CytoSorbents™

Working to Save Lives Through Blood Purification

CytoSorbents Corporation (NASDAQ: CTSO)
Q3 2015 Earnings and Operating Results Conference Call
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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 Third Quarter 2015 Financial Results Conference Call. 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, Sharon, and good morning everyone. Welcome to the CytoSorbents third quarter 2015 operating and financial results conference call. Joining me today from the company management are:

- Dr. Phillip Chan, Chief Executive Officer and President
- Kathleen Bloch, Chief Financial Officer, and
- Vincent Capponi, Chief Operating Officer
- Chris Cramer, VP of Business Development
- 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 this 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 as of today, Friday, November 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 of the third quarter by Dr. Chan and Ms. Bloch. Following that presentation, we'll open the line to your questions during the live Q&A session with the rest of the management team.

At this time, it's 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. Welcome. The management team is pleased to be here today. Following the presentation, we'll have a live Q&A session and then an official transcript of today's call will be available within the next week on our Web site at www.cytosorbents.com. For those of you who would like to learn more about our flagship product, CytoSorb, I would encourage you to visit www.cytosorb.com where we have a lot of new and current information.

Slide 4:

CytoSorbents is a leader in critical care immunotherapy. We are leading the prevention or treatment of life-threatening inflammation in the ICU and cardiac surgery using our CytoSorb blood purification technology. Severe inflammation is deadly in the ICU. Millions of people every year are admitted to the intensive care units and hospitals worldwide each year with deadly inflammatory conditions such as sepsis and life-threatening infection, acute respiratory syndrome and lung injury, burn injury, trauma, pancreatitis, influenza, cancer immunotherapy and other inflammatory diseases.

In these conditions, massive inflammation driven by an activation of the immune response and the development of a cytokine storm, causes cell death and organ failure. Nearly half of all deaths in the ICU are due to organ failure where there are no effective therapies. Because of the lack of effective therapies, approximately one in every three patients dies and the cost can be staggering. The lack of active therapies leads to patients lingering days to weeks at a time in the Intensive Care Unit at a cost of $2,000 to $3,000 a day, on average. Therefore, it is not surprising that we spend nearly 1% of our gross domestic product, defined as the value of all of the goods and services produced by United States, on critical care medicine every single year.

Slide 5:

We also know that severe inflammation is dangerous in open-heart surgery. Many of us on the phone know someone who has had open heart surgery, just one of the more than 1 million open heart surgery patients in the U.S. and European Union every single year for things like coronary artery bypass graft surgery, often called CABG, or valve replacement or repair surgery, heart or lung transplantation, congenital defect repair, aortic reconstruction, and many other different types of cardiac surgeries. In complex cardiac surgeries, patients are on the heart and lung machine and the operating table for a very long time, which can cause destruction of blood cells and can trigger a cytokine storm and severe inflammation. This inflammation then leads to organ dysfunction and failure, such as lung or kidney failure, instability of blood pressure, cognitive changes, and intestinal injury. Before now there were no effective ways to prevent this from happening.

Slide 6:

That is where we come in. CytoSorb removes the fuel to the fire of inflammation, targeting a $20 billion or more opportunity in critical care and cardiac surgery. We are approved in the European Union as the only specifically approved extracorporeal cytokine filter. CytoSorb is clinically proven to remove key cytokines from the blood of critically-ill patients. We are approved for use in any situation where cytokines are elevated. That means we can be used on-label for all of the diseases that we have talked about. Because CytoSorb is a broad spectrum adsorber, we can also remove many other inflammatory mediators such as free hemoglobin, bacterial toxins, and activated complement, for example.

Slide 7:

The therapy is safe and has been well-tolerated in more than 8,000 human treatments, mainly in critically-ill patients, with no serious device related adverse events, including in more than 1,000 cardiac surgeries. The goal of our therapy is to try to prevent or treat organ failure. This is in contrast to the current strategy where clinicians in the intensive care unit lack effective therapies to help control deadly inflammation and to prevent organ injury from happening. Without effective therapies, patients often spiral down into this black hole of organ failure, to be supported at the very bottom with life-support machines such as mechanical ventilation and dialysis that attempt to keep the patient alive, but typically do not help the patient get better, and in many cases can harm the patient.

Our strategy is different. Our goal is to pre-emptively strike against this deadly inflammation, prevent it from causing this massive sequelae of damage to the body, thereby hopefully helping to improve patient outcomes and survival, while decreasing the massive cost of ICU and patient care. Because of this, we believe that we are well-positioned to potentially revolutionize critical care medicine with CytoSorb.

Slide 8:

Now when we talk about evolution of the CytoSorb market, I think this diagram maybe helpful to some to understand what it is that we are trying to do. We divide the market for CytoSorb into three major categories, A, B and C. Where we are focused today is predominantly in Categories A and B.

Category A is where patients have advanced disease. These patients are often well into their clinical course. They are very difficult and expensive to treat and they have a very high risk of death. This is where our CytoSorb technology has the most compelling risk -reward ratio at any phase, either early or late.

Category B is where we believe our sweet spot is. This is where patients are very sick - they are in the intensive care unit with organ dysfunction – but this is where we think CytoSorb is the most effective. Many of these patients will get better, but at huge costs, and we know that at least one in three patients in many of these diseases will get worse and die. CytoSorb, in this case, is used early and aggressively to help change the course of the illness and in doing so, is intended to change the course of their illness, potentially improving their outcomes and reducing costs.

