CytoSorbents™

Working to Save Lives Through Blood Purification

CytoSorbents Corporation (OTCBB: CTSO)
Q2 2014 Earnings and Operating Results Conference Call
August 12, 2014 @ 4:15 pm Eastern

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

Operator:

Good day, everyone and welcome to the CytoSorbents 2014 Second Quarter Financial Results Conference Call. Today's call is being recorded and at this time I'd like to turn the conference over to Amy Vogel. Please go ahead.

Amy Vogel – Moderator:

Thank you operator and good afternoon. Welcome to CytoSorbents Second Quarter 2014 Operating and Financial Results Conference Call. With us today are:

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

Before I turn the call over to Dr. Chan, I'd like to remind listeners that during the call, management's prepared remarks may contain forward-looking statements which are subject to risks and uncertainties. Management may make additional forward-looking statements in response to your questions today. Therefore, the Company claims protection under Safe Harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. Actual results may differ from results discussed today and therefore, we refer you to a more detailed discussion of these risks and uncertainties in the Company's filings with the SEC. Any projections as to the Company's future performance represented by management include estimates today as of August 12, 2014 and the Company assumes no obligation to update these projections in the future as market conditions change.

During today's conference call, we will first have an overview presentation covering the financial and operational highlights for the quarter by Dr. Chan and Ms. Bloch. We again have taken everyone's submitted questions and will do our best to address them in the presentation, and

also in the Q&A session with management to follow. Thanks everyone again for participating. If we do not answer your question, we would ask that you contact the Company directly after the call today.

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

Phillip Chan - CEO:

Thank you very much Amy and thank you to everyone for submitting your questions and making time to join the call today. Welcome. Unfortunately Chris Cramer, our VP of Business Development, is out sick, but I will cover some business development matters in my remarks.

Following a short introduction for new and potential investors, Kathy will go over our financial progress for the second quarter of 2014, followed by a discussion of our cardiac surgery trial, the potential application of CytoSorb® in Ebola treatment, some case report studies, and then a Q&A period.

I would also encourage investors to visit our website at www.CytoSorb®ents.com to obtain a copy of earlier transcripts and presentations. Also a recent interview by The Wall Street Transcript will also be available on our website very shortly that covers some additional questions today in greater detail.

Slide 4: With that let me turn to slide four. CytoSorbents is an emerging leader in the $20 billion critical care immunotherapy space. We are leading the prevention or treatment of life threatening inflammation in the intensive care unit.

Slide 5: Inflammation plays a major role in nearly every known disease. This could be life threatening conditions like sepsis, trauma, burn injury, influenza, Ebola virus infection, and others. It could also be autoimmune diseases like rheumatoid arthritis, inflammatory bowel disease, psoriasis and lupus, heart disease, peripheral artery disease, cancer, cancer cachexia, graft versus host disease, neurodegenerative diseases like Alzheimer's, multiple sclerosis, Parkinson's, and many, many others. The unfortunate part is that uncontrolled inflammation wreaks havoc on the body and can be deadly.

Slide 6: The problem with severe, uncontrolled inflammation is that it can cause cell death and organ injury, ultimately leading to organ failure. Organ failure is when vital organs like the heart, the brain, the kidneys, the lungs or the liver stop working and that is incompatible with life. Organ failure causes nearly half of all deaths in the ICU today, but little can be done to prevent or treat it. And this is where our technology comes in.

Slide 7: CytoSorb® removes the "fuel to the fire" of inflammation. CytoSorb® represents one of the most powerful immunotherapy tools to control inflammation. It is approved in the European Union as the only specifically approved extracorporeal cytokine filter and is clinically proven to reduce key cytokines in blood in critically-ill patients.

Its approved for use in any situation where cytokines are elevated and has been used safely in more than 3,000 human treatments with no serious device related adverse events reported.

Slide 8: The heart of the technology is a highly porous polymer bead roughly the size of a grain of salt. These beads have millions of pores and channels in every single bead allowing them to act like tiny sponges to remove harmful substances from blood, based on size as well as surface adsorption. It is protected by 32 issued U.S. patents and multiple applications pending. It is manufactured at our ISO 13485 certified facility in New Jersey, and it is one of the highest-grade medical sorbents on the medical market today.

