CytoSorbents Corporation (NASDAQ: CTSO)
Q2 2016 Earnings and Operating Results Conference Call
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This official company transcript has been edited for clarity and does not differ materially in content from the actual conference call except where noted. Slide numbers have been inserted to allow readers to follow along with the associated presentation.

Operator

Good day everyone and welcome to the CytoSorbents Second Quarter 2016 Financial Results Conference Call. If you have a question during today's call, please press the star key followed by the digit one on your touchtone phone and be sure your mute button is turned off to allow your signal to reach our equipment. Today's call is being recorded and at this time I'd like to turn the conference over to our moderator, Amy Phillips. Please go ahead.

Amy Phillips – Moderator

Thank you and good afternoon. Welcome to CytoSorbents Second Quarter 2016 Operating and Financial Results Conference Call. Joining me today from the company are:

- Dr. Phillip Chan, Chief Executive Officer and President
- Vincent Capponi, Chief Operating Officer
- Kathleen Bloch, Chief Financial Officer
- Chris Cramer, VP of Business Development

Unfortunately, Dr. Christian Steiner, VP of Sales and Marketing from Germany, is not able to join the call today. 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 9, 2016 and we assume no obligation to update these projections in the future as market conditions change.

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

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

Phillip Chan - CEO

Thank you very much, Amy, and welcome everyone to the call.

Slides 3-6:

CytoSorbents is a critical care-focused immunotherapy company using blood purification to prevent or treat life-threatening inflammation in the intensive care unit and cardiac surgery using CytoSorb® blood purification. CytoSorb® removes the fuel to the fire of inflammation and targets the $20 billion worldwide opportunity in critical care and cardiac surgery.

CytoSorb® is approved in the European Union as the only specifically approved extracorporeal cytokine filter and is clinically proven to reduce key cytokines in the blood of critically-ill patients. It is approved for use in any situation where cytokines are elevated and is compatible with standard dialysis and heart-lung machines in hospitals worldwide. It also removes many other inflammatory mediators such as free hemoglobin, bilirubin, bacterial toxins, activated complement, and host of others that are contributing to this uncontrolled life-threatening inflammation. It has been safe and well-tolerated now in more than 14,000 human treatments performed worldwide.

Left unchecked, uncontrolled systemic inflammation can damage organs, sending these patients spiraling down into organ failure. CytoSorb® is designed to aggressively control this deadly inflammation upfront by reducing key inflammatory mediators from blood, taking the "edge" off of the inflammation so that it does not cause organ injury or failure. The goal is to treat early and aggressively, with the hope of preventing or limiting the adverse events caused by inflammation, thereby improving patient outcome and survival while decreasing the massive costs of ICU and patient care.

CytoSorb® is not just for the tens of millions of people worldwide who are admitted every year for diseases like sepsis, acute respiratory distress syndrome, burn injury, trauma, pancreatitis,

influenza, and complications of surgery. What I think is very unique about our company is how strategically positioned CytoSorb® is to respond to the ever growing health threats throughout the world. Whether or not it be the ever present threat of the epidemic "du jour" like H1N1 Swine Flu, Ebola, MERS, or SARS. Whether or not it's the nearly 10 million people who die every single year from sepsis - the overzealous immune response to life-threatening infection. These include well-known celebrities such as Muhammad Ali and Patty Duke who died recently, but also includes many well-known people in the past such as General Norman Schwarzkopf, Bernie Mac, Bob Hope, James Brown, Leslie Nielsen, Jim Henson, and many others. It also includes many patients who are affected by the various natural disasters that happen on a regular basis such as tornados, earthquakes, landslides, and wildfires, as well as terrible tragedies such as casualties of war, the terrorist attack on Bastille Day last month in Nice, France where a truck driver plowed through a large group of people watching fireworks, killing 85 people and traumatically injuring more than 300. Or the terrorist bombing in Brussels in March where 32 people were killed and more than 300 were injured, 62 of which were critically injured. Unfortunately, this is the world we live in, but fortunately this is the role that CytoSorb® was intended to play.

With that, let me turn it over to Kathy to cover our financial highlights for the quarter. Kathy?

Kathleen Bloch - CFO

Slide 7:

Thank you Phil, and good afternoon everyone. For today's call, I will provide an update regarding CytoSorbents' second quarter 2016 financial results, including product sales progress, a review of the recent financing we completed with Bridge Bank, and also an update around our working capital and cash runway.

Slide 8:

CytoSorb® product sales for Q2 2016 were approximately $1.9 million, which is a 140% increase over product sales of approximately $773K for Q2 2015. Our Q2 2016 annualized product sales run rate rose to $7.4 million, which is more than double our annualized run rate of approximately $3.1M one year ago.

Total revenues, which includes product sales and grant revenue were approximately $2.2 million for Q2 2016; as compared to approximately $964K for Q2 2015, an increase of approximately 131%.

In Q2 2016, our gross margin rose to approximately $1.3 million, an increase of approximately $850K as compared to gross margins of approximately $499K for Q2 of 2015. We continue to experience strong gross profit margins on product sales—for Q2 2016, gross profit margins

increased to approximately 68%, largely as a result of the sales mix, as compared to gross profit margins of approximately 63% for Q2 2015.