You can see that as we move down this pyramid of categories, the total addressable markets get larger and larger. Our goal today is to drive standard of care in Categories A and B.

Category C is what I call the blue sky applications of CytoSorb. It really is remarkable how many different applications CytoSorb has been used for even today. I don't think that we have even imagined all of the potential uses of CytoSorb in the future. Category C also describes patients that are sick, but can get better on their own or can get better faster, or have a better outcome, with some help. The use of CytoSorb in these patients will be dictated by cost, risk-benefit, as well as the potential to prevent or treat chronic diseases. This is a much broader market than the ICU market alone. That said, be assured that we are putting a tremendous amount of effort into developing Categories A and B, and with clinical data we hope to be able to become standard of care in these markets.

So, with that let me turn it over to Kathy to go over the financial highlights for the quarter. Kathy?

Kathleen Bloch - CFO

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

Slide 10:

Turning to our financial results, for the third quarter of 2015 our CytoSorb product sales were approximately $1.1 million, which is the highest quarterly product sales in our company's history. This represents a 4% increase over the third quarter of 2014 where product sales were approximately $1 million. The decrease in the exchange rate of the Euro had a negative effect on our reported results, which we will cover in more detail in a little bit.

Grant and other income was $272,000 for the third quarter of 2015, as we achieved certain billable milestones related to our DARPA grant activities during the quarter. And finally we note that we were able to achieve gross profit margin on product sales of approximately 63% in the third quarter of 2015.

Slide 11:

Next, our nine months revenue results. CytoSorb product sales for the nine months ended September 30, 2015, were approximately $2.5 million, which is a 13% increase over the first nine months of 2014 product sales of approximately $2.3 million. As with the third quarter, product sales for the nine months were negatively impacted by the declining exchange rate for the Euro, our gross profit margins of product sales were approximately 62% for the nine months ended September 30, 2015.

Slide 12:

Next we look at our chart of product sales by quarter. The light-blue bar that is the bottom portion of the bar on this chart represents our actual reported sales. Note: our record Q3 2015 sales of $1.1 million represents an increase of approximately $300,000, or 39%, over sales in the third second quarter of 2015. In the first nine months of 2015, the average exchange rate of the Euro was $1.12, as compared to the first nine months of 2014 when the Euro exchange rate averaged $1.35.

As the majority of our product sales are in Euros, this decline resulted in a significant reduction in our reported sales, when compared to the same period of 2014. To demonstrate this impact,

we added the dark blue portion to the top of the 2015 quarterly bars. This adjusts the sales for the first, second and third quarters of 2015 as if the Euro to dollar exchange rate was unchanged from the same period in 2014.

So were it not for the decrease in the exchange rate of the Euro, product sales for the third quarter of 2015 would have been approximately a $150,000 higher than our actual reported sales, which is 14% of total product sales. In other words, if we eliminate the impact of the drop of the exchange rate of the Euro relative to the dollar in the third quarter, product sales for Q3 2015 would be approximately $1.2 million. Likewise adjusted for the change in the Euro, our product sales for the first nine months of 2015 would have been approximately $3.0 million; which is an increase in product sales over the first nine months of 2014 of approximately $694,000, 31% increase as compared to the 13% increase which we actually recorded.

Slide 13:

Then the next chart shows our trailing 12 months product revenue and I've included the same adjustment to eliminate the impact of the decline in the Euro, and again that is represented by this dark blue bar at the area at the top of the bar. So with the adjustment for the Euro decline, our trailing 12-month product sales at the end of the third quarter of 2015 is approximately $3.8 million compared to approximately $2.6 million for the previous year, an increase of $1.2 million or 46%.

I want to make the few comments regarding our product sales expectations. First of all, we continue to see repeat orders from both distributors and direct customer and we are seeing steady quarter-over-quarter improvement in direct sales, both as a result of adding new customers and also from repeat orders from existing customers. We added two new sales people to our team in the third quarter of 2015 and we also plan to add two more direct sales people towards the end of the year, which should further fuel direct sales.

Also, with regard to distributor initial orders in a first nine months of 2015, we have not seen the benefit of the initial product rollouts in France, Poland, Sweden, Norway, Denmark and Finland by Fresenius, nor the rollouts in Australia and New Zealand through our distributors in those countries. So these territory products rollout are expected to also have a positive impact on our future quarters.

Slide 14:

And finally some notes on our working capital position and our cash runway. As of September 30, 2015 we had approximately $9.3 million in cash and short term investments. Our gross cash burn in the third quarter of 2015 was approximately $2.4 million. This was partially offset by the receipt of approximately $568,000 in cash from the exercise of options and warrants.

Our working capital, excluding the warrant liability which is a non-cash item, was approximately $10.3 million at the end of September 2015.

Turning to our capital structure, as of September 30, 2015, on a fully diluted basis, we have approximately 29 million common shares outstanding. On November 4, 2015, we entered into a controlled equity offering sales agreement with Cantor Fitzgerald through which the company may offer to sell from time-to-time, through Cantor, shares of the company's common stock not to exceed an aggregate amount of $25 million.

This provides the company with a very cost effective and flexible means of raising capital, if needed, with pricing at the market without a discount and without warrants resulting in significantly less dilution and better stock performance during the program, compared with certain other traditional financing arrangements.