Slide 9: The goal of CytoSorb® is to prevent or treat organ failure. Rather than letting patients spiral down the well of organ failure and inflammation, our goal is to try to stabilize these patients when they come into the intensive care unit thereby reducing the severity of illness and helping reduce the cost of ICU care. We believe that because of this and because of the many applications suitable for this technology, we have the potential to revolutionize critical care medicine.

Slide 10: CytoSorb® is currently marketed in 19 countries around the world, in fact its available for sale in all 28 countries in the European Union but it's currently sold today directly in Germany, Austria and Switzerland and with established distribution in 16 other countries including the U.K., Ireland, Netherlands, Turkey, Russia, India, Taiwan and the Middle East covering approximately 1.7 billion lives. We are currently expanding to other EU countries and countries outside the EU that accept the CE mark.

Slide 11: The technology has also been the beneficiary of more than $15 million in U.S. Government support. This includes our almost $4 million five-year contract with DARPA under the Dialysis-Like Therapeutics program to treat sepsis, $1.15 million in a Phase I and Phase II SBIR contract with the U.S. Army for burn injury and trauma research and more than $3 million committed by the U.S. Air Force in funding a 30-patient human pilot study in trauma that the FDA has approved to move forward with. Skipping down to the bottom here, NHLBI, or the National Heart, Lung and Blood Institute, a division of NIH, is also supporting another product under advance development called HemoDefend that is designed to purify blood transfusion products in order to reduce transfusion reactions.

So with that, let me turn it over to Kathy to talk about our second quarter 2014 operating and financial highlights. Kathy?

Kathleen Bloch - CFO:

Thank you, Phil. Good afternoon everyone.

Slide 13: For today's call, I will be providing an update regarding CytoSorbents' revenues and I will also comment on the Company's progress related to up-listing to a national exchange, either NASDAQ Capital Market or NYSE MKT.

As you will see, our comparative financial results demonstrate strong revenue growth.

For the first half of 2014, total revenue was approximately $2.1M, which is an increase of 215% compared to total revenues of approximately $663K for the first half of 2013.

Product sales for the first half of 2014 were approximately $1.2M, which is an increase of approximately 300% over product sales for the first half of 2013 of approximately $304K.

Grant income and other income for the first half of 2014 was approximately $854K, which is up 138% as compared to grant and other income of approximately $359K for the first half of 2013.

First half 2014 blended gross margins were approximately 36%, while our CytoSorb® product gross margins were approximately 63%.

Slide 14: Turning to the quarter ended June 30, 2014, product sales for the quarter were approximately $663K, that's a 418% increase over product sales of approximately $128K for the second quarter of 2013.

Second quarter 2014 product sales were the highest quarterly product sales in the Company's history. Gross margins on these product sales in the second quarter of 2014 were approximately 65%. Our grant and other income was approximately $361K for the second quarter of 2014, as compared to grant and other income of approximately $164K for the second quarter of 2013.

Total revenue for the second quarter of 2014 was approximately $1.0M which is an increase of 252% compared to total revenues of approximately $291K for the second quarter of 2013.

Slide 15: Now, we'll look at the Company's historical quarterly sales for each of the last eight quarters since we began commercialization of CytoSorb® in late 2012.

With our record, second quarter product sales of $663K, the Company has now posted its fourth consecutive quarter of double-digit quarter-over-quarter growth. Our current annual run rate is now in excess of $2.6M, as compared to an annual run rate of approximately $500K just one year ago. As always, at these early stages of commercialization, we continue to point out to our investors that we may experience quarter over quarter variations in sales. Many different factors influence each quarter's sales results including when new distributors come on board, when CytoSorb® achieves final product registration in new territories, the timing of repeat orders, and other seasonal factors such as holidays in the territories where we sell our products, as well as many other factors. For example, Germany celebrated six public holidays during the second quarter which effectively shut the country down for days at a time.

Slide 16: This chart best depicts the rapid growth we are seeing in CytoSorb® sales. For each quarter, it summarizes the trailing twelve months of CytoSorb® sales and once again it continues to demonstrate the acceleration and upward trend that sales are taking overall. Sales for the twelve months ended June 30, 2014 were approximately $1.8M, as compared to sales for the twelve months ended June 30, 2013 of approximately $406K. This represents an increase of approximately $1.34 million, or a year-over-year product sales increase of 331%.