Slide 9:

Now, let's take a look at our quarter over quarter product sales…

Our second quarter 2016 product sales of approximately $1.9 million represented our best quarterly product sales ever. Q2 2016 product sales were approximately $255K or 16% higher than Q1 2016 product sales. Q2 2016 represented the fifth consecutive period for which we have reported quarter over quarter product sales growth as well as our fourth consecutive quarter of record sales.

We also note that the change in the Euro relative to the dollar did not have a material impact on our sales when comparing 2016 to 2015.

Slide 10:

Turning to our six months financial results, CytoSorb® product sales for first half of 2016 were approximately $3.5 million, which is a 134% increase over product sales of $1.5M for the first half of 2015.

Grant revenue grew 177% from $210K for the first half of 2015 to $582K for the first half of 2016.

Total revenues, which includes product sales and grant revenue were approximately $4.0 million for first half of 2016, as compared to $1.7 million for the same period in 2015, an increase of approximately 139%.

Slide 11:

Next, we will take a look at our trailing twelve months product sales chart.

We now have enough history to be able to present this chart on a year over year basis. This chart illustrates the trailing twelve months products sales for the last four years and it clearly demonstrates the increasing trajectory we are experiencing. The three year compound annual growth rate (or "CAGR") was 145% over this period.

We are pleased to be experiencing increases in both direct and distributor sales. The overwhelming majority of our product sales increases are a result of repeat orders from our existing customers, then to a lesser extent as a result of the addition of new customers and territories. But we believe the impact of new customers and territories will become significant.

Slide 12:

Part of our growth is being driven by distributor and partner sales. Let's look at the world map. As we have indicated we have expanded distribution to include 37 countries around the world. Just in the last quarter alone, we've had many important distributors come on line, who are now either contributing to revenue or in a position to contribute to revenue. Fresenius had its official product launch in six countries – Poland, France, Sweden, Denmark, Finland, and Norway. In May, we achieved product registration in Russia, and our distributor, Intensivmed, placed their very first order. We also received our first orders from Vietnam, Spain, and Portugal in Q2 2016. In July, we announced that we have added new distributors for Hungary, the Czech Republic, and Slovakia, and all of these countries have contributed to our revenue as well.

Slide 13:

In fact, we expect geographic expansion to be a powerful driver of our future growth. In January 2016, we had established distribution in 32 countries, but previously discussed that only 15 countries were actually contributing to revenues, as shown on the far left side of this chart. The remaining 17 countries were in the process of receiving approval to distribute CytoSorb®, completing registration, awaiting market launch, or some other matters necessary before beginning to commercialize CytoSorb®.

We have had good success in moving countries to a revenue-producing status. In August 2016, we have expanded distribution to 37 countries, but more importantly, we now have 28 countries who are in the "contributing to revenue" category. In addition, we expect to have Canada, which is a very important market for us, come on line soon.

We anticipate the standard ramp up period for these new countries, as the sales teams gain physician support and usage. But by bringing these new territories into "revenue producing status", and driving order growth, adoption, and repeat sales in these countries, we believe we have laid the foundation for dramatic growth. We fully expect that the synergy of our mixed model of direct and distributor sales will contribute to a significant inflection point in our product revenue growth in the future.

Slide 14:

Now, I'd like to comment on our recent debt financing…

On June 30, 2016, we entered into a Loan and Security Agreement with Bridge Bank, a division of Western Alliance Bank (NYSE: WAL), by which the Bank agreed to loan the Company up to an aggregate of $10 million, and we drew down on the first $5 million term loan which provided

approximately $4.9 million in net proceeds that will be used for working capital purposes and to fund general business requirements.

The financing terms are very competitive compared to other debt and/or equity options. The loan bears interest at the 30-day US dollar LIBOR rate plus 7.75%, which was 8.2% at June 30, 2016. The effective interest rate on the term loan, including all fees required to be paid over the life of the loan, is 10.0%. The Company will enjoy an interest only period for the first 12 months of the loan, then will be required to pay 36 equal payments of principal, plus interest, with a maturity date of July 1, 2020. There are no financial covenants related to this first $5M term loan.

Subject to certain conditions, the Company has at its sole discretion the ability to receive another $5 million term loan. If this additional tranche is taken, an additional six month interest only period would be added. Bridge Bank will be entitled to a "Success Fee" of 6.37% of the funded loan amount upon a "liquidity event" or if our common stock trades at $8.00 or above for five consecutive days. The Success Fee, if applicable, will be payable in stock or in cash at the Company's sole discretion.

We are very pleased to have been able to secure this non-dilutive funding and to be working with a premier provider of commercial services in Western Alliance Bank.

Slide 15:

Of course, the most important factor about the debt financing is that it supplied non-dilutive working capital to fund our ongoing operations and clinical trials. As we have stated in the past, given the state of the equity markets, we viewed debt as a useful bridge to a more traditional financing. As of June 30, 2016, we had approximately $9 million in cash and short-term investments, which should provide funding for our operations for slightly more than one year.