So far in 2015, 84 healthcare companies have filed 91 ATM, or "at the market", programs or approximately $3.4 billion in aggregate value. The Cantor controlled equity offering was one of the first "at the market" programs available to public companies and Cantor has been a leader in executing these aftermarket offerings. Cantor is also a trading powerhouse with research distributed to over 7,000 institutional clients. This equity offering will give the company another powerful tool to help raise capital, when needed to fund the clinical trials which are aimed at making CytoSorb the standard of care.

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

Phillip Chan - CEO

Slide 16:
Thank you very much Kathy, now on to some operating highlights. As we discussed in the press release today, the first item is that we submitted our application to the FDA to seek Expedited Access Pathway designation for CytoSorb to treat sepsis. The FDA has established the Expedited Access Pathway, or EAP, program to facilitate the approval of medical devices that either treat life-threatening conditions or prevent permanent disability and have no approved alternative treatments.

EAP designation is the equivalent of breakthrough designation for drugs and biologics, but for medical devices. Given that the application is under review, it would not be appropriate for us to discuss it at this time, but we will have an update in the future at the appropriate time.

Slide 17:
In terms of our cardiac surgery partner update, I'm pleased to announce that the evaluation by our cardiac surgery partner in France, one of the top four cardiac surgery companies in the world, is now successfully completed. We are currently in discussions with the cardiac surgery partner and we will have an update at the appropriate time as well.

In the meantime, CytoSorbents has been used in more than an estimated 1,000 intra-operative cardiac surgery cases to date in Europe.

Slide 18:
Preliminary results from some of the recent clinical activity in cardiac surgery were presented at the Second International CytoSorb Users Meeting in Berlin in November. These studies were evaluating safety and inflammatory mediator biomarker reduction using CytoSorb intra-operatively in a heart-lung machine in low-risk cardiac surgery patients.

The first study was conducted at the University of Hamburg- Eppendorf. This was a 20 patient randomized, controlled pilot study, which is now complete. The second one was a 37 patient randomized, controlled pilot study at the Medical University of Vienna, which is also now complete. At the University of Cologne, interim data from 142 of 300 patients comparing 21

patients undergoing off-pump surgery, 61 patients with on-pump surgery without CytoSorb, and 60 patients who had on-pump surgery with CytoSorb.

The general high-level preliminary results from these studies demonstrated that the therapy was well-tolerated and safe without device related issues. There was no removal of heparin, no bleeding or coagulation issues, and no device setup concerns. Also, preliminary initial cytokine data demonstrated that some cytokines are removed in CytoSorb treated patients compared to control patients, but overall inflammation in these shorter, lower risk surgeries was not very high. Cytokine and other inflammatory mediator analysis is continuing.

Similarly, the risk of adverse events and mortality were low in both treatment and control groups. Now that safety has been determined, all three clinical trial sites are interested in extending their treatment experience to complex cardiac surgery; to patients that are very similar to those that we are studying in our REFRESH trial where the risk of inflammation and adverse events are much higher.

The completed studies are in the process of being prepared for journal submission.

Slide 19:

And that leads us to a REFRESH update. Our REFRESH trial is the REduction in FRee Hemoglobin trial. It is a 40-patient, eight center, randomized controlled safety and feasibility study in the United States using CytoSorb intra-operatively in a heart-lung machine bypass circuit in patients undergoing complex cardiac surgery. These include, for example, aortic reconstruction, multiple valve replacements, and other types of longer surgeries. The end points include safety and free hemoglobin removal from blood.

I'm pleased to say that we are working with some of the leading cardiac surgery centers in the country in this trial and these includes Baylor College of Medicine, Baystate Medical Center, Columbia University, Cooper University Hospital, University of Kentucky, University of Maryland, the University of Pennsylvania, as well as University of Pittsburgh Medical Center.

The study has started with one site currently screening to enroll patients and a total of 6 out of 8 sites will be in the similar position before the end of November.

Slide 20:

In addition to what Kathy mentioned, we are currently working with Fresenius in the initial marketing to critical care key opinion leaders in multiple countries where they have exclusive distribution rights, including France, Poland, Denmark, Finland, Norway and Sweden. CytoSorb will not only be certified on the existing Fresenius multiFiltrate, but as we discussed last time, it will also be certified on the newly launched multiFiltratePRO. We are expecting a formal roll out of CytoSorb in the next several months and as Kathy noted, in Q3 2015, we achieved record results with no contribution yet from Fresenius. So we look forward to when their orders begin to impact our top-line growth.

Slide 21:

Another thing that we achieved recently was the award of a Phase 2 SBIR contract by NHLBI (National Heart, Lung and Blood Institute) for HemoDefend. Our highly porous, biocompatible bead platform enables a broad and valuable pipeline. We have been talking about CytoSorb

exclusively during this call, but we have a number of other products under development. One that is under advanced development is called HemoDefend and this is the product that is designed to try to improve the quality and safety of the blood supply.

Slide 22:

We know that blood transfusions carry risk. There are 85 million packed red blood cell transfusions worldwide every year, with 15 million in the U.S. alone. Although blood transfusions are considered relatively safe, there are more than 65,000 transfusion reactions reported in the United States alone. The exact cause is unknown, but relates to many of the non-infectious containments in blood such as free hemoglobin, cytokines, bioactive lipids, antibodies and other things. When a transfusion reaction occurs, it not only potentially puts the patient in harm's way, and can even lead to death, but it also causes a huge administrative burden on hospitals due to the need to keep records and documentation, and to do follow-up testing of these patients. It is very time consuming and very expensive.