With regard to expectations, sales momentum remains strong, and we expect that this positive trajectory in the trailing 12 months sales will continue into the current quarter.

Our balance sheet remains secure with more than $9.6 million in cash and short-term investments at June 30, 2014, and we are continuing to execute on our stated path for the commercialization of CytoSorb®.

And now, I'd like to turn to the Company's planned up-listing.

Slide 17: Management remains committed to up-listing to a major national exchange before the end of 2014 because of the many advantages it brings. Currently, we have few institutional investors, because most hedge funds, pensions, and mutual funds cannot invest in OTCBB companies that are penny stocks or less than a certain market cap. An up-listing removes this restriction and will enable these larger investors to take positions in our stock. We believe this will significantly improve trading volume in our stock, and thereby enhance liquidity for all investors.

We believe that an up-listing will also improve our visibility and credibility with the investment community. Many research analysts know our company and follow our progress, but do not cover us because we are an OTCBB penny stock. By removing this restriction, we would be a major step closer to expanding our research coverage. And importantly, a national market listing would also reduce our cost of capital and enable us access to more sources of capital.

Previously, we had met with representatives at the NASDAQ and the NYSE MKT and we've reviewed and evaluated the listing requirements for each exchange. We've already taken many steps to prepare for the up-listing, which I will review in some detail. In July 2014, we announced the Company's consolidation of its SEC and international legal counsel with the global law firm, DLA Piper LLP. DLA Piper is one of the largest international business law firms with offices in most major markets around the world and legal expertise across a broad range of practice areas which include corporate and finance, litigation and arbitration, Sarbanes Oxley compliance, government affairs, labor law, intellectual property and technology, and tax. DLA Piper's expertise, particularly in the medical device sector, will be invaluable as we execute our transition to a nationally-listed company later this year. We have since adopted a Code of Business Conduct and Ethics and are currently updating our Insider Trading Policy, all of which are required governance items for the major exchanges.

We've also made numerous improvements to our system of internal controls over financial reporting, both here in the U.S. and in Germany, and we are currently in the process of selecting an independent third-party provider who will help to manage the documentation and testing of our system of internal controls, which is another requirement for a Company traded on a major exchange.

Other activities to meet the remaining listing requirements are also underway. For example, we are currently actively interviewing financial experts to serve on our Board of Directors and act as the Chairperson of our to-be-formed independent Audit Committee.

We are currently working to expose institutional investors to our story ahead of the up-listing. Creating demand on the other side of an up-listing is a key part of our strategy.

We are also working to simplify our capital structure. We expect to enact a reverse stock split to bring our stock price up to the minimum price required by the major exchanges, but this ratio will be dictated by the share price at the time of the up-listing. It is important for shareholders to understand that a reverse split does not change the value of your holdings. For example, if you have 1000 shares at $0.30 per share, that is valued at $300; after a 1 for 10 reverse split, you will have 100 shares at $3, also valued at $300. It is also important for shareholders to remember that we have repeatedly stated that we will execute the up-listing when the Company is ready and when we are experiencing major operational momentum—such as continued growth in sales, a new strategic partnership, advances in our U.S. Pivotal trial, to name a few—and that is the principal that continues to guide us overall in the up-listing process.

At this point I'd like to turn the call back to Phil. Phil?

Phillip Chan - CEO:

Thank you very much, Kathy. Now I'd like to go over some items and questions that shareholders have submitted particularly as they relate to our U.S. cardiac surgery pivotal trial plans and the Ebola outbreak.

Slide 19: Just to give you some background on cardiac surgery. There are approximately 1 million cardiac surgeries requiring cardiopulmonary bypass in the United States and in the European Union annually, with another half a million in the rest of the world, particularly in India and China.

These are done for many different reasons. One of the most common is for coronary artery bypass graft surgery for blocked heart arteries. Others include valve replacement, cardiac defect repair in congenital heart disease, for example, heart or lung transplantation, as well as LVAD or left-ventricular assist device implantation for heart failure.