Turning to our capital structure, as of June 30, 2016, we had approximately 29.5 million common shares on a fully diluted basis.

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

Phillip Chan - CEO

Thank you very much, Kathy. What I would like to do now is cover key operational items before going into the live Q&A period.

Slide 17:

First, let's discuss our REFRESH (Reduction in FREe Hemoglobin) I trial. As most of you recall, this is a 40 patient, eight center study, evaluating the safety and efficacy of intra-operative use

of CytoSorb® in a heart lung machine during elective, non-emergent complex cardiac surgery that is expected to last longer than three hours. This includes procedures like aortic reconstruction, CABG redos, multiple valve replacements, congenital defect repair, and other types of complex cardiac surgeries.

The primary endpoints of the study are safety and the reduction of plasma free hemoglobin that can cause post-operative complications. Plasma free hemoglobin is a result of hemolysis of blood, where red blood cells, which contain hemoglobin, break open and release their contents into the blood. Hemolysis is caused by cardiotomy suction, where blood is sucked under negative pressure from the surgical field, causing many cells to explode. It is also caused by shear forces as blood courses through the artificial blood circuit at five liters per minute. It is also caused by the administration of blood transfusion products, particularly packed red blood cells that have typically degraded during storage, and add a burden of free hemoglobin to the patient.

Slide 18:

Free hemoglobin is very toxic because not only is the iron in hemoglobin very toxic, causing the formation of oxygen radicals that can damage blood vessels and tissues, but it is also a very potent scavenger of nitric oxide. Nitric oxide is the body's most prevalent vasodilator that causes blood vessels to dilate and blood to flow throughout the body. With decreased amounts of nitric oxide present in the post-operative period, blood vessels will clamp down and patients will often suffer high pressure and decreased blood flow to the lungs, the intestines, the kidneys and other vital organs, leading to stress on the heart, which was just operated on, as well as potentially organ dysfunction and organ failure following the surgery.

We are working with eight major cardiac surgery centers, including Baylor and Texas Heart Institute, Baystate Medical Center, Columbia University, Cooper University Hospital, University of Kentucky, University of Maryland, University of Pennsylvania, and the University of Pittsburgh Medical Center.

In May, we reported that the Data Safety Monitoring Board, or DSMB, analyzed safety data from the first 24 patients and found no safety concerns and recommended completion of the trial. We are currently nearly complete with our enrollment, with 44 patients enrolled, to target a total of 40 patients, who have completed all aspects of the trial. We expect to announce top-line data during the European Association for Cardio-Thoracic Surgery ("EACTS") Conference in Barcelona at the beginning of October. Pending the successful completion of REFRESH I and agreement with the FDA, we expect to begin a pivotal registration REFRESH IItrial early next year.

Slide 19:

The next update is on Fresenius Medical Care. We previously entered into a multi-year partnership with Fresenius, the world's largest dialysis company, for exclusive distribution of CytoSorb® for critical care applications in France, Poland, Denmark, Norway, Sweden and Finland. As Fresenius has mentioned, they view CytoSorb® as a key part of their growth strategy in critical care and have committed to annual minimum purchases to maintain this exclusivity.

This relationship leverages Fresenius' critical care leadership and industry-leading sales force and distribution to bring CytoSorb® to patients and physicians throughout these territories. This partnership also has a potential for broader future synergy and expansion, given that Fresenius is one of the leading producers of dialysis machines and disposable blood purification products worldwide. You can see how a product like CytoSorb® fits well into their business model.

Slide 20:

In May 2016, Fresenius launched CytoSorb® with a 30 person intensive care unit sales force that is also selling Fresenius products. Fresenius is actively marketing and selling CytoSorb® in its target countries now and has a busy schedule in actively promoting CytoSorb® in upcoming critical care conferences. This slide shows just one of a number of places where CytoSorb® is being exhibited in the Fresenius booth with the Fresenius dialysis machine. In this case, this is a photo taken of the Fresenius multiFiltrate Pro, which is Fresenius' newest dialysis machine.

Slide 21:

In addition, they have also developed a wide range of marketing collateral including this nine page product brochure, of which you see four of the pages. This is an example of what their sales force is currently using to bring CytoSorb® to their customers in these countries.

Slide 22:

A quick update on Biocon, the largest biopharmaceutical company in India. They were selling broad spectrum carbapenem class antibiotics to treat serious infections in the intensive care unit. We are now combining the treatment of the infection with the treatment of the massive inflammatory response with CytoSorb® to have what we believe is the most comprehensive treatment for sepsis today.

Biocon has seen significant growth in India with expansion now into Sri Lanka, and are currently funding and conducting the first investigator-initiated study in India using CytoSorb® in sepsis patients. They have also established a separate sales division to focus specifically on all aspects of CytoSorb® market development and sales. In the next couple of months, we'll be embarking on yet another key opinion leader speaker series in India where they bring key opinion leaders from throughout the world who have experience with CytoSorb® to educate and give lectures about how to use CytoSorb® best amongst their various customers in India.

