CytoSorbents Corporation (OTCBB: CTSO)
2013 Third Quarter Earnings Conference Call Transcript
November 6, 2013 @ 4:15 pm Eastern

Operator:

Good day ladies and gentlemen. Thank you for standing by. Welcome to the CytoSorbents 2013 Third Quarter Earnings Conference Call. During today's presentation, all parties will be in a listen-only mode. Please press star, zero, for Operator assistance at any time. This conference is being recorded today, November 6, 2013.

I would now like to turn the conference over to our host, Mr. Valter Pinto of Alliance Advisors. Please go ahead, sir.

Valter Pinto – Alliance Advisors - Moderator:

Thank you, Operator, and good afternoon. Welcome to CytoSorbents 2013 Third Quarter Update Conference Call. With us today are:

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

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 November 6, 2013, and the Company assumes no obligation to update these projections in the future as market conditions change.

During today's conference call, we will first have an overview presentation covering the financial and operational highlights for the quarter by Dr. Chan and Kathleen Bloch. We again have taken everyone's submitted questions. We will do our best to address them in the presentation and in the question-and-answer session with management to follow. Thanks, everyone, again, for participating. If we do not answer your question, we do ask that you either contact myself at Alliance Advisors or the Company directly after the call.

At this time, I'd like to turn the call over to Dr. Phillip Chan. Phil, please go ahead.

Phillip Chan - CEO:

Great. Well thank you very much, Valter, and welcome everyone to our Third Quarter 2013 Earnings Conference Call. Thank you, everyone, for taking the time to join us for the call today.

For those of you who are new to the story, CytoSorbents is a critical care-focused company working to save lives by targeting uncontrolled inflammation through blood purification. Inflammation plays a major role in nearly every known disease, as was highlighted in this *Time* article "Inflammation, the Secret Killer". Inflammation plays a major role in life threatening conditions such as sepsis and trauma, autoimmune diseases like rheumatoid arthritis, inflammatory bowel disease, psoriasis and lupus, heart disease, peripheral artery disease, even cancer, cancer cachexia, graft versus host disease, and neurodegenerative diseases such as Alzheimer's disease, multiple sclerosis and Parkinson's, and many, many others. In fact, uncontrolled inflammation wreaks havoc on the body and can be deadly.

One of the reasons why it can be so deadly is that severe inflammation causes organ failure. Organ failure occurs when vital organs such as the heart, lungs, brain, kidneys, or liver stop working. That is not compatible with life and it causes nearly half of all deaths in the ICU today, but little can be done to treat or prevent it.

CytoSorb® is designed to remove the "fuel to the fire" of inflammation from blood. In fact, CytoSorb® is the only specifically approved extra-corporal cytokine filter in the European Union. What that means is that cytokines and other inflammatory mediators are removed by CytoSorb®. Cytokines and these inflammatory mediators are the substances in blood that drive inflammation. CytoSorb® is clinically proven to reduce key cytokines in blood by 30 to 50% in critically ill patients, and it is in fact approved for use in any situation where cytokines are elevated. We now have safety data on more than 1,100 human treatments, where there have been no serious device-related adverse events, and where the therapy has been well tolerated.

What we're hearing out in the marketplace today is that CytoSorb® may represent a powerful new strategy to control severe inflammation in the ICU [intensive care unit]. Many of the therapies located on the left and the right of the CytoSorb® cartridge here are perhaps well known to people on the phone. On one hand there are things like NSAIDs [non-steroidal anti-inflammatory drugs], like Motrin, or aspirin, or anti-oxidants that are weak anti-inflammatory drugs and too weak to control the inflammation seen by critically ill patients. Even stronger substances such as anti-cytokine antibodies and anti-integrin antibodies are no match for the severe inflammation seen in the ICU. On the other hand, there are many other drugs like corticosteroids, chemotherapy, anti-rejection organ transplant drugs, radiation, immune system ablation and anti-leukocyte antibodies that are very powerful at controlling the immune response, but in many cases too strong.

What we're hearing is that CytoSorb® is really one of the first truly immunomodulatory therapies out there on the market today, because you can adjust the dose with the amount of treatment that you give these patients. It's sort of like a Goldilocks story where the treatment is "just right".

So, the goal of CytoSorb® is to actively prevent or treat organ failure in many life-threatening conditions such as sepsis, acute respiratory distress syndrome, burn injury, trauma, pancreatitis,

influenza, and complications of surgery that form a market of about $10 to 15 billion alone in the United States and in Europe. The goal, of course, is to improve patient outcome and survival while simultaneously decreasing the massive cost of ICU and patient care.