The problem with cardiac surgery is that patients often develop inflammation due to many things that are associated with cardiac surgery starting from cracking open the chest, stopping the heart from beating, bypassing the blood into a heart lung machine, sucking up blood from the field with cardiotomy suction, blood transfusions, reversing heparin anticoagulation with protamine, and many other aspects of the surgery.

This can lead to a production of cytokines, activation of complement, and a release of free hemoglobin that work together to induce inflammation, causing cellular injury and organ injury ultimately leading to multiple organ failure, particular lung and kidney failure, in a certain percentage of patients.

In high risk surgical patients, the risk of developing kidney and lung failure could be as high as 30%. There has been no technology that is easily introduced into the heart lung machine blood circuit that can directly reduce cytokines, complement factors, free hemoglobin and other

inflammatory mediators, directly from the entire blood volume. Cell saver blood washing typically only treats salvaged blood.

Leukoreduction filters are used today to remove cytokine-producing white cells, but do not work to remove cytokines directly. This, we believe, is a multimillion dollar market that we may be able to address with our cytokine filter.

Slide 20: That being said, CytoSorb® can be used two different ways in cardiac surgery. One is intra-operatively in a bypass circuit, parallel to the main heart lung machine blood circuit, as you see on the left hand side. Or the device can be used with a standard dialysis machines to treat the patient after the surgery is done, when the patient is recovering in the intensive care unit.

Slide 21: When we first talked to you about this cardiac surgery trial, we were really focused on either the intra-operative usage of CytoSorb® to prevent post-operative complications, which is option number two, or the post-operative use of CytoSorb® to treat post-operative inflammation, which is number three.

In our discussions with our advisors, we have elected not to pursue the post-operative approach at the current time. However this approach is being pursued by many investigators in Europe.

Instead we are focused on the intra-operative usage of CytoSorb®. And now based on our discussions with our key advisors, there may be a third path that we could take, which is the use of our CytoSorb® therapy intra-operatively, but rather than looking at clinical endpoints such as a reduction in organ dysfunction, there maybe an opportunity to actually get approval for CytoSorb® in the United States based upon a demonstration of inflammatory biomarker reduction. This has a number of advantages over a traditional cardiac surgery trial that would be envisioned in number two in that it would be a shorter trial. It would be a less expensive trial. It would be a less risky trial. And instead of being a PMA, which is the most rigorous path for approval for medical devices through the FDA, this could potentially be a de novo 510(k) path.

So, although we have delayed our submission of the IDE application, what we've been doing with the time has been to do a lot of *in vitro* simulations looking at the reduction of inflammatory biomarkers. And I'm pleased to say that those results have been very satisfactory. So our goal right now, pending discussions with the FDA, is to potentially do an inflammatory biomarker reduction study, and we would expect to submit an IDE in the fourth quarter of 2014. Of course, this is dependent upon successful discussions with the FDA and an acceptance by the FDA of this trial strategy.

Slide 22: Along these lines, we have been encouraged by a recent paper, in fact the first paper published describing the intra-operative usage of CytoSorb® during cardiac surgery, in the journal KardioTechnik. This was a retrospective 40 patient cardiac surgery trial, where 20 patients received CytoSorb® therapy intra-operatively, and 20 patients did not, in the heart, lung machine circuit. This was a study done at the University of Munich, Grosshadern campus, which is one of the largest hospitals in Southern Germany. These patients underwent high risk surgery with hypothermic cardiac arrest and anterograde cerebral perfusion.

The treatment was associated with a statistically significant reduction in interleukin-6 and procalcitonin in the three day post-operative period, compared to control. This gives us visibility on a U.S. pivotal trial in cardiac surgery as it relates to a reduction in inflammatory markers. This paper can be found on our website for download.

Slide 23: Turning to the Ebola virus outbreak. Ebola is one of the most deadly viruses known with a very high mortality rate of 50% to 90% depending upon the strain. It is also very contagious and typically transmitted through contact of bodily fluids. Following an incubation phase up to three weeks, it has an abrupt onset of symptoms including high fever, chills, weakness and body pain followed by more severe symptoms including diarrhea, cough, headache, and bleeding with vomiting of blood or blood in the stool. It is often called Ebola hemorrhagic fever.