Slide 23-24:

A driving goal across the industry is to continually improve the safety and quality of blood supply at reasonable cost. I think one of the reasons why our technology has been very competitive in this HemoDefend grant process is because it has the potential to be a very cost effective solution. HemoDefend is a small in-line point-of-transfusion filter that sits between the bag of blood and the patient. This filter contains our hemocompatible porous polymer beads that can remove a broad range of contaminants from packed red blood cells. In fact, it is designed to remove substances less than 1 kDa in size to substances greater than 150 kDa in size. So everything from small drugs to large antibodies, for example.

The HemoDefend cartridge is a high flow, low resistant filter that works by gravity and can deliver the entire unit of blood within 20 minutes without the need of a pump or any kind of special pressurizing equipment. It is not expensive, it does not contain any leachable antibodies, ligands, or any affinity agents, and it is gamma sterilized and has a long shelf life at room temperature, thereby making it an easily produced item. The goal of HemoDefend is to wash blood without actually incurring the time, cost, and expense of washing blood with a machine. It aims to improve the quality of blood by removing a broad number of contaminants such as potassium, free hemoglobin, antibodies, cytokines, inflammatory mediators as well as bioactive lipids. On the right hand side of this slide is some data from our Phase 1 SBIR program where we collaborated with Dr. Larry Dumont at the Geisel Medical School at Dartmouth University. You can see here the ability of our technology to remove significant quantities of these potentially harmful contaminants.

Slide 25:

So we are pleased to announce now that NHLBI has awarded us a $1.5 million Phase 2 SBIR contract that will help advance HemoDefend towards human treatment trials and commercialization, particularly in surgery and critical care where the need is greater. Unlike what we saw in the REFRESH and ABLE trials, where most patients only received an average of one or two units of blood, we are talking about patients who are receiving many more units of blood. These include so called "massive transfusions", where patients are given up to 10 units of blood within 24 hours. Because the risk of transfusion reactions is cumulative, every bag of blood represents an additive risk of having a transfusion reaction. We are pleased to be underway with that program currently.

Slide 26-27:

With that, I would like to change gears and talk about some examples of patients who have been treated by our technology. First, however, our European team has put together a short video from our Second International CytoSorb Users Meeting where we talked to a number of key opinion leaders who were in attendance there to get their thoughts on number of different subjects. For those of you on the phone my apologies, there is no way to have audio play during the call. So if you could just hang on for about three to four minutes, the video will be played in its entirety and we will be ready to go back with the case report studies. For those of you on the webcast you should be able to view this without a problem. Here we go.

[Audio/Video Presentation]

Slide 28-30:

So we are back online and hopefully you enjoyed that video. If you would like to share that video with someone, or if you would like to replay it later, the video is available now on our cytosorb.com website as well as some other videos, including a short brief video from our Second International CytoSorb Users meeting.

Now one of the case reports that I want to share with you involved a young girl with toxic shock syndrome. What was remarkable about this case is that she was only four years old and 38 pounds. To date, our therapy has predominantly been used only on adult patients, typically patients between the ages of 18 to 80 years old. This little girl was stung by an insect on her right leg, which then became infected. For those of you who are a little sensitive to pictures, the next several pictures may be disturbing so you may want to turn away, but please keep the audio on.

She was admitted just a few months ago to the Medical Center of the University of Debrecen in Hungary. This is a Fresenius medical center in Hungary that is affiliated with the University. She was diagnosed with a Staph aureus infection of her leg and was positive for toxic shock syndrome toxin and treated with antibiotics. This is an actual picture of her right leg.

Despite antibiotics, her condition rapidly worsened and she developed a severe systemic inflammatory response syndrome, with multiple organ failure. She required mechanical ventilation, as you can see here, for acute respiratory distress syndrome, one of the worst forms of lung injury. She developed septic shock requiring vasopressors, and she developed acute kidney failure as well.

Her clinical picture was complicated by extensive capillary leak syndrome, a broad drop in all of her blood levels with areas of hemorrhage and she was also progressing towards scalded skin syndrome, which again is akin to having a massive burn injury all over the body. This is when they brought in CytoSorb. She was stabilized with 72 hours of CytoSorb treatment and standard hemodialysis therapy for her kidney failure with regional citrate anticoagulation. She continued with dialysis for five days afterwards as her kidneys began to recover.

Remarkably, she made a complete recovery after three weeks and CytoSorb was credited with helping to save her life and helping to prevent an amputation of her leg. When I discussed this with our Hungarian distributor at the European Society of Intensive Care Medicine, she relayed

the initial story to me and the data you see here was actually provided by Professor Jozsef Balla who is from the University of Debrecen.

The distributor mentioned to me that she just had a visit with the critical care doctor and the family had gone there by chance to thank the doctor and team for helping their daughter. The distributor said it was a very remarkable and rewarding experience to have this little girl sit on her lap, alive and well after she had been through so much. We were very pleased to have had such a very positive outcome in this young child. The case was actually presented at the Hungarian Pediatric Congress.

