsored as well as investigator-initiated studies that are specifically performed in a randomized-controlled fashion to prove this to be the case. And we are absolutely committed to doing that. But what we are seeing right now is that it's such a major unmet medical need, and when they see the success with the product in their own hands, it is becoming standard of care in these pockets in different hospitals around Germany. So hopefully that answers your question.

Operator

And you will go next to Jan Wald with Benchmark Company.

[Jan Wald](#) - Benchmark Company

I guess I have a couple of questions left. Phil, you talked in the call about registration and then reimbursement, how do we understand what needs to happen in the European countries and in Asia in terms of getting the registrations completed and then eventually getting reimbursement?

[Phillip Chan](#) - Chief Executive Officer and President

In terms of registration in Europe, technically the bar is very low to get registration in Europe because of our CE Mark approval. In fact, the registration process for individual countries in the EU typically only takes several months. For example, in Fresenius' case, all these countries are registered. So that's not an issue.

Outside of the European Union, however, they will accept CE Mark approval, but typically the process of registration is longer. They require more documentation, each individual country typically has its own requirements in terms of documentation. Some are very detailed and some just require different documents that we need to produce, and that kind of thing.

So from that standpoint, it's a process that takes time. But the good part is that with the Saudi FDA approval and the market authorization there, it's a big leg up in the GCC countries and so we expect those registrations to continue to move very rapidly. In Russia, again, that's taking a long

time, but we do believe that we are nearing the end in terms of obtaining Russian registration. And then other countries, as they come along, like Israel and others, where we are in the process now.

Reimbursement is a separate issue and often requires some amount of data to obtain reimbursement. As you know, we have reimbursement in both Germany and Austria today. In certain parts of India and certain hospitals and patient populations, there is private pay as well as government reimbursement. In Turkey, there are tender orders and there are certain ways to bundle things to obtain reimbursement. And in other countries, they are finding ways to get paid. In the United States, of course, there's the DRG (diagnosis related group) reimbursement, which is a form of a one lump sum payment. So in the United States, for example, if we were to get approval here for the treatment of sepsis, we would just fall under that DRG. We could always apply for a separate code that would take time, but we would still be able to be reimbursed under the DRG pretty much right away.

I think we are spending a lot of resources in terms of seeking reimbursement in different countries and that's just a process that takes time. Going into the second half of this year, I've just talked about all the kinds of data that we are looking to generate in these case series, these investigator-initiated studies and other things. I think these data will be extremely helpful in obtaining and accelerating the reimbursement process all over the world.

[Jan Wald](#) - Benchmark Company

And I guess one last question, if you don't mind. When you talked about the opportunity to go through the expedited review, you talked about lesser endpoints to achieve early market approval, and then more stringent endpoints in a post-market study. Would you help me understand the difference between the two?

[Phillip Chan](#) - Chief Executive Officer and President

Sure. For example, in the area of sepsis, the standard primary endpoint for all Phase 3 pivotal clinical studies in the past has been 28-day all-cause mortality. And there has only been one company ever to achieve 28-day all-cause mortality improvement in a pivotal trial, and that was Eli Lilly with their Xigris product that was the only product ever FDA approved to treat sepsis. Xigris has been subsequently taken off the market and there are currently no therapies that are approved to treat sepsis.

Now, when we talk about lesser endpoints, we are talking about things like days in the intensive care unit, days on the ventilator, hemodynamic stability, and use of vasopressors. These are the types of softer endpoints where we are clearly seeing the benefit of CytoSorb today in our clinical usage throughout the world.

And so we believe that if the FDA is willing – and the EAP guidance suggests they are willing - to accept these lesser endpoints. That means that these trials, because of the higher rate of efficacy in these lesser endpoints, could be smaller, cheaper, and faster, thereby helping accelerate early market approval.

Operator

And we will go next to Brian Marks with Zacks Investment Research.

[Brian Marks](#) - Zacks Investment Research

Since we are on the subject of a potential EAP success trial, so can you talk about what you are thinking in terms of size of the trial and length of the trial in terms of potential enrollment?

[Phillip Chan](#) - Chief Executive Officer and President

Right now, the data designation plan is being set and it would be premature for me to talk about that right now. But suffice it to say, our aim in this data designation plan is that we are not looking to do an all-comers trial, meaning we are not looking to take every sepsis patient that walks through the door or that's in the ICU. I think that has been a major stumbling block and a major reason why most sepsis trials in the past have failed.

The heterogeneity of the sepsis population is quite immense. It depends on what kind of bacteria that they are infected with - gram-positive, gram-negative bacteria, anaerobic bacteria, fungal infections, viruses, etc. The site of infection is very important such as the lungs, the kidneys, the urinary tract, the abdominal cavity, cellulitis on the skin, meningitis in the central nervous system, and others. The age of the patient is a risk factor. High levels of cytokines versus those with lower levels of cytokines also predicts mortality. So as you can imagine, there are a very complex set of variables and because of this, it is very complex to actually design clinical studies in sepsis. That being said, we do believe that we have ideas based upon our clinical data, based upon the clinical usage in the marketplace, etc, on the particular trial design and that is what we are going with to the FDA.