Patients typically die, with time of death from the onset of symptoms anywhere between 6 to 16 days, culminating in a cytokine release syndrome that stimulates deadly inflammation and ultimately organ failure.

One of the key reasons why Ebola is so deadly is its ability to evade the immune system resulting in an advanced infection that triggers an overactive immune response, leading to organ failure. It does so by initially suppressing the antiviral cytokine immune response, which then allows robust viral replication. It also causes the production and release of soluble viral glycoproteins. These normally coat the surface of the virus but when they are soluble, they are free floating and can interfere with white blood cell activation and also act as decoys so that antibodies cannot neutralize the virus.

The scientific rationale behind using CytoSorb® in Ebola virus is that we may help patients by reducing "cytokine storm" primarily, but also by potentially removing soluble glycoproteins which are about 50 kDa in size, which is right in the size range that CytoSorb® can remove, thereby delaying the onset of fatal inflammation and organ failure while buying the patient time for the immune system to kill the virus.

And when you look at patients who survived Ebola virus infection, they typically have very high titers of protective antibodies, and in fact these high titers of protective antibodies have been used to help transfer immunity to patients who are currently infected with the Ebola virus.

Slide 24: So could CytoSorb® help? This is one of the major questions that have been posed to us. Well, the 2014 Ebola epidemic in West Africa has been called an international emergency by the World Health Organization and continues to grow, already infecting nearly 1,900 people and claiming more than 1,000 lives. Based on estimates, the epidemic is expected to continue throughout the year.

There are now some experimental therapies being tried, but there is no definitive treatment for Ebola today. Our strategy for outreach includes reaching out to many different organizations including the World Health Organization, the FDA, the CDC, as well as government agencies such as USAMRIID, non-profit organizations, and also hospitals treating Ebola patients inside and outside of West Africa, particularly those in Europe and the United States where patients with advanced infection have been (at least some of them) have been sent.

The problem with treating patients directly inside West Africa is that the level of medical care is typically very poor, and only until you go to westernized medical centers do you have the ability to treat with dialysis-type products. When we have more information on the potential usage of CytoSorb® in this Ebola epidemic, we will of course let the public know.

Slide 25: So turning to business development, given Chris Cramer's absence, let me remind you that our polymer bead technology enables a diverse and valuable pipeline. As you see here, CytoSorb® is used for critical care and high risk surgeries and has been CE mark-approved, but we have a number of products in development, as well as ones that we have not yet even disclosed publicly, where the products have the potential ability to be out-licensed and developed by other companies. One of our most advanced products under development that Vince will talk about a little bit later, is HemoDefend. This product is designed to try to help purify the contaminants out of the blood supply that can cause transfusion reactions and adverse outcomes including death.

Slide 26: Many of you have seen this slide before, but this is just here to reiterate the many areas where we touch medicine. It could be the renal dialysis space; it could be the critical care space, the catheter space, cardiac surgery, blood transfusion as well as biotech and immunotherapy. We have ongoing discussions with a number of these strategic partners for potential business relationships and we hope to have additional detail on those in the months to come prior to our up-listing.

A major strategic partnership that we currently have is with Biocon, which is the largest biotechnology company in India, often called the "Amgen of India." Biocon has been seeing quite a bit of success after its launch of CytoSorb® in September 2013 in the country. And in fact they are one of our largest distributors in terms of distributor sales, and they continue to re-order product on a very regular basis. They have increased their commitment to CytoSorb® and are now hiring a dedicated sales force to help sell CytoSorb® in India, which is fantastic.

And in September, BioCon will be embarking on a city by city tour throughout India with one of our key opinion leaders to talk about the use and applications of CytoSorb® in the areas of critical care. They have already had a number of their own success stories that they are working to publish as well.

Slide 27: So I'd like to finish my comments with just a couple of case report studies that I think you would find very interesting. CytoSorb® has the ability to be used in any clinical situation where cytokines are elevated, and one of these situations which you have not heard of before is in acute graft dysfunction.

Acute graft dysfunction is a major complication after transplantation of solid organs. In this particular case, we are talking about liver transplantation and it is a life threatening event that requires emergency re-transplantation. Now as many of you know, the wait list is typically very long to get a matched donor organ for a specific patient. However, in an emergency re-transplantation they have no choice but to take a typically mismatched organ and to transplant it into the patient to try to help save the patient's life.