The heart of our technology is a highly biocompatible and very porous polymer bead that acts like a tiny sponge to remove harmful substances from blood. Each of these beads is roughly the size of a grain of salt, but when you magnify them up close, each bead has millions of pores and channels that can remove things by pore capture as well as surface adsorption. Things that are too big cannot fit in the pores and are not removed. Very small things go straight through the beads. But, appropriately sized molecules will get trapped in the vast network of pores and channels in every single bead, thereby permanently being removed from blood. This is a technology that is protected by 32 issued U.S. patents and multiple applications pending, and is manufactured at our ISO 1345 certified facility in New Jersey, and in fact is one of the highest-grade medical sorbents on the medical market today.

These beads enable a very broad technology portfolio. The first picture here is our CytoSorb® cartridge designed for critical care in high-risk surgery. This is a product that is CE mark-approved, but we have a host of other products behind this, including HemoDefend™ for blood transfusions, a product that we'll talk about a little bit later, as well as ContrastSorb, DrugSorb and BetaSorb, that are under advanced development.

In addition, this technology has been the beneficiary of more than $15 million in U.S. Government support. DARPA has awarded us a $3.8 million five-year contract as part of its Dialysis-Like Therapeutics program to treat sepsis by removing cytokines and pathogen-derived toxins. We are currently in year two of this program. The U.S. Army awarded us a $1.15 million SBIR contract for the treatment of trauma as well as burn injury research. The U.S. Air Force recently funded a 30-patient human pilot study in trauma that is valued at approximately $3 million. The FDA has approved this trial to begin this year, and we hope to have our first enrollment in the next couple of months. The U.S. Department of Health and Human Services also awarded us a $0.5 million grant because our therapy has the potential to save lives and reduce costs. In addition, our major collaborator Dr. John Kellum at University of Pittsburgh Medical Center was awarded $7 million over five years as part of an NIH grant to help develop this technology for the treatment of sepsis. And most recently, we were awarded a $0.2 million Phase I SBIR grant to advance our HemoDefend™ purification technology to improve the quality and safety of blood transfusions.

So with that, I'd like to turn it over to Kathy Bloch, our Chief Financial Officer, to go over some of the financial highlights for the quarter. Kathy?

Kathleen Bloch - CFO:

Thank you, Phil, and good afternoon, everyone.

I'm pleased to be able to report CytoSorbents' third quarter 2013 financial results. For today, I'll be focusing on three areas. First, a review of the Company's financial highlights; second, revenues, and in particular product sales of CytoSorb; and finally, our cash position and the sources of capital that we have available to us to fuel our business.

So, this first slide provides a summary of our key financial results for the three- and nine-month periods ended September 30th 2013. More details can be found on our Form 10-Q which was filed earlier today. As you can see, CytoSorbents achieved record quarterly revenues in the third quarter of 2013 of $881,000. Revenues for the nine months ended September 30th 2013 were $1.54 million, which included more than $500,000 in product sales. So, let's look a little more closely at our product sales.

This chart illustrates the product sales of CytoSorb® for each of the last five quarters, since we began commercialization of the product. First of all, note that the product sales for the third quarter of 2013, that's the bar to the far right, represented the highest quarterly product sales achieved to date. And, they were in fact approximately 59.1% higher than the product sales for the previous quarter, ended June 30th 2013. At the current time, we are seeing continued strong momentum in our fourth quarter 2013 product sales.

Next, let's take a look at the product sales trends. This chart summarizes our 12 trailing months of CytoSorb® sales, and we believe it demonstrates the successful path on which our commercialization efforts are tracking. Let's just take a moment to make sure everyone understands exactly what is depicted on this chart. The first bar on the left, entitled "Q4 2012" represents the sales of CytoSorb® for the 12-month period ended December 31st 2012. The next bar, entitled "Q1 2013", represents the sales of CytoSorb® for the 12-month period ended March 31st, and so on. And so finally, the bar that we see at the far right represents CytoSorb® sales for the 12 months ended September 30th 2013, and in fact that's approaching $600,000. This chart, we believe, demonstrates the positive trend in sales overall. And it removes the lumpiness that may be observed when looking at purely quarter-over-quarter results.

Now, let's take a look at our gross margins. Our gross profit margins on product sales for the third quarter of 2013 were approximately 71%. For the nine months ended September 30th, 2013, our gross profit margins were approximately 64%. The gross profit margin is affected by the ratio of direct sales versus sales to distributors. Obviously, direct sales command a higher margin. We currently have four distributors plus our partner Biocon in India, and we are in active discussions with other potential distributors. As our sales mix between direct sales and distributors changes, our gross margins will be affected, but given any mix, we do expect gross margins to remain very strong. Finally, it's important to note that as our product sales increase, the gross margin will provide a source of working capital for the Company. So, let's turn to working capital.