Slide 31:

The second application is something that we really haven't talked about before. This is using CytoSorb for liver support. There are a number of liver dialysis therapies out there. Some are investigational like the ELAD device from Vital Therapies, and some are commercialized like MARS (Gambro/Baxter) and OPAL (Albutec). This is a case of a 36 year old male patient with ulcerative colitis who was treated with immuno-suppressive drugs to control his ulcerative colitis, but wound up developing Pneumocystis and cytomegalovirus (CMV) opportunistic infections.

He developed septic shock and multiple organ failure, with acute respiratory distress syndrome, kidney failure requiring continuous renal replacement therapy (CRRT), a form of hemofiltration and hemodialysis, and acute liver dysfunction with very high levels of toxic bilirubin, attributed to CMV-induced viral hepatitis.

They first tried standard liver dialysis treatments called MARS and OPAL, which use albumin to non-specifically bind toxins and remove them from the body. But as you can see from the graph below, neither device helped to reduce these very high levels of bilirubin. Then when CytoSorb was instituted, the levels of bilirubin went down dramatically 48% and then another 36% with the next treatment. You can actually see the bilirubin, which is yellow, being retained in our cartridge, because our beads are white and when you flush these cartridges the beads in the entire cartridge have turned yellow.

This is just one of many treatments so far in liver failure patients, where the device has been used as either a substitute or as an additive process for liver support. This is another potentially significant market for us, particularly since it is a market that exists today after having been developed by other companies that market MARS and OPAL and other types of treatments.

Slide 32:

This third case is about a patient with pyelonephritis. This is a serious infection of the kidney. This 56 year old patient was admitted and diagnosed with urosepsis, or sepsis from a urinary tract infection, caused by an obstruction, and subsequent infection of his right kidney. They put a stent in the ureter, but the patient decompensated rapidly and went into shock with a rapid need for vasopressors.

Remarkably, when they measured his Interleukin-6 (IL-6) levels…this is a cytokine that is most closely associated with severity of illness and death in sepsis…his level was one million picograms per mL. All of us on the phone here are typically less than 10 picograms per mL and patients with even severe septic shock are typically in the 500 picograms to 10,000 picograms

per mL range. So he was having a massive cytokine storm. Now surprisingly, this is not the only patient that we've treated successfully with cytokine levels in this range. In this case, the induction of CytoSorb therapy led to a dramatic reduction in IL-6 to the 200 picograms per mL range, which was concomitant with an increase in blood pressure and hemodynamic stabilization following just a couple of days of treatment.

Slide 33:

Last but not least, CytoSorb has recently been used to help treat victims of the nightclub fire tragedy in Bucharest, Hungary. On October 30th, pyrotechnics from an inside concert caught the nightclub on fire. A combination of limited exits, excessive smoke and fire, and a stampede of people trying to get out, led to 27 people dying in the blaze with another 146 people hospitalized with serious burns, smoke inhalation, and trauma related injuries. 80 to 90 of the survivors were in serious or critical condition and of those, 29 of those hospitalized were so badly burned that they could not be immediately identified.

Many of the injured were treated with CytoSorb at local hospitals and we hope that we have been able to help them. Our thoughts and prayers are with the victims and families of this terrible tragedy.

With that said, that concludes our formal remarks. Lee please open it up for the Q & A session. Thank you.

Question-and-Answer Session

Operator

[Operator Instructions] We'll take our first question from Jonathan Aschoff of Brean Capital.

Jonathan Aschoff - Brean Capital

What is the average selling price and the range of the direct and distributor sale mix?

Phillip Chan - CEO

We have not broken that out directly, but what we have said is that our direct ASPs are typically above $1,000 per cartridge, but we have not broken out what the ASPs are for distributor sales. We have blended gross margins of 63%, as we previously mentioned.

Jonathan Aschoff - Brean Capital

How about the direct and distributor sales mix?

Phillip Chan - CEO

We've not broken that out either. Right now the reason why we haven't done that is because of the lumpiness of distributor sales. When we sign a distributor, there is typically some type of stocking order, then followed by purchases as they develop the market. So because of that, it varies quarter-to-quarter between the ratio of direct and distributor sales.

Jonathan Aschoff - Brean Capital

Can you give me the reorder versus new orders for 3Q?

Phillip Chan - CEO

Although we have not broken that out historically, we have been talking about that as a benchmark potentially in the future. But what we can tell you is that historically as well as in the third quarter, reorders are the predominant orders that are making up bulk of our product sales.

Jonathan Aschoff - Brean Capital
So how many of the target doctors have been reached by your direct sales force? Are you going to add more than, I believe you said two by the end of the year, are you going to go beyond that or stop and see how that does?

Phillip Chan - CEO
When you look at other major international companies that focus on the direct sales territories that we're focusing on, their sales force is comparably sized. So because critical care medicine is typically in the ICUs of major hospitals, you can target those ICUs relatively efficiently with a relatively small sales force. It is very different from the very large primary care sales force that many pharmaceutical companies need to develop in order to get at those private offices all over the place.

So I think for now we are looking to bring on a medical science liaison who will help our sales people in the market, we're also, as Kathy mentioned, adding two additional sales people hopefully to show up early in 2016 and we think that should suffice for the moment.

Jonathan Aschoff - Brean Capital
But did you tell us how many of the target docs you guys have reached?