Slide 23-24:

On the next slide, we are also proud to announce that we now have had more than $18 million in government support towards the development of our technology. This slide includes the potassium binding polymer contracts that we announced yesterday. We were recently awarded a total of approximately $650,000 in SBIR contracts to continue development of novel potassium binding polymers. This includes roughly $500,000 in a Phase II enhancement of our previously awarded $1.15 million U.S. Army Phase I and Phase II SBIR contract to develop polymers to treat patients with burn and traumatic injuries. Our recent awards also include a new contract from the Defense Health Agency, which is a $150,000 Phase I SBIR contract also to treat hyperkalemia.

The goal of these programs is to develop rapid treatments for severe hyperkalemia that can kill wounded war fighters and civilians suffering from severe trauma, burn injury, massive blood transfusions, kidney failure, and other conditions. These patients can often die of sudden cardiac arrest from deadly arrhythmias caused by severe hyperkalemia.

For example, on the right hand side, you can see a number of electrocardiograms (EKGs), the first strip on top is normal sinus rhythm. This is what most of us on the conference call hopefully have, in terms of a regularly beating heart. However, with the rise in potassium, you can start to see EKG changes, most notably the peaked T waves here in the second EKG. As the levels of potassium continue to rise, the cardiac rhythm can rapidly deteriorate into life-threatening ventricular tachycardia, seen in the green strip. Then ventricular fibrillation, which is the random and non-productive contraction of the ventricles of the heart, can then lead to sudden cardiac arrest and asystole, or the lack of electrical activity in the heart seen in the last EKG below, ultimately leading to the death of the patient.

This program represents a new product category for the company and takes advantage of our polymer's massive porosity and surface area and potassium binding chemistry to directly bind and remove potassium in blood. Although dialysis has been considered the definitive treatment for potassium, these polymers may actually be better suited in conditions like severe burn injury and severe trauma due to their faster kinetics, the ease of treatment, and importantly, the ability to reduce cytokines, myoglobin and other toxins that are generated during trauma and burn injury that standard hemodialysis cannot remove.

Just as the final point, there is a company called Relypsa (RLYP), a NASDAQ traded company that was just acquired by the Switzerland based Galenica for $1.5 billion, solely for its recently FDA approved orally administered potassium binding resin, Veltassa. This is a resin that was designed to treat mild to moderate hyperkalemia that is often seen in dialysis patients. It is not intended for the treatment of life-threatening severe hyperkalemia, but provides a very interesting comparable for our potassium binding polymer technology.

Slide 25:

The next slide is a pitch for you to visit our CytoSorb.com website to view the case of the week. This is a series that has had excellent feedback from both physicians and investors on the many exciting case reports presented on our website. These cases highlight the ongoing successes that clinicians continue to have as they treat earlier and more aggressively. Our goal using these reports is to broadly teach our users how and when the therapy is being used most effectively, as well as to give investors an idea of how CytoSorb® is broadly being used in the marketplace today.

Slide 26:

There are two case reports that I wanted to share with you, one is the most recent case report on the website. This case involves a 75 year old man with a history of surgery for urinary tract cancer, who developed a urinary tract infection after replacement of a ureteral stent designed to conduct urine from the kidney to outside of the body through a urostomy, as you can see depicted in the lower picture. The patient became very sick following the replacement of the catheter and was subsequently diagnosed with an E. coli infection. Despite broad spectrum antibiotics, he rapidly developed septic shock with severe hypotension and a lactate of 14.3 mmol/L indicating that his tissues were not getting enough oxygen, to the point where his body was no longer undergoing oxygen-based respiration, but was undergoing anaerobic glycolysis and producing lots of lactic acid. The hypotension required the use of multiple vasopressors, including norepinephrine and dobutamine. His kidneys also shut down, requiring the need for renal replacement therapy or dialysis.

This patient was extremely unstable and that is when the physician initiated treatment with CytoSorb® for a total of 30 hours. Treatment with CytoSorb led to a significant stabilization of the blood pressure with the weaning of dobutamine after three hours and 50% reduction of norepinephrine in 24 hours. His lactate was halved in 10 hours and returned to normal after 24 hours suggesting a restoration of adequate blood pressure and blood flow to his vital organs, as well as peripheral tissues. The patient was eventually weaned off of renal replacement therapy and mechanical ventilation within six days of CytoSorb® treatment and was transferred to a normal hospital ward two weeks after CytoSorb® treatment and went on to make a full recovery.

Slide 27:

The second case report was recently published in the Journal of Artificial Organs last month. This case report is about a previously healthy 33-year-old woman, who gave birth five months ago. This woman could have been your granddaughter, your daughter, your sister, or your niece. She presented with a four-day history of flu-like symptoms, and went to the hospital with symptoms of breathlessness, confusion, chest pain, and abdominal pain.