This graph talks about our working capital position and how we intend to finance the business in the coming quarters. So, first of all, as of September 30th, 2013, with adjustments for convertible note funds received in early October, we have cash on hand of just less than $3 million. And, you can see that's the highest cash balance that we've had over the last four quarters. We believe that this cash will be sufficient to fund operations through the second quarter of 2014. In addition, we continue to receive funding for our R&D efforts from government grants, and we are targeting new grant funding for the future. As we already mentioned, as our product sales increase, this will also contribute capital to offset expenses. We also have the opportunity to monetize our assets with strategic partnerships; but more about this later. And, as we have in the past, we have the availability to raise capital through traditional equity and convertible notes. And finally, if needed and when eligible, we have our financing facility with Lincoln Park Capital.

At this point, I'd like to turn the call back to Phil to cover some of the operational highlights for the quarter. Phil?

Phillip Chan - CEO:

Thank you very much, Kathy.

As we detailed in our press release today, our focus is on driving now departmental usage of our CytoSorb® therapy. We are moving away from the key opinion leader phase and now working to address the larger number of medical professionals in each hospital.

We will soon have a number of reference sites. We are currently working with KOLs in the largest and most important university and public hospitals in most of the major cities in Germany and many in Austria and in the United Kingdom. Usage of CytoSorb® at many hospitals is increasing, both in the number of patients being treated but also in the number of physicians using the therapy, and also the number of departments using it within a single hospital. An example of these departments include: the surgical intensive care unit or the SICU, the medical intensive care unit or the MICU, the trauma ICU, as well as cardiac and high-risk surgery departments. We believe that these will become reference sites for CytoSorb® in the near future.

In order to access this great opportunity, we're actively expanding our direct sales force. We currently have more than 100 key opinion leaders who are either using the product or committed to using CytoSorb® in clinical studies or in clinical practice. By the end of 2013, we're targeting seven sales reps, up from four sales reps currently, and have recently added a clinical support specialist to help with the sales of CytoSorb® and training of sites that are using the product. The goal here is to convert what is now hundreds of thousands of dollars in sales to millions of dollars in sales as we drive usage and adoption by not just the key opinion leaders but by the junior and senior physicians within each department.

Another major operational highlight for the Company was our partnership with Biocon, which I think Chris will go over later in much greater detail. Biocon is the largest biotechnology company in India and on World Sepsis Day, Biocon and CytoSorbents announced a strategic partnership with initial distribution in India and select emerging markets. Biocon currently has about $467 million in 2013 revenue, and are actively targeting total revenue of more than $1 billion with an 18% CAGR. As you can see from their portfolio, they have a number of different proprietary products in many different areas, and if you look at the Comprehensive Care group that is focused on critical care, you will see a number of products, particularly Imicelum and Penmer. What our collective vision is between Biocon and CytoSorb is to create the most comprehensive treatment for sepsis by combining Biocon's proprietary antibiotics to treat the primary infection while CytoSorb® treats the massive inflammatory response. Sepsis is a major problem in India. India has a population of about 1.2 billion people, and if you walk into their ICUs, one in every four patients in the ICU has or develops sepsis. We expect that Biocon will contribute revenue growth for us in 2013.

In addition, we are focused on driving clinical data for our CytoSorb® therapy, and we have now increased our investigator-initiated studies from 18 last quarter to now 26 in the current

quarter. In fact, three of these studies have begun enrollment, and we expect initial data from these studies by the first half of 2014. And, these range the gamut of applications for CytoSorb®. In the background, you see all the different applications that have been used already with CytoSorb®, and the checkmarks represent where we are seeing these investigator-initiated studies.

In addition, we have published on our website a number of different case report studies. I won't spend the time today to go over these in great detail, but we'll post this presentation on our website and you can read about how severely ill these patients were that were reported upon with CytoSorb® therapy.

This patient for instance was a 46-year-old woman who had a 64% likelihood of dying from a Candidemia infection. This is a yeast infection in the blood, and is very difficult to eradicate. Yet she survived with our therapy.

This is a patient who was 80 years old with end stage kidney failure as well as Type II diabetes with a serious Staph aureus pneumonia. And, what you can see here in this graph, is that prior to CytoSorb® therapy, a lot of the inflammatory mediators and other things like vasopressor usage were rising, but with CytoSorb® therapy, we were actually able to modulate these and bring them down to more normal levels, and this patient again went on to survive.