Phillip Chan - CEO
We are in the majority of university and public hospitals throughout Germany today as well as in Austria. We have been making inroads in Switzerland as well. That is our direct sales territory. I think that as a surrogate for this, when you go to these critical care conferences and we host research symposia, the attendance continues to grow. At our last symposia there were more than 300 physicians in attendance and that was an international conference. We see similar types of numbers when we have our German and German speaking country focused initiatives as well.

So I would say many hundreds of key opinion leaders internationally and they continue to grow. As you know, we used to use key opinion leaders as a surrogate for adoption, but they are just too numerous to count at this point and so we've stopped providing that number.

Jonathan Aschoff - Brean Capital
What was the original timeline for Fresenius to start selling, was it always Q1 2016?

Phillip Chan - CEO
No, I think Chris Cramer can actually give a little bit more detail on this, but I think that our goal was to try to get this launched in Q4 this year. So it still may happen, but maybe Chris if you'd like to give a comment on that?

Chris Cramer - VP Business Development
I'd say overall we're in the final stages of preparing for a full market launch. In Q3 2015, a lot of pre-marketing work was done to focus on building support of what I'll call local physicians

champions in the six countries that are covered under the partnership. These are physicians that are highly respected and are thought leaders in the field of critical care. So this quarter, we expect them to begin with initial use of CytoSorb, and our goal is to leverage the positive experiences from these physicians as we start to broadly introduce CytoSorb across the FMC territory. In addition to what Phil had also mentioned, there are various technical operational preparations that are expected to wrap up soon.

So overall I'd say both sides are coordinating very closely, we want ensure a successful rollout and we expect to go live with what I would call first full commercial efforts in the six countries starting in Q1 2016.

Jonathan Aschoff - Brean Capital
Okay. Well congrats on the revenue guys. Thank you very much.

Phillip Chan - CEO
Thanks very much Jonathan.

Operator
Our next question will come from R. K. Ramakanth of HC Wainwright.

R. K. Ramakanth - HC Wainwright
My question is on the revenues, how sustainable are these -- is there any lumpiness in this number? Based on your 2015 guidance, it looks like you could record about the same number in next quarter, but I just want to understand how sustainable this number is and what kind of growth you could think about in the coming year?

Phillip Chan - CEO
Yes, I'll ask Kathy and Christian to comment on this as well. I think what we are very encouraged by is the fact that this quarter was actually very broad based in terms of contributions by the different segments. These include distributor and direct sales, reorders from major reference sites, new orders, etc. So across the board, it was very strong. There was no concentration necessarily of any one customer beyond what we've seen historically in the past. Now last year in Q3, it was an unusually strong quarter given the fact that we had a number of distributors come online at that time placing initial opening orders and other things. This year, we see the ordering activity as much more sustainable than what we saw last year and I think that bodes well in the future.

Kathy and Christian did you have any other comments?

Christian Steiner – VP Sales & Marketing Germany
Thank you, Phil. I want to just confirm what you have said, I think this quarter was a healthy quarter with very organic growth. The direct market, especially Germany, is our model market for our business and our commercialization. We had started there first, so the development of the market is much more advanced compared to the other markets. The development of the market in Germany is very encouraging. For example, so far we have increased the number of ordering customers dramatically compared to last year, more than 50%. This is contributing to a more sustainable revenue stream that should help drive further growth.

R. K. Ramakanth - HC Wainwright
Great. In terms of the ex-U.S. marketing strategies, you've been talking about the top four cardiac surgery companies in Europe and -- so I thought by now the evaluation should be done and probably even be in the launch phase. What's going on there, what was the timeline, and when will they finally make a decision as to launching the product?

Phillip Chan - CEO
Yes Chris, is that something that you would like to comment on as well?

Chris Cramer – VP Business Development
Yes, sure Phil. Hi R.K. How are you?

R. K. Ramakanth - HC Wainwright
Good.

Chris Cramer – VP Business Development
As Phil mentioned, the evaluation was completed in Q3 2015, and as part of this project we worked with one of the top surgical teams in France. CytoSorb was used intra-operatively on patients undergoing complex cardiac surgery - notably these patients were very similar to those that will be enrolled in the REFRESH trial. I would say that overall, the clinical valuation went very well, in fact as good as we could have expected and it reinforced many of the positive attributes of CytoSorb that we're seeing in the field today. So I thought that was very good.

Currently we are in discussions with the partner about potential next steps and at this point we can't comment anymore on that, but we'll keep everyone informed as to our progress on future goals.

R. K. Ramakanth - HC Wainwright
Okay. Thank you and talking about the REFRESH study and the EAP designation, how does EAP designation help in terms of conducting clinical studies or review or approvals, where does it help you in terms of the development within the United States?

Phillip Chan - CEO
Sure. So I will talk more generally, and these comments are not related to our specific application. I think the FDA had realized that there were a lot of unapproved but promising medical devices that could be helping patients who had no other treatment options. But because of the stringent restrictions that the FDA has on safety and efficacy, it was difficult for those potentially useful products to make it into the market. But if patients, who had no other treatment option, were willing to undertake the risk of using these products, provided that the devices were safe, then there should be a mechanism in place for patients to have that option.

Of course, the FDA's role is to protect and ensure the safety of the U.S. population and to make sure that devices meet these safety and efficacy requirements. So they launched the Expedited Access Pathway, or EAP, program for medical devices that mirrors the breakthrough designation pathway for drugs and biologics. Devices that achieve EAP designation will be essentially put on a fast track for potential early market approval. This would be followed by the FDA approval of the data designation plan, which would lay out a clinical study that would need to be performed to obtain early market approval.