On ICU admission, she was diagnosed with Swine flu, or H1N1 influenza, complicated by a very severe secondary bacterial pneumonia with heavy growth of a Panton-Valentine leukocidin (PVL+) Staph aureus infection. PVL is pore-forming toxin roughly 34 kDa in size. This means the toxin is lying right in the middle of the size spectrum of substances that CytoSorb® targets. This PVL toxin is known for causing a necrotizing pneumonia, causing a rapid destruction of tissue and tissue architecture, resulting in abscess formation and cavitation of organs, with a destruction of white blood cells. This PVL positive strain is estimated to occur in about 5% of all Staph infections and is typically fatal in up to 75% of cases.

The patient presented with profound acute respiratory distress syndrome, which is one of the worst forms of lung injury. She also had severe heart failure with a very low ejection fraction, so her heart was not pumping well at all. She required high amounts of three different types of vasopressors to boost her blood pressure. She also had marked neutropenia, or very low white blood cell counts, likely due to destruction by the PVL toxin, further compromising her ability to clear the infection. She also developed a serious lactic acidosis and kidney dysfunction with the low production of urine requiring a hemodialysis-type treatment.

Despite antibiotics and despite using veno-arterial, VA ECMO, which is a way to oxygenate blood outside of the body as well as provide circulatory support to the body, the patient's condition did not improve. You can see that on the graph to the right. CytoSorb® was then added two hours after the institution of VA ECMO and continued for about 24 hours. Here you can see a very rapid reduction in the need for vasopressors, which is a surrogate indicator for improved hemodynamic stability in this patient.

The patient was completely weaned off all vasopressors within 24 hours. The investigators also added on IVIG, intravenous Immunoglobulin, as well as clindamycin as a way to try to further turn off production of this toxin while CytoSorb® was removing the toxin. Having turned the tide, she ultimately went onto recover with normal heart function and some residual lung dysfunction in a two month follow-up visit following her discharge.

Suffice it to say, I think if not for the heroic efforts of her physicians and if not for the availability of next generation, advanced products to treat sepsis, like CytoSorb®, it's probably safe to say that this woman would have died. We are very proud to have had a role in helping her survive.

Slide 28:

I'd like to conclude with our outlook for the second half of 2016. As we have said before CytoSorbents has not historically given financial guidance on quarterly results until the quarter has been completed. However, we currently expect a strong second half of 2016 with the achievement of numerous operating milestones. In addition we fully expect that the second half of 2016 CytoSorb® sales, as well as total revenue, will exceed those in the first half of 2016.

That concludes our current prepared remarks, and now I would like to open it up to a live Q&A session.

Amy?

Amy Phillips - Moderator

Thank you Dr. Chan. Operator, we are ready to poll for questions.

Operator

Thank you. As a reminder, if you do have a question, press star one on your touchtone phone. Please make sure your mute button is turned off to allow your signal to reach our equipment.

We will take our first question today from Jason Kolbert from the Maxim Group.

Please go ahead.

Gabrielle Zhou – Maxim Group (for Jason Kolbert) Congratulations on a solid quarter. We are really excited by the growth. I have couple of questions here. The first one is, what are the criteria you put in place when you sign up a distributor? How do you set the benchmark goal and how you measure the performance of a distributor? Thank you.

Phillip Chan

Hi Gabrielle. Sure, that's a good question. We seek distributors who have extensive experience in critical care sales. They also typically are required to have experience in some type of extra-corporal circulation, whether or not it be dialysis, hemofiltration, ECMO, or other types of apheresis technologies.

We are looking for committed partners that have a well-balanced and potentially synergistic product portfolio with CytoSorb®. But we also look for a manageable portfolio, where they can commit the type of attention that we would expect from them to sell CytoSorb® into the marketplace.

All of our distributor agreements come with exclusivity for their particular territories, but they also come with expectations of minimum purchases of CytoSorb® in order to maintain exclusivity. We also follow our distributors and their orders on a very regular basis to make sure that they are achieving their goals. We support them extensively with marketing materials, clinical data, reimbursement support, and other types of support, as well as training on a regular basis in order to make sure they are bringing the latest and greatest knowledge of how to use CytoSorb® best to their customers in their territories.

Gabrielle Zhou – Maxim Group (for Jason Kolbert) Okay, great. Can you walk me through what it will take to reach critical mass in Europe and at what point does the use of CytoSorb® become a routine modality? How many KOLs need to adopt the product before it can become a mainstream product in the marketplace? Does it make sense for us to be tracking KOL adoption at this point?

Phillip Chan

We used to use KOL adoption as a benchmark for interest in CytoSorb®. But as of more than a year or two ago we stopped doing that, because the number of KOLs had become too numerous for us to keep track of, as the awareness of CytoSorb® has expanded throughout the market. There are just so many people thinking about how to use CytoSorb® in clinical usage that we can't keep track of them all. There are literally thousands of intensivists throughout the European Union and throughout the world that could use CytoSorb®. We are more focused on following adoption by key department or hospital accounts in our direct sales territories of Germany, Austria, and Switzerland. And through distributor sales and reports, we also estimate the activity in other countries.