And then this patient was reported on by investigators from Linz in Austria. This was a 37-year-old patient with alcoholic liver cirrhosis, who developed septic shock with liver failure. There is a specific organ failure score called the CLIF-SOFA [Chronic Liver Failure Sequential Organ Failure Assessment] score used in patients with chronic liver failure. Based upon that score, her predicted mortality was greater than 90%. And, what you can see here is, that with four consecutive treatments, we were able to reduce many of the predictors and risk factors of mortality, and this woman actually went on to survive. Very interesting to note, the IL-6 level here was 27,423 pg/mL. Those of us on the phone should have an IL-6 level of about 10 pg/mL. Within a single six-hour treatment, we were able to bring her IL-6 level down to 2,260 pg/mL and then, over the course of the next several days, bring her down to high normal values. We stabilized her and she went on to have definitive treatment with a partial lung resection and again went on to survive, despite having a very high expected mortality rate.

In addition to our case report studies, we have had an increased presence at major conferences. Now, we haven't really publicized many of these, or put out press releases on these conferences, but we've exhibited at many conferences in the third quarter including the European Society of Intensive Care Medicine conference in Paris, France; the sixth International Congress of the German Sepsis Society in Weimar, Germany; the American Association of Blood Banks (AABB) conference for HemoDefend in Denver, Colorado; the Cytokines 2013 conference in San Francisco, California; the Military Health System Research Symposium, formerly known as ATACCC, in Fort Lauderdale, Florida; as well of course the Rodman & Renshaw conference in New York.

And, we also attended the European Society of Cardiovascular Surgery conference in Vienna, Austria, where we met with a number of potential strategic partners in this space. One of the reasons why we attended this particular conference is what we're seeing in the clinic today. We are seeing a lot of interest related to the potential application of CytoSorb® in cardiac surgery.

What you see here on this page is, on the left hand side, a standard cardiopulmonary bypass machine. This is what is often called a heart-lung machine. When you do surgery on the heart, you basically need to stop the heart from beating, and obviously a patient can't stay alive if that happens, so they bypass their blood to a heart-lung machine that not only pumps the blood to the rest of the body while they operate on the heart, but also oxygenates the blood as well. As it turns out, cracking open the chest with a sternotomy, operating on the heart, putting someone's blood through a heart-lung machine, suctioning blood from the field, reversing heparin anticoagulation with protamine, and many, many other things that occur during the surgery create cytokine storm and inflammation.

And so, this is really a burgeoning area for us. From a cardiac surgery standpoint, there are about one million cardiopulmonary bypass surgeries in the United States and Europe annually. These include well known surgeries such as coronary artery bypass graft surgery, often called CABG surgery; open valve repair surgery; heart or lung transplantation; left ventricular assist device implantation; and cardiac defect repair, amongst others. Patients often develop inflammation due to cytokine storm and the release of free hemoglobin caused by hemolysis during the surgery. In the diagram on the right, you can see how cytokine storm and free hemoglobin will result in inflammation and vascular injury that can lead to multiple organ failure. Lung failure as well as kidney failure are particularly common, particularly in high-risk patients who are on the operating table for a long period of time. To date, there has been no technology that has been able to easily or directly reduce cytokine storm and free hemoglobin. What has been used in the past and even today are leukoreduction filters sold by companies like Terumo and Pall Corporatoin, that are used to try to remove cytokine-producing white blood cells. The sales of these leukoreduction filters generate millions of dollars in revenue, but what they found out is that these leukoreduction filters don't work because they can't directly remove cytokines.

Well, CytoSorb® represents one of the only technologies on the market that can be easily implemented into a cardiopulmonary bypass circuit within minutes and without the need of another dialysis machine to run the device. In fact, you use the blood pump from the cardiopulmonary bypass machine to run blood through our device. So, CytoSorb® is ideally suited for cardiopulmonary bypass. It's effective at removing excess cytokines and free hemoglobin. It installs into the cardiopulmonary bypass circuit easily and within minutes, literally two to three minutes. It is a drop-in replacement for leukoreduction filters, but does a better job. It utilizes blood flow generated by the cardiopulmonary bypass circuit; there is no need for the perfusionist to worry about another machine to run, which is critical. It is blood in, blood out; there is no dialysate, no ultra-filtrate to be concerned about. It is a very high-flow low-resistance technology that can accommodate high blood flow rates, at least up to 400 mL a minute, and in fact it's even been tested to about 1 liter a minute without hemolysis. We use it in a bypass circuit in the cardiopulmonary circuit that is running at about 5 liters a minute.

In addition, CytoSorb® has extensive surface area. As we've heard before, it has 7+ football fields of surface area in a single cartridge, compared to one to three square meters, or the size of your kitchen table, of surface area in membrane-based filters. CytoSorb® is also highly compatible with systemic heparin anticoagulation, which is used extensively during cardiopulmonary bypass. This figure is just an example of our ability to remove free hemoglobin. What makes your red blood cells its characteristic red color is the presence of hemoglobin within the red blood cells. But, when that free hemoglobin is released due to

hemolysis of the red blood cells, it goes into the plasma and can cause plasma to look very similar to as it does on the left hand side. We've been able to demonstrate with our treatment that we are able to reduce free hemoglobin very rapidly to the more straw-looking color of traditional plasma.