For EAP designated devices, the FDA would be initially willing to forgo traditionally difficult primary endpoints to hit such as 28-day all-cause mortality, in favor of an approval trial that used less stringent endpoints, such as days in the ICU for example, provided that the devices were safe. However, the program would also require the sponsor, or the developer of the medical device, to commit to a post-market trial strategy to eventually meet the stringent requirements of the FDA on efficacy and safety.

So, in short, the EAP Program is essentially a type of fast track for devices that treat major unmet medical needs. It provides a collaborative working relationship between the FDA and the company where they would assign a senior person to help expedite the acceptable design of this data designation plan. So that is a little bit about the EAP, does that answer your question R.K.?

R. K. Ramakanth - HC Wainwright
Yes, that's good. And the last question for me is on HemoDefend. Now that you have a $1.5 million contract, what is the development timeline for this and how is this grant different from what was done before?

Phillip Chan - CEO
Our Phase I SBIR contract was predominantly a development phase program. We were taking our existing technology that we were already developing, and optimized it to obtain the performance I showed you on that summary slide. These data are very good and a poster on this project was actually selected as a top poster at the 2015 American Association of Blood Banks conference. The product was also chosen as a product worthy of being featured in the National Heart, Lung and Blood Institute Innovation conference that will be coming up very shortly.

The Phase 2 SBIR contract is designed to take development to the next level. As with all SBIR, or Small Business Innovative Research, programs, the goal is to push the product towards commercialization. We have the polymer and it will undergo some additional optimization. We have also worked out many different things related to commercialization and will look to test this in man. This will involve taking human packed red blood cells that have been purified with the HemoDefend technology and evaluating that blood in humans.

R. K. Ramakanth - HC Wainwright
Okay. Thank you very much.

Phillip Chan - CEO
Thank you, R.K.

Operator
And our next question will come from Andrew D'Silva of Merriman Capital.

Andrew D'Silva - Merriman Capital
Good afternoon everybody and thanks for taking my call. First just a few questions. With your internal models today as you look out into 2016, are you expecting the majority of your revenues to come from internally derived initiatives as they have in the past like in Germany and surrounding areas? Or are you expecting third-party relationships such as Fresenius and Biocon and your distributor networks to be the majority of your 2016 product sales this time? Also if

you could just highlight any regions that you expect to outperform the norm, we can then dig a little deeper in the landscape there?

Phillip Chan - CEO

Sure, as I mentioned in the press release, I think that here at the end of 2015, we are seeing a convergence of a lot of the different things we have been working that could potentially contribute to our revenue growth in 2016. Our first full year of commercialization in 2013 was predominantly driven by a small direct sales force. In 2014, it was complemented by some early activity in partnering and early distributors. In 2015, it was a combination of strategic partners, distributors and direct sales, but with a lot of big territories for example like France, and Poland, Sweden, Norway, Denmark, Russia, Middle East and others that were developing but not yet contributing actively to our revenue.

So in 2016, we see this all coming together, which is why we are so optimistic about our potential growth in 2016, particularly with the kind of momentum that we are seeing now. Kathy is there anything that you might want to add to that?

Kathleen Bloch - CFO

No, I think you stated that right. It has been a mix and the direct sales were developed much earlier than the distributor sales. So we still have some lumpiness and catch up in the distributor area, but they are going to be growing, particularly as we move ahead and add new territories and as we receive repeat orders from existing distributors.

Phillip Chan - CEO

Christian, maybe if you want to comment also about your perspective?

Christian Steiner - VP Sales and Marketing Germany

Yes, as I said in the call earlier, the direct market is kind of a "model market" that is useful in helping to predict how other territories will develop. As Kathy said, we have started direct sales one to two years earlier than in the most of the distributor markets. That means that all the information, projects and campaigns that we are conducting here in Germany, Austria and Switzerland, will be leveraged in other markets as well to help speed the learning curve and provide a short cut in those other territories.

Andrew D'Silva - Merriman Capital

So just to recap on that, is it fair to assume into 2016 that a greater portion of your revenues will come from third-party distribution and strategic partnerships versus internally derived initiatives?

Phillip Chan - CEO

I think that we are seeking a balance. Clearly direct sales are a very strong engine of growth right now with broad based support in our direct sales territories from key opinion leaders, reimbursement, and an established infrastructure. Because of this, we are well-positioned to increase sales more rapidly. But of course the lower margin distributor sales and partner sales are important to our business and we see that contributing as well. To give you a little bit of guidance, our goal is to increase our blended gross margins between those two through a combination of customer diversification as well as a reduction in the costs of goods sold.

So I think that it will be a broad based revenue growth model going forward.

Andrew D'Silva - Merriman Capital
And then just a follow-up on Fresenius, I don't know if the question was asked in this way yet, but did they actually place their initial fulfilment or stocking order as of today or are we looking for that initial order to be met in the first quarter?

Phillip Chan - CEO
I think we expect that as they move into the markets in the formal launch, they would want to have enough stock available to be able to do that. So whether or not that's in Q4 or Q1 we don't know.

Andrew D'Silva - Merriman Capital
But there was no official timing requirement for them to actually place their stocking order or some time deadline that they had to meet?