The inflammatory response however in this case is very robust and accounts for most of the systemic complications and increased mortality in this procedure. This case involved a patient who is a 46-year old man with a history of liver cirrhosis, who underwent an initial liver transplantation that failed. He then underwent a second emergency liver transplant but with a liver that was ABO blood type incompatible. CytoSorb® was used during the re-transplantation surgery to stabilize the patient hemodynamically, and with the therapy he was able to be weaned off all vasopressor support by the end of the therapy.

Below you see a table looking at the effect on key cytokines during the first treatment which is called CytoSorb® number one, and then the second treatment which is called CytoSorb® number two. The legend below the table shows what T1, T2, T3 means. T1 means start of surgery, T2 mean after graft reperfusion, T3 means end of surgery, T4 and T5 mean before and after, respectively, the second CytoSorb® cartridge. And what they saw was that key cytokines such as IL-6, IL-8 and MCP-1, TNF and IL-10 were decreased significantly.

So not only were they seeing an improvement in hemodynamic stability, but they were also correlating this with a key reduction in inflammatory and certain anti-inflammatory cytokines. In this patient, liver function returned to normal five days after surgery and he left the post anesthesia care unit after seven days. At a 4 month outpatient follow up, the patient was doing very well with normal liver function. This case report study was presented by the surgeon at a major clinical conference.

Slide 28: On this next slide is a case of toxic shock syndrome. Many of you have heard of toxic shock syndrome before as it relates to the use of tampons, but it can happen in any Staphylococcal or Streptococcal infection. This is a case report of a 17 year old man who suffered an injury to his ankle and unexpectedly began to develop a fever. He rapidly deteriorated and was hospitalized the next day at a major hospital in Rotterdam, Netherlands where antibiotics were started immediately. However, he continued to decline and was admitted to the ICU where he went into shock.

The patient became globally red and swollen and was suspected to have toxic shock syndrome. Now on the right hand side are pictures of other patients; one is an infant with toxic shock syndrome and the other is the hands of an adult, and you can see the severe redness and peeling of skin that are common in what is called scalded skin syndrome. Toxic shock syndrome is a direct result of a toxin called Toxic Shock Syndrome Toxin number 1 (TSST-1) and toxins called exfoliatins that are released during a Staphylococcal infection that triggers the immune response and the release of large amounts of cytokines, that can lead to severe fever and shock, while the toxins attack the structure of the skin, causing a massive sloughing of the skin cells.

This patient was suspected to have toxic shock syndrome and they surgically explored the injured ankle revealing the Staphylococcal infection, thereby confirming the diagnosis. At this point, the patient was still in shock and developed respiratory failure requiring intubation.

At this time, it was decided to start the patient on CytoSorb® and within five minutes of treatment, his blood pressure began to increase, and after three hours of treatment the patient's swelling and redness had completely resolved.

This is another case where the intervention of CytoSorb® was directly correlated with the improvement in the patient. The total CytoSorb® treatment was only 14 hours and the patient went on to a full recovery. This case report happened just very recently.

These are the types of successes that we continue to see, and I think these are encouraging to physicians that our device is actually helping to improve clinical outcomes and changing the course of patient's disease.

That concludes our formal presentation. Let me turn it over now to Amy to begin the Q&A session.

Amy Vogel - Moderator:

Thank you Dr. Chan. Over the last week, we have collected a number of questions from investors.

Q: Christian, could you please give us an update on sales and the development of the different markets.

Christian Steiner

Yes, of course. Thank you, Amy.

We had another strong performance in the second quarter. We saw significant growth in sales in both our direct and distributor markets, and are very much on track with our sales plan for the year. Currently, direct sales of CytoSorb® still account for the majority of our product revenue and we were pleased to achieve our sales targets despite many public holidays and accompanying bridging days in Germany that make the second quarter, from a sales opportunity standpoint, a short quarter. Re-order volume of direct sales, probably the most important indicator of continued use and adoption, account for most of our direct sales and showed healthy 25% quarter-over-quarter growth. At certain hospitals, we are seeing that CytoSorb® is being regularly used for specific indications. That is the first step to becoming standard of care at those hospitals. Although the majority of our sales efforts are focused on our existing customers, we continue to expand our new customer base, with moderate quarter over quarter growth for new orders, following a substantial increase in Q1.