We believe cardiac surgery is a major opportunity for us. Cardiac surgeons and patients both want zero complications. CABG surgery is so routine today that no one expects patients to die, yet it happens, although at a low frequency, but it shouldn't happen at all. And, this is one of the reasons why cardiac surgeons are very interested in our technology. So, although early, the initial experience with many cardiac surgery patients has been very promising. Clinical trials can be done very rapidly in this space. A typical center can do three to five cardiac surgeries per day, and so you can really rack up many patient experiences in a very short period of time. And, cardiac surgery represents a total addressable market of more than $500 million in the U.S. and Europe alone, particularly if we can establish CytoSorb® as standard of care therapy. And interestingly, it is a market that sits separate from critical care, and represents a completely separate market opportunity for CytoSorb® and could represent a beachhead for us to work off of as we approach more risky applications.

So, another operational highlight is our $200,000 NHLBI SBIR award for HemoDefend. NHLBI is the National Heart, Lung and Blood Institute and a division of the National Institutes of Health. And, the award was specifically designed to help us advance CytoSorb—advance HemoDefend toward commercialization. We are collaborating with Dr. Larry Dumont, who is the Director of the Center for Transfusion Medicine Research and also Associate Professor of Pathology at the Geisel School of Medicine at Dartmouth. The goal is to further develop and characterize the HemoDefend technology to reduce contaminants in transfused blood products that can lead to transfusion reactions and adverse outcomes including death, particularly in high-risk surgery patients such as cardiac surgery patients as well as critically ill patients. So again, this award is a major step toward commercialization of both "Beads-in-a-Bag, as you see on the top here, on the right, as well as the inline filter on the bottom.

Another area of progress has been our dosing study. Vince will discuss this in greater detail later, but as we discussed last time, the goal of the dosing study is to determine the safety and preliminary efficacy of extended treatment, either more hours of treatment per day or more days of treatment, to help inform the design of a U.S. pivotal sepsis trial. Enrollment, we're pleased to say, has significantly accelerated, with a total of eight clinical sites including major clinical centers in Germany that you see below. And again, as we have said before, we plan to have at least interim data analysis for 2013.

Last but not least, we were a proud sponsor of World Sepsis Day and the Sepsis Heroes Gala. This was an ad that we had in the Sepsis Alliance brochure. "In life-threatening conditions such as sepsis, trauma, lung injury and severe burns, a lot depends on you making it out alive." This really addresses at its core, how dangerous these critical illnesses are. So, we were also an official sponsor of World Sepsis Day that was hosted by the Global Sepsis Alliance, and a sponsor of the Sepsis Heroes gala that was put on by the Sepsis Alliance here in the United States.

So, in terms of comments for Q4 2013, as Kathy had mentioned, we're seeing very strong momentum of CytoSorb® sales in the early part of Q4 2013, and without a doubt we are expecting record fiscal performance for all of 2013, our first full year of commercialization.

Finally, this is a slide that many of you have seen in our investor presentation, but I think it's worth reiterating. Why is CytoSorbents attractive as an investment today? We are at the ground floor of commercialization, poised to create significant value with an approved product, CytoSorb, that may revolutionize critical care medicine, save lives and reduce costs. It truly has blockbuster potential by addressing major critical care illnesses like sepsis - some of the biggest unmet medical needs in medicine today.

If you're worried about the technology and if it's real, we have validation of our Company and our technology from many fronts, including Biocon, DARPA, the U.S. Army, the U.S. Air Force, NHLBI and NIH, scientific advisors and analysts from Zacks as well as Brean Capital. We have a very unique and highly profitable product and a pipeline with little to no competition. You've also seen that our gross margins are very healthy for a medical device company. And, we're led by an experienced and responsible management team, many of whom you have met on the previous conference call but who will also be manning the question-and-answer session today. And we are relatively undiscovered at a fully diluted market cap of about $50 million. When you look at an analysis of companies that have undergone an uplisting to the national exchanges, we compare very favorably to those companies. Most of those companies are still in late stage clinical studies, don't even have a product on the market, and are burning tens of millions of dollars per quarter. We are running this company very tightly and have a product that is on the market generating an increasing amount of revenue. And, last but not least we have potential major catalysts in the next six to nine months, including revenue growth, partnerships, clinical data, uplisting, institutional ownership, and more.