In terms of becoming standard-of-care, clearly that is our goal. I'm pleased to say that there are a number of hospitals, particularly in our direct territories, that have already adopted CytoSorb® as a de facto standard-of-care for the treatment of a number of different illnesses. This has been based upon the successes they have already seen amongst many such patients in their hospitals. This has occurred even before having large scale randomized controlled studies. They've seen it work in their own hands, and I think that is ultimately what has been the most convincing in terms of adopting CytoSorb® as standard of care for these applications. These include many of the major university hospitals and public hospitals in Germany and we expect that number will continue to grow in the future.

Gabrielle Zhou – Maxim Group (for Jason Kolbert)

Great. So can we now switch gear to the U.S. trial? What are the next regulatory steps for you to move forward the REFRESH trial?

Phillip Chan

We are looking to do a soft lock on our database after the last patient is enrolled and we expect the last patient to enroll within the next couple of weeks. We anticipate an analysis of these data and announcement of top-line data, as I mentioned, at the EACTS Conference at the beginning of October. We also plan to complete a much more extensive analysis of the data and if everything is as we expect, are looking to meet with the FDA, most likely in the fourth quarter of this year, with the goal of finalizing the path for the REFRESH II registration trial. As I mentioned previously, I think the FDA is waiting for our data from this REFRESH I safety and feasibility study before opining upon the exact path for regulatory approval. It could be de novo 510(k) path as a free hemoglobin filter, for example, or it could be the traditional PMA path - which we expect to be the default pathway - in a larger trial of roughly 300 to 400 patients. In

such a trial, we would be looking at clinical outcomes such as the need for vasopressors, days in the intensive care unit, and time on the ventilator, as endpoints for that registration trial.

Gabrielle Zhou (for Jason Kolbert)
Okay, great. Thank you, Phil. Again congratulations.

Phillip Chan
Thank you very much, Gabrielle.

Operator
We'll take our next question from Sean Lee with HC Wainwright.

Sean Lee – HC Wainwright
Hi Phil and Kathy. Congratulations on the strong quarter and thank you for taking my questions. How is manufacturing capacity handling the increase in demand from your distributors? Do you expect to be supply constrained at any time in the near-term?

Phillip Chan
Yes, I can certainly let Vince talk to that point, but currently we believe that we have enough capacity, particularly with improvements in manufacturing that we've had recently, to be able to supply demand for the next one to two years. Maybe Vince you like to give a little bit more color.

Vincent Capponi
Sure. Hi, Sean. Basically as Phil mentioned we are continuing to do a number of operational improvements at this end to increase the capacity that we have in the current location and believe that we have adequate capacity to meet demand over the next one to two years. We also have obviously put in contingency plans, that should the volume increase significantly, how to essentially duplicate what we have here in another location to double the capacity, for instance. But I think it's safe to say for the next one to two years, we have enough capacity.

Sean Lee
Great to hear. Second question is on the recently launched distributors. Which ones are contributing already to the second quarter number and which ones do we expect to come online during third quarter, or will we see their impact in the next quarter's numbers?

Phillip Chan
Kathy, did you want to take that?

Kathleen Bloch
Yes, sure. As we mentioned, we are in 37 countries and if we just look at our slide of our country distribution, we currently have 28 contributing to revenue. That doesn't mean that they

necessarily all contributed to Q2 revenue, but most of them have contributed to revenue through June 30, 2016.

Sean Lee
I see. Thank you for the clarity. That's all I have.

Phillip Chan
Thanks, Sean.

Operator
Nextwe'll go next to Andrew D'Silva with Merriman Capital.

Andrew D'Silva
Good afternoon guys. Thanks for taking my call. Just a couple of quick questions. First off could you elaborate on whether there were any large stocking orders during the quarter that could have distorted the Q2 results or were they fairly in-line with previous quarters from a stocking standpoint?

Phillip Chan
Yes, it was fairly in-line from previous quarters from a stocking standpoint. We believe that the growth in Q2 was fairly organic in nature and expect that trend to continue going forward.

Andrew D'Silva
Thank you for that and as far as initiatives go, how often are you getting updates from the sales team at Fresenius? Do you feel like they are up to speed on the product? And is their willingness to up-sell there charting with your expectations right now?

Phillip Chan
Sure. So why don't I turn it over to Chris Cramer our VP of Business Development who has worked very closely with Stefan Baudis, our International Sales Director, on these particular accounts. Chris, would you like to give some color on that?

Chris Cramer
Sure, thanks. I think to your first question we stay in very first close contact with all of our partners and distributors. We typically meet with them or talk to them on the phone at least once every two weeks. For Fresenius in particular, as Phil has mentioned, the focus for them has really been on selling activities across all countries. Today they're actively promoting CytoSorb® throughout their territories.

Just to give you a sense of some of the success stories they've had. I can give you a few examples. For example, in Finland they've recently conducted what they call "Scandinavian ICU Days" where they bring physicians from all across Scandinavia to talk about new therapies. And

CytoSorb® was a key focus there. Subsequent to that, they had four centers that were trained on CytoSorb® and they had their first patient treated in early July. The patient had gram negative E. coli sepsis and the feedback from the doctors there was that they were very satisfied and impressed with how quickly the treatment helps. Obviously that was a very positive result and we're hoping to get a case report back from that treatment.