Our Distributor business also continues to grow, with strong re-order performance from Turkey and India, in particular. As mentioned, we are waiting for final product registration in Russia and the Middle East, which we hope to get soon, and we just signed on Taiwan. To date, we have not yet had meaningful sales from these countries. However, the dialysis and blood purification markets are very strong there, and we expect these territories to be significant contributors to our revenue growth going forward. We also expect to expand distribution to a number of other countries by the end of the year, and are on track to do so.

We also intensified our marketing efforts as discussed during the two previous investor calls. CytoSorb® therapy has been presented at several conferences by a number of users, for

example, at the International Liver Transplant Society Meeting in London where the use of CytoSorb® after liver transplant was discussed. What was particularly interesting was our CytoSorbents satellite symposium at the Joint Meeting of the German and Austrian Society for Internal Medicine and Critical Care Physicians. The attendance at our symposium was completely full, with almost 20% of the whole conference participating in our session. Furthermore, we have been invited by certain potential strategic partners to inform their customers about this new extracorporeal therapy at specialized conferences. We have participated in two of these meetings in Germany already, and a third one is planned to take place in Berlin later this year.

Q: What do you think is needed to establish CytoSorb® as a standard-of-care-therapy for septic shock or other indications?

Severe sepsis and septic shock are our largest target markets. They account for 10-20% of all ICU admissions. In other countries, such as India, nearly a quarter of all ICU patients have sepsis. But sepsis is a very complex disease, and no single patient is exactly alike. Historically, this has made sepsis very difficult to treat. We believe that CytoSorb® attacks sepsis in many ways that has not been possible before. CytoSorb® works to reduce cytokine storm to control deadly inflammation, but it can also remove certain bacterial toxins, and importantly, in animal models of sepsis, it can help redirect the activated immune system to target the infection and avoid injury to healthy organs.

To make CytoSorb® standard of care for sepsis requires that we develop strong medical evidence that the therapy works, and that we collaborate with medical societies, both nationally and internationally. We are currently considering a larger scale randomized controlled trial in sepsis, to take place in Germany, that should help answer this question. In the meantime, we have many investigator initiated studies in severe sepsis and septic shock that are either enrolling or are planned that will help generate additional data.

Furthermore, our international registry, which will help collect data on how CytoSorb® is best used, is currently online and in beta testing. The official launch is planned for World Sepsis Day in September. Also, as discussed earlier, we continue to see quite dramatic case reports where CytoSorb® has worked extremely well. We take these cases and try to learn as much as possible from them.

Finally, we need to show evidence also of economic benefit in order to achieve reimbursement worldwide. For CytoSorb®, if we can save just 1 or 2 days in the ICU, the therapy would already pay for itself. We have seen this many times already. We plan to include cost effectiveness measures in all of our major clinical trials.

Q: When will we begin to see data?

We currently are concentrating our efforts here in Europe to generate the appropriate medical evidence and are making a lot of progress. During the last quarter, two case reports in intensive care medicine, and a 20 vs 20 patient retrospective controlled study from University of Munich using CytoSorb® during cardiac surgery, have been published. We are reaching a stage where

there are many of these case reports being prepared with quite a number of key opinion leaders planning to either publish or report their positive experiences at regional, national and international conferences as well as at other medical centers, where we want to introduce CytoSorb® therapy.

We have a number of ongoing investigator-initiated studies for different applications. We hope to see data from two studies in cardiac surgery, one at the University of Hamburg Eppendorf, and one at the Medical University of Vienna, by either the end of this year or first quarter of next year. Recently, a major 100 vs 100 patient, prospective, randomized controlled study using CytoSorb® intra-operatively during cardiac surgery has been started at the University of Cologne. These are just some examples of studies where data is being generated. We expect to see much more data in the next 6 to 12 months.

Thanks very much Christian. Another topic on many people's minds is the Air Force trauma trial, and grant programs such as DARPA. Vince, could you please elaborate a little regarding the progress in these programs?