So with that, let me turn it back over to Valter to begin the question-and-answer session.

Valter Pinto - Moderator:

Thank you, Dr. Chan. Over the past several weeks, we have collected a number of questions from investors. I think one of the most common questions relates to sales of CytoSorb®. From the presentation, I think we've heard that sales of CytoSorb® are beginning to accelerate. Christian, what is your perspective being on the front lines?

Christian Steiner – VP Sales and Marketing:

Thank you, Valter. I am in charge of all direct sales of CytoSorb® in Germany, Austria, and Switzerland and am also in charge of distributor sales elsewhere in the world. CytoSorb® is a really unique product, but one that intensive care doctors around the world can easily understand and also easily use. CytoSorb® is positioned to address many major unmet medical needs in the ICU. So, there is a lot to talk about with these physicians. Having launched many new products into the ICU in the past, CytoSorb® is following a well understood trend to market adoption. In fact, the response we are experiencing in the market is much greater for CytoSorb® than for anything I have worked with previously.

In general, bringing new therapies like this to wide acceptance in critical care medicine requires accomplishing the following points. The first is, of course, to find the early adopters and generate positive treatment experiences. Two, bring important KOLs on board who can multiply the message. Three, build reference center accounts, with high usage and deep penetration.

And four, create awareness and discussions in the medical and scientific community. And five, show medical and economical benefit in the target indications. That, I think, is one of the most important points. And six, of course, achieve sufficient reimbursement in the respective health systems.

So, CytoSorb has been on the market with our team since the fall of 2012 and there are several major applications that are rising to the top. These include, of course, number one: severe sepsis and septic shock. This remains the most important patient group. And number two is the systemic inflammatory response syndrome caused by cardiac surgery as explained by Phillip before. This is a very homogeneous and nicely defined patient group, and CytoSorb® is being used here either intra-operatively, in a bypass circuit in the heart-lung machine, or postoperatively when the clinical picture deteriorates.

So, besides these two major groups, the therapy has also been successfully used in a number of other applications, and these include trauma, severe influenza, severe pancreatitis, also liver failure, fungal sepsis, drug intoxication and others.

So, in the past 12 to 15 months, we have successfully worked with several early adopters for each of the major indications, and after a phase of evaluation therapy and going through a learning curve to understand exactly how and when to use a CytoSorb® in these new indications, we are now developing a number of key sites that will be reference centers or "lighthouse accounts".

So, with our small sales team in place, we have established a network of more than 100 key opinion leaders, and that means clinicians who are known for their expertise on a national or international level and potentially can give lectures on their results and also on the topic in general. As Phillip said before, we are in the majority of the big university hospitals in our direct sales territories.

Valter Pinto - Moderator:

Thank you. Can you comment on the strategy to get more business from key accounts?

Christian Steiner – VP Sales and Marketing:

Yes, sure. Increasing the use and deepening the penetration in these reference centers and existing accounts requires of course more resources. So, in the next three to six months, we will increase the number of sales reps from four to seven, and furthermore, we have started to build a team of application specialists who will increase our presence and frequency of physician trainings. And, although the therapy is very easy to use, this will enable us to expand the number of CytoSorb-trained medical professionals visiting these sites, and also at the end increase the number of treatments.

The increase of awareness within the medical community about the existence of CytoSorb® is constantly rising. We see a big impact from our sales activities as well as from the conference exhibitions we attend. Of course, as more clinical results are generated with oral and poster presentations at scientific meetings, as well as with the publication of data, you will see this drive more discussions.

And, to catalyze this, we are also planning a number of sponsored industry sessions at upcoming congresses, starting with the National Interdisciplinary Critical Care Medicine Congress, DIVI, in Leipzig, Germany, in December this year. And also, we have scheduled our first big users meeting with more than 15 speakers presenting and discussing their experiences and results. And, we also plan at this meeting to discuss the ongoing study projects that are either ongoing or being planned.

I think that these studies in our direct markets will eventually build the body of medical as well as economical evidence to drive adoption towards regular, and finally standard care of use.

Currently there are 26 investigator initiated study projects that are being planned or have already started within the last 18 months. Such studies have to go through an up to 12 month process until they are approved and ready to start. All projects are designed to generate more knowledge about how to use CytoSorb® in a variety of different situations and conditions, while helping to design and prepare the pivotal trials that are intended to eventually show medical and of course also economical benefit. Any positive data will generate awareness and discussion, which is crucial for continued traction of our CytoSorb® therapy.

And of course, a number of more significant projects with renowned partners are in the pipeline. We will report on those as soon as it is appropriate.

Valter Pinto - Moderator:

Thank you. What else are we doing from a marketing perspective?