Then in Poland, which you may recall was one of the first FMC countries to record CytoSorb® sales, they've been off to a fast start there. Recently they've offered CytoSorb® in a tender and so we're hoping to hear more about that soon. I hope that helps to bring some color to some of the activity going on with FMC. We're hoping to have more of these kind of success stories to relay in future calls.

Andrew D'Silva
So basically you guys are fairly happy with the way things are charting right now with Fresenius? It's on target with your expectations?

Phillip Chan
Yes absolutely. I think that we've seen a tremendous amount of commitment and resources from them going towards the launch of this product and we have full confidence in their team and their ultimate success in these countries. As Chris mentioned we have been in contact with them very frequently during and after the launch. I think Chris was talking with them much more frequently than once every couple of weeks. They participated in our sales and distributor trainings, they participated in our User's meeting, and have done a nice job in putting together the marketing strategy and sales push behind CytoSorb®.

Andrew D'Silva
Got it, great, well thank you for answering my questions and good luck for the rest of the year.

Phillip Chan
Sure Andy, thanks very much.

Operator
We'll take our next question from Brian Marckx with Zacks Investment Research.

Brian Marckx
Hi guys, nice quarter. Kathy, a couple of questions for you. Product margin as you mentioned was up quite a bit. You mentioned that the product mix had something to do with that. Can you address that? Then with the additional territories coming on that are obviously distributors, does that affect gross margin at all?

Kathleen Bloch

Yes, thanks Brian. In terms of product mix, a larger percentage of our sales for this quarter were from direct sales, positively impacting our gross margin. The sales mix happened to be this way in the quarter, but it is not necessarily indicative of what we expect to see in the future. The mix really depends on a number of factors, many of which we cannot predict. We expect that there may come a time when lower margin distributor sales may exceed direct sales, which may result in lower blended gross margins. However, right now, direct sales are very strong, which we expect to continue for the foreseeable future. Regardless of the sales mix, we continue to improve our manufacturing operations to try to reduce our cost per device. In fact, this year we have been able to reduce our standard cost by about 10% to 15% compared to last year, and we expect to achieve continued cost reductions, helping to boost our blended gross margins over time.

Phillip Chan

Thanks Kathy. And maybe to give a little bit more color. We continue to drive costs out of our low volume manufacturing -- a positive as we continue to manufacture out of our current facility. As we gain volume, and as we look to move to a larger plant, we expect to significantly benefit from economies of scale and continued manufacturing efficiencies.

Although the blended product gross margin for this quarter was a healthy 68%, we believe that over time, based on a variety of different factors, there is no reason we cannot drive direct gross margins to greater than 80% and the blended gross margin significantly higher than where it is today.

Brian Marckx

Got you. Okay, that makes sense. In terms of the revenue growth, is it possible to quantify how much of the recent growth is coming from reorders, which is probably most of your direct sales anyway, versus the new territories that came online or new accounts in general?

Phillip Chan

Kathy, would you like to comment?

Kathleen Bloch

Yes, Brian, in any given quarter the vast majority of our sales are coming from repeat orders or reorders from existing hospitals or distributors.

Brian Marckx

Okay, alright. Then would it be fair to say that you expect to see a greater contribution by new accounts, new territories, distributors and partners going forward?

Phillip Chan

Yes, I think that's within the realm of possibility. Right now, we are seeing strong momentum of direct sales, partially because we started selling direct a full year or more ahead of our first

distributors and partners. We expect to see a similar pattern of sales momentum with our indirect sales as well over time. But for now we expect direct sales to continue to be a major contributor of our revenue going forward.

Brian Marckx

Okay. So if we can talk about REFRESH just a little bit. It sounds like you are targeting 44 total patients for a 40 patient clinical set. Does that mean that you have 36 that are enrolled right now? Or is there may be a patient cushion or two there?

Phillip Chan

No. In fact, we have enrolled above the 40 patient target. We now have enrolled 44 patients total into the REFRESH I trial. We have the ability to go up to approximately 52 or so patients in the study. Let me explain that for a minute, because it may be unclear. For example, when patients are enrolled into the study, they are enrolled based on the expectation that they will complete the study, but also based on the estimation of the surgeon on how long the patient will be on cardiopulmonary bypass – a key inclusion criteria for our trial. They typically make this estimation based upon the expected complexity of the cardiac surgery procedure. In our trial, we have specified that patients should be on cardiopulmonary bypass for longer than three hours with a minimum amount of time on cardiopulmonary bypass required. Sometimes the surgery goes extremely smoothly and the operation is shorter than expected, and patients don't achieve that minimum time required on cardiopulmonary bypass. That's just one example of why a patient would potentially not complete all aspects of the study. So there are factors like this that happen all the time in trials, which is one of the reasons why we are over-enrolling in order to account for those patients that won't meet the full criteria of the study.

Brian Marckx

Okay. I think you said that you expect to be fully enrolled in the next few weeks. It sounds like there has been a little bit of a delay relative to the initial expectations. Can you explain what has happened?

Phillip Chan

I don't think there was any delay. We had previously guided that we expected to finish trial enrollment by mid-year. And I think that we're on pace to do that. I think our goal is to try to get the data ready to announce by the EACTS Conference in early October. That is our interim goal.