[Brian Marks](#) - Zacks Investment Research

Just wanted to step back to REFRESH and assuming that you go that way, can you talk about what the potential variety of biomarkers that you might be interested in looking at in REFRESH and are some of those potentially similar to the biomarkers that were in the small Germany trial, I think that was done or was published last year?

[Phillip Chan](#) - Chief Executive Officer and President

Yes, so there was a study done at the University of Munich, a 40-patient retrospective study, 20 control, 20 using CytoSorb intra-operatively during complex cardiac surgeries and what they showed was that intra-operative treatment with CytoSorb led to a reduction in inflammatory mediators in the post-operative period compared to the control. And that was statistically significant for things like procalcitonin, interleukin-6, there were some statistical significance with fibrinogen and others.

In cardiac surgery, there are a number of things that are activated during cardiac surgery. For example, there is the activation of complement. Complement is part of your body's immune system that helps fight infection, and activated complement forms pores in cells and causes them to explode. This is useful, for example, if a cell is infected by something. It is well-known, however, that activated complement can lead to adverse outcomes including death. In cardiac surgery, it is also very clear that a number of different cytokines, such as IL-6, are elevated. Free hemoglobin is also elevated because of hemolysis and the mechanism that we talked about before. Then there are all sorts of different inflammatory mediators like C-reactive protein, fibrinogen - which is acute phase reactant - and others that are indicative of an inflammatory response. These are examples of some of the inflammatory mediators that we will be looking at in the REFRESH trial.

[Brian Marks](#) - Zacks Investment Research

And with REFRESH I, is that something that is publishable, assuming it is positive?

[Phillip Chan](#) - Chief Executive Officer and President

Absolutely. The ability to remove free hemoglobin has not been possible before either intra-operatively during cardiac surgery or even post-operatively during cardiac surgery. Nothing out there can remove free hemoglobin in real time, except for the administration of haptoglobin, but that still doesn't reduce the effects of free hemoglobin in the body, and doesn't have any effect on any other cytokines or inflammatory mediators.

That being said, we do believe that the ability to reduce these inflammatory mediators would be a very important discovery, particularly anything that links the reduction of free hemoglobin with improvement in clinical outcomes. In this REFRESH study, the primary endpoints are about safety and free hemoglobin reduction. But in the pivotal study, it could potentially be about free hemoglobin reduction alone or could be about free hemoglobin reduction and improvement in clinical outcomes as well. It was interesting, in our conversations with the FDA, they have acknowledged that free hemoglobin can cause dangerous problems and if we could show that a reduction in free hemoglobin can actually improve clinical outcomes, that would be a major advance in cardiac surgery. So we are very excited about what we are doing. I think it's also well acknowledged by a lot of the clinicians who are involved in this study. They all see these complications after complex cardiac surgery. So I think there is a lot of support there. If we were able to show benefit, it would be a very impactful study.

[Brian Marks](#) - Zacks Investment Research

Let's say that REFRESH comes out positive, you go to REFRESH II, can you talk about what REFRESH II that you envision entails in terms of the scope and enrolment size and number of sites? And then in terms of endpoints, are there additional endpoints that you layer on top of that or is it kind of the same endpoints in initial REFRESH?

[Phillip Chan](#) - Chief Executive Officer and President

What we have said before, I don't think has changed. I think the FDA will look at the results of this initial REFRESH I trial, at the values of free hemoglobin and other things, before we agree to a trial protocol for REFRESH II. They have left the door open for a possible de novo 510(k) filing, where the endpoints would be a reduction in free hemoglobin, for example. We believe that would be a small trial. That would be likely be a 100 patient trial that we could execute upon very quickly. And that is using CytoSorb intra-operatively during cardiac surgery and just looking at free hemoglobin reduction.

Now, the other trial that we could do is a PMA trial where we would be looking at clinical endpoints, such as the incidence of acute kidney injury, or the time it took someone to get off of the ventilator after cardiac surgery, with or without our product. That study would be roughly a 300 to 400 patient study, but it would be exactly the same design. It would be treating the patient intra-operatively during surgery - that's all you do- and then you just follow the patient post-operatively to look at clinical outcomes as well as free hemoglobin and other biomarkers. In the de novo 510(k) trial, you just flip the primary and secondary endpoints around in the two studies, where the primary endpoint is free hemoglobin reduction and the secondary endpoints are clinical outcomes.

[Lee Roth - Moderator](#): And that does conclude the Q&A portion of today's call. I'd like to turn it back over to Dr. Chan for any comments and closing remarks.

Phillip Chan - CEO: Great. Thank you everyone for taking the time today to get on this call and to get an update on the company. We certainly appreciate your participation and shareholder support. If you have any other questions, please feel free to reach out to Amy Vogel at avogel@cytosorbents.com and we will try to get you answers to some of your questions as needed. In the meantime, we look forward to the next update on the next quarterly call. Thank you all very much and good night.