Christian Steiner – VP Sales and Marketing:

In this context, and to get the CytoSorb® message to the medical world, we also have started a nine-month project to implement all of the necessary marketing, sales and also public relations projects. This includes, for example, refining the messaging for the CytoSorb® therapy, as we know much more now after the first 15 months in the market; rebuilding the website with a product and customer focus; implementing a robust customer relationship management system to keep better track of the opportunities as they are growing; then developing and producing adequate materials to promote CytoSorb® therapy even more professionally; and also to start using public relations methods to better publicize positive experiences and treatment results.

Beside the main activities on the direct markets, we are also building a network for the markets covered by our distribution partners, as mentioned by Phillip. All of the knowledge and processes that have worked in our direct markets needs to be transferred to our partners. We have just finished our fourth distributor's training meeting at the Berlin offices and are now looking forward to successfully spreading the CytoSorb® message throughout Europe and the rest of the world. Thank you.

Valter Pinto - Moderator:

Well thank you very much, Christian; that was very helpful. Let's move on to business development. Chris, could you disclose more information about the Biocon partnership? Will Biocon be manufacturing CytoSorb?

Chris Cramer – VP Business Development:

Thanks, Valter. As Phillip mentioned earlier, the partnership with Biocon will focus on commercializing CytoSorb® in India and select surrounding regions for the treatment of sepsis. To be clear, CytoSorbents will continue to manufacture CytoSorb® in the United States while Biocon will handle all marketing and sales responsibilities within the territory.

To comment a little bit further, what truly sets this partnership apart, and what I think makes it special, is the ability to combine CytoSorb® with Biocon's antibiotics to offer the most comprehensive treatment for sepsis on the market today. Simply put, no one else has the ability to treat the two main components of sepsis, which are the massive inflammatory response and the underlying infection, like we can. We think this is a very powerful message and we're excited to be partnering with Biocon to bring this novel therapy to the market.

Valter Pinto - Moderator:

How will the CytoSorbent-Biocon partnership work? And, what can we expect in terms of commercialization and future product sales?

Chris Cramer – VP Business Development:

Sure. I believe Biocon is an exceptionally strong partner for CytoSorbents, with deep expertise in introducing innovative new therapies like CytoSorb® into the hospital setting. Biocon's network will enable rapid access, education, training, and support of physicians in the largest hospitals throughout India and surrounding territories. We're committed to supporting Biocon as well, and have presented to many key opinion leaders in India to make them familiar with our technologies. This type of direct access and interaction is extremely valuable to accelerating market adoption.

With that said, CytoSorb® will be marketed and sold via Biocon's critical care commercial organization. We've been working very closely with them to build awareness of CytoSorb® amongst key opinion leader physicians, register the product, and conduct extensive internal training to ensure a successful market launch. We expect Biocon's field marketing and sales organization to be selling into key accounts in the next several months.

Needless to say, we're extremely excited about the opportunity to work with a market leader like Biocon. We believe this partnership has the potential to change the treatment of critical care illnesses such as sepsis, and we're confident that our work will lay the groundwork for an expanded partnership in the future.

Valter Pinto - Moderator:

Thank you, Chris. Any early feedback from Biocon relative to interest, demand or sales in India for CytoSorb?

Chris Cramer – VP Business Development:

So, while we haven't formally started selling the product yet in India - but will be very soon as we wrap up training this week - we've had some positive early signals. First, it's important to point out that sepsis is a very challenging condition to deal with, no matter what part of the world you're in. On top of that, there are no approved therapies to treat it today, so physicians are always very eager to hear about new treatments.
With that said, overall the physicians we've spoken with have been very excited about CytoSorb, because it finally gives them a therapy that makes sense to help treat their septic patients. Virtually all physicians expressed interest in learning more about CytoSorb® and even potentially trying it on their patients as soon as possible.

Valter Pinto - Moderator:

And, Chris, can you provide an update relative to your discussions with potential partners for both CytoSorb® and HemoDefend?

Chris Cramer – VP Business Development:

Sure. We continue to make strong progress towards establishing strategic partnerships for our two most advanced assets, CytoSorb® and HemoDefend™. As Phil mentioned earlier, we've been very active with our partner outreach and development activities. For example, we recently participated in several critical care and cardiac surgery medical conferences in Europe and the United States. These conferences are very important to our BD strategy, as they give us the opportunity to meet face to face with key decision makers. I'm pleased to report that we've received very positive interest from multiple strategic partners. Although I cannot disclose specific details on these opportunities, I can say that we are talking with many of the top players, and in some cases, have advanced beyond initial introductions and are now exploring how we might potentially work together.