Vince Capponi

Thank you, Amy. As we discussed in the last Investor update, the US Air Force-funded rhabdomyolysis trial is up and running, and we are working with the second site to bring this group on as soon as possible. We have been targeting critically injured patients with the very highest levels of myoglobin released from injured muscle. These patients are at the highest risk of developing acute kidney injury. However, this high threshold has made it difficult to find suitable patients to enroll who meet all of the inclusion and exclusion criteria of the trial. As a group, we are currently discussing with the US Air Force lowering this threshold to include patients with still very high levels of myoglobin, but at levels that are more commonly seen. We do not think that this will negatively impact the study, as the primary goal of the study is to reduce high levels of myoglobin.

Regarding the DARPA, DOD SBIR and HemoDefend SBIR, we continue to make progress on all three grants, having received approximately $358K in Q2 2014 grant revenue. We recently had an excellent discussion with the new Program Manager of the DARPA DLT program and are looking forward to finishing our Year 2 efforts and begin planning for Year 3, of our 5 year contract. During Year 3, we will be taking various new technologies that we have developed under the program, and beginning pilot scale production to produce enough devices for DARPA integrator, Battelle Labs, to test in large animal models.

We have currently completed the burn injury portion of our US Army Phase II SBIR contract and are working on the trauma injury model currently. This is a program that is very exciting, because we have been developing quite a number of new technologies. Once this is completed, we will discuss with the US Army about potentially advancing to a Phase III study.

We are also finishing our very ambitious Phase I HemoDefend SBIR contract with our collaborators at Dartmouth. We are currently summarizing the data in support for applying for a Phase II SBIR contract to further advance this application.

Concerning new grants, we have identified a number of additional grant opportunities that we believe are well-aligned with the CytoSorbents platform technology. These grants range from HemoDefend type applications to address blood quality, to the treatment of inflammatory conditions specifically associated with biowarfare. As we develop these opportunities, we will discuss them in the context of both financial benefit to the company and technology advancement in future updates. Securing non-dilutive funding to advance development of the CytoSorbents technology platform continues to be one of our key objectives.

Q: Thanks, Vince. Have you started construction on a new manufacturing facility given the uptick in sales?

We have begun several initiatives since our last update regarding capacity build. First we have begun certain infrastructure updates to our existing facility. These infrastructure updates will allow us to further increase our capacity to satisfy our near term needs as we pursue our next objective, a new plant build out. To that end, we have begun the process of looking at alternative options, including larger facilities, to provide both a near and long-term increase in manufacturing capacity. In addition, we have begun the process of identifying several engineering firms to quote on our plant design. The firms will help us with the facility modifications, equipment installations and start-up. The preliminary engineering we completed earlier will facilitate this process and should reduce the total time necessary to bring a new plant on line. Outsourcing of manufacturing always remains an option but for reasons of maintaining control over the know-how, controlling production lead times, and maximizing gross margins, we have elected to maintain this in-house.

Q: What is the current status of the development of HemoDefend™ product?

Regarding HemoDefend™, we have recently secured additional space for our process and equipment development engineering. Separating the HemoDefend development process from our manufacturing equipment allows us the ability to continue the process and equipment development testing without disruption to our manufacturing operations. Concurrently, we continue to work on the design to establish the best geometry and device size for the in-line filter application. As we progress down the HemoDefend development pathway, we will provide updates from time to time.

As an additional note, based on clinicaltrials.gov, and the Canadian counterpart, www.controlled-trials.com, it appears that the two large randomized controlled studies looking at the impact of age of blood in cardiac surgery patients, called the RECESS trial, and critically ill patients, called the ABLE trial, are completed. If not too soon, we may hear about the data, or at least top-line data, at the upcoming AABB, or American Association of Blood Banks, conference in late October. If one or both of these studies demonstrates increased risk with the transfusion of older blood, it could significantly elevate the value of approaches like HemoDefend that help purify the blood of degradation products like free hemoglobin that have long been associated with the increased risk of older blood.

Well, we seem to have covered the major questions. Dr. Chan, do you have any closing remarks?

Dr. Chan:

Thank you, Amy. Thank you everyone for being on the call today. If you have any additional questions, feel free to forward them to Ms. Amy Vogel at avogel@CytoSorbents.com and we will try to address them in our next update. Thank you again and have a great evening.

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