Phillip Chan - CEO
We are within this first term year of the agreement and we believe that they will meet their requirements.

Andrew D'Silva - Merriman Capital
Okay. Fantastic and the last question, can you just remind me again as to what the differences between the REFRESH I and II trials are?

Phillip Chan - CEO
REFRESH I is a feasibility and safety study where we are using CytoSorb intra-operatively in elective cardiac surgery patients undergoing complex cardiac surgery procedures. It is designed to give the FDA comfort with this product in the United States amongst U.S. clinical trials sites. Again, it is a relatively small study with 40 patients amongst eight centers. The primary end point is safety and the primary efficacy end point is a reduction in free hemoglobin. What we have said in the past is that we plan to meet with the FDA prior to REFRESH II, and get guidance from them on what REFRESH II will look like. It could potentially take one of two paths: 1) a potential de novo 510(k) where FDA may accept biomarker reduction as an end point after analyzing our biomarker data from REFRESH I or 2) a larger study that would look at clinical endpoints as the endpoint. This study would be significantly larger than the de novo 510(k) biomarker end point.

But we expect the design of the REFRESH II trial and the selection of the patients to be very similar to REFRESH I. In fact, if we made efficacy and a reduction in adverse events the primary endpoint of REFRESH I, we could almost roll those patients into REFRESH II.

Operator
And our next question will come from Steve Brozak of WBB.

Steve Brozak – Managing Partner & President
Good afternoon. CytoSorb is obviously addressing a critical unmet need. What kind of feedback has FDA given you and can you give us some background on how things have progressed with

FDA? Also clinicians are an integral part of dealing with FDA; what kind of momentum and advocacy are you seeing with that?

Phillip Chan - CEO

Currently today, we have three FDA approved IDEs (investigational device exemption). One in the treatment of acute respiratory distress syndrome, one for the treatment of trauma and rhabdomyolysis currently the subject of a trial being funded by the U.S. Air Force, and the third IDE is approved for cardiac surgery for our REFRESH trial. So the FDA knows our technology well. The FDA has also been well-integrated into the DARPA program where we collaborate with likes of Harvard Wyss Institute, MIT, NxStage Medical, Battelle Labs, and others. Through this collaboration, we have had additional contact with the FDA.

In terms of key opinion leaders, we are working with hundreds of key opinion leaders throughout the world. We also have three very strong advisory boards: one in the area of sepsis and critical care, one in trauma, and one in cardiac surgery. Dr. John Kellum, our Sepsis Advisory Board Chair, who is the Vice Chair of Research in Critical Care at the University of Pittsburgh Medical Center, has been a long standing collaborator of ours over the course of more than a decade of research. He has done most of the pre-clinical animal work on our technology in the area of sepsis, and is considered one of the major key opinion leaders in using blood purification to treat life threatening illnesses such as sepsis, as well as in acute kidney injury in critical illnesses.

For our REFRESH trial, we have an outstanding cardiac surgery advisory board, and are working with major clinical trial centers. We are also working with some of the top cardiac surgeons in the country. From that standpoint, we feel comfortable with the level of support we have seen and we are grateful that they have such interest in our technology.

That being said, we are not yet approved in the United States and as we get closer and closer to the market in the U.S., we plan to focus more on expanding the awareness of our technology here.

Steve Brozak – Managing Partner & President

You had mentioned acute respiratory distress syndrome, or ARDS. Many critically-ill patients are in the ICU on mechanical ventilation with this serious problem and it can rapidly lead to a significant negative spiral. What are the Europeans saying in terms of feedback back to you?

Phillip Chan - CEO

When we look at the clinical benefits of the technology, we see stabilization of hemodynamics and blood pressure as one of the major benefits. Blood pressure is extremely critical to being able to circulate oxygenated blood to your vital organs. If they don't get blood and oxygen, they will become ischemic and permanently damaged. A second benefit is in the area of capillary leak syndrome. Normally the cells lining the blood vessels are tightly connected, preventing fluid from leaking through the blood vessel wall. In deadly inflammatory conditions with high levels of cytokines, however, cytokines can cause a disruption of the tight junctions holding these cells together, allowing fluid and inflammatory cells to leak from the blood vessels, into the air sacs or alveoli of the lung, essentially drowning a patient from the inside out. This is a hallmark of acute lung injury and acute respiratory distress syndrome. When this capillary leak

syndrome happens in the rest of the body, there can be tissue swelling, and decreased blood flow to vital organs, leading to organ failure.

Currently, we have a number of studies that are looking specifically at ARDS, capillary leak syndrome, and hemodynamic stability in critically-ill patients. We hope that these studies will formally demonstrate the benefit of CytoSorb therapy to improve clinical outcomes.

Steve Brozak – Managing Partner & President
Well again thank you for those answers and obviously looking forward to the first KOL in the U.S. who demands the ability to use CytoSorb for their patients. Thank you.

Phillip Chan - CEO
Thank you.

Lee Roth - IR
Thank you very much. We're showing no further questions at this time. Right now I'd like to turn the call back over to management for any closing remarks.

Phillip Chan - CEO
Thanks Lee. Thank you everyone for taking the time today to get on the call in the middle of the morning. We certainly appreciate your participation and 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 everyone and have a great day.

Operator
Thank you and that does conclude our conference for today. I'd like to thank everyone for their participation and have a great day.