Also, because there is a high level of interest from multiple partners, we are reworking our contract strategy to allow us to work with more than one strategic partner in certain territories, for specific market applications such as cardiac surgery. This would enable us to effectively maximize the opportunity for CytoSorb® in a given territory.

Like CytoSorb, we are aggressively advancing our BD efforts for HemoDefend™. For example, recently CytoSorbents was an exhibitor at the American Association of Blood Banks, or AABB, the largest medical conference for health care professionals and corporate organizations involved in blood management. AABB was particularly valuable as it enabled us to connect with all of the major strategic players that we know as well as new ones for the HemoDefend platform. We're pleased to report the value proposition for HemoDefend continues to resonate in the market, and there's strong interest from multiple strategic partners for both the HemoDefend inline filter and the HemoDefend beads in a bag. Currently, we're engaged in follow-up partnering discussions with several top players, and we hope to have more positive news to report at the end of the year.

Valter Pinto - Moderator:

Thanks very much, Chris. Another topic on many people's minds is the dosing study. Dr. Chan discussed it briefly but, Vince, can you please elaborate further?

Vincent Capponi – COO:

Sure. Thanks, Valter. Although we can't provide any specific clinical results associated with the 24-hour dosing at this point, our preliminary analysis of the safety data suggests that the 24-hour treatment is well tolerated. I want to emphasize this is preliminary data and has not been fully vetted by our data safety monitoring board, but we are satisfied with the preliminary analysis. In addition, our effort to bring on new trial sites has already borne fruit, with a significant increase in the enrollment in the trial as Phil mentioned earlier. Again, we plan to have more to discuss by year end regarding the dosing study.

Valter Pinto - Moderator:

Thank you. What is the status of the DARPA program?

Vincent Capponi – COO:

Sure. Regarding the DARPA program, we started our second year award, and we were recently approached by Battelle, DARPA's system integrator, to accelerate our development program so they can integrate CytoSorb's technology into early animal studies. We really view this as a very positive endorsement of CytoSorbents' technology, and look forward to continuing refinement of the polymer technology in line with DARPA's program milestones. We also just came back from a DARPA principal investigator meeting, where we presented our progress, and we're really excited about how our technology complements those from other technology providers and how it seems to be all be coming together at this point.

Valter Pinto - Moderator:

Thank you, Vince. That was very helpful. Kathy, can you talk a little more about the uplisting?

Kathleen Bloch - CFO:

Yes. So, as we have indicated in the past, it is the Company's intention to uplist to a more robust national exchange, where we can reach more investors, in particular institutional investors, and where we'll be able to achieve greater demand for our stock. We are still on target to do this in the next six to nine months, and we believe this is a core requirement for the Company's long-term success. From a funding standpoint, an uplisting will allow us to raise capital at better terms, so that we can limit shareholder dilution, as we work towards increased CytoSorb® sales and towards cash flow break-even. We have also been working hard putting the fundamentals in place which will allow us to gain momentum to support an uplisting in the future.

Valter Pinto - Moderator:

Thank you. Do you expect to see continued fluctuations in sales, quarter-to-quarter? Or, is it beginning to stabilize for various reasons including greater participation by the distributors?

Kathleen Bloch - CFO:

We continue to guide investors that quarter-over-quarter growth may have some lumpiness while we're in these early stages of commercialization. However, as illustrated by our 12-month trailing revenue chart that we showed earlier, we are seeing a very positive trend in product sales, and we are also experiencing a greater number of recurrent orders. So, we expect to see further stabilization and visibility of sales in the future.

Valter Pinto - Moderator:

Okay. Thank you, Kathy. And finally, Vince, what are the plans around manufacturing?

Vincent Capponi – COO:

Sure. Our intention is to continue to manufacture CytoSorb® in the United States at our ISO 13485-certified manufacturing facility in Monmouth Junction, New Jersey, near Princeton. Management expects that our current location will be adequate to support our manufacturing needs for the next two to three years. When additional manufacturing capacity becomes necessary, we will likely remain in the immediate area, to take advantage of our existing human expertise. We're currently working on plans for a scaled-up manufacturing facility and have already looked at several different levels of capacity at this point.

Valter Pinto - Moderator:

Okay, great. Thank you. Those seem to be the major questions. Dr. Chan, any closing remarks?

Phillip Chan - CEO:

Yes. Well thank you everyone for submitting questions and participating in the call. If any of you have additional questions, feel free to forward them to Alliance Advisors. We look forward to providing the next update very soon. And with that, have a great evening, everyone. Thank you.

Operator:

Thank you. Ladies and gentlemen, this concludes our conference call for today. If you would like to listen to a replay of today's conference, please dial 1-877-870-5176. And, international participants may dial 1-858-384-5517. We'd like to thank you for your participation, and you may now disconnect.