When you have a study with multiple sites, people from the outside expect that you will start off with all of the centers right away. Practically speaking, that doesn't happen for a number of reasons. For example, contract negotiations between a clinical site and the sponsor in any study are always complicated, and that takes time. Then again, our last study center to begin the trial has done very well, and is now one of the top enrollers in the study. Sometimes things work in your favor and turn around very quickly.

Brian Marckx
So kind of more administrative stuff rather than anything really fundamental to the actual design of the trial, or anything related to that, is that fair to say?

Phillip Chan
Yes, that is fair to say. I think that we expect that fully-staffed and with all the clinical sites onboard, this kind of study can enroll extremely quickly. The patient population is there. We are not dealing with a small subset of patients. We are dealing with patients undergoing complex cardiac surgery procedures that amounts to 20-25% of all of the cardiac surgeries that are occurring every year in the United States, or approximately 100,000 to 125,000 complex cardiac surgery procedures.

Brian Marckx
Okay, great. Thanks a lot, I appreciate it guys.

Phillip Chan
Sure. Thanks, Brian.

Operator
We'll now take our next question from Jonathan Aschoff with Brean Capital.

Jonathan Aschoff
Hi, guys. Congratulations on the strong quarter. I was wondering what are your top, let's say five or so, distributor countries for sales to-date? Can you give us that?

Phillip Chan
We haven't disclosed that information to date, Jonathan and I apologize. But I think that when you look at our territories, the ones that started first are typically the ones that are the strongest because they have had more time in the marketplace to gain market awareness of the product and to gain customer support, usage, and other things. We do see that time plays a very important factor in productivity.

Jonathan Aschoff
Okay. More so than the size of the market in that country, at least now, correct?

Phillip Chan
At least now, but I think that we have very large expectations for countries like India and Russia which is a big believer in blood purification, for example. Even Vietnam has started recently but is another territory that has a lot promise, as do the Middle East countries, and others. So it is a combination of both.

Jonathan Aschoff

Okay. Just to be clear, there wasn't some large initial shipment to Fresenius that was a factor in the strong second quarter? Is that true there was or there wasn't?

Phillip Chan
There was not. Fresenius had bought ahead of the launch as you would expect them to do but we do expect them to be contributors in the quarters coming up.

Jonathan Aschoff
Okay. So clearly the better margins are driven by direct sales in second quarter?

Phillip Chan
That is correct.

Jonathan Aschoff
How could REFRESH succeed in and of itself, yet not be helpful in proceeding to a pivotal trial, at least in the eyes of the regulators?

Phillip Chan
It's interesting. The randomized controlled studies that are ongoing or that have completed in Europe including for example, the one in Medical University of Vienna, the University of Hamburg-Eppendorf, as well as the one at University of Cologne…those trials have focused predominantly on the mild to moderate risk cardiac surgery patients, by necessity. I think their ethics committees wanted to first establish safety and feasibility in a lower risk patient population using a new product in cardiac surgery.

REFRESH I is the first randomized controlled study looking at the use of CytoSorb® in this high risk cardiac surgery patient population, where the adverse event rate is high. For example, the incidence of acute kidney injury is expected to be in the 30% percent range. In this patient population, the incidence of other adverse events such as post-operative circulatory collapse, respiratory failure, and others are also quite high. In May, the Data Safety Monitoring Board concluded that there were no safety issues in the first 24 patients. This was reassuring as safety is one of the primary endpoints of this trial.

If REFRESH I shows that intra-operative use of CytoSorb® is safe, then we expect that it will encourage clinicians throughout the world to use CytoSorb® in their complex cardiac surgery patients where CytoSorb® is expected to have the most profound benefit. I would point out that today, there have been more than 2,500 open heart surgeries in Europe where CytoSorb® has been used safely during surgery, and that many of these cases have involved complex cardiac surgery. So the safety data from REFRESH I will be very important.

Now in the area of free hemoglobin reduction, this study was never designed to look at statistically significant reductions in free hemoglobin. That is what a pivotal study, potentially

the de novo 510(k) study, is intended to show. In our discussions with the FDA, we believe that their interest in free hemoglobin stems from the fact that they want confirm that based on the specific patient population that we have defined by the inclusion and exclusion criteria of the trial, that these patients are having a problem with high levels of free hemoglobin after all the data are analyzed. This is expected to provide an important data point for the FDA to determine which path to guide us down for REFRESH II: either a de novo 510(k) or a PMA. There has never been a technology that could remove free hemoglobin in real time from circulating blood before and we hope to validate high levels of free hemoglobin in this patient population.

So we believe the FDA is primarily looking at safety, but they are also looking at this free hemoglobin endpoint to make sure that we're not barking up the wrong tree and we're not doing a futile trial.

Jonathan Aschoff
Okay, thank you Phil.

Phillip Chan
Sure.

Operator
We'll now take a question from Steve Brozak with WBB Securities.

Ahmad Samad (for Steve Brozak)
Yes, hello this is Ahmad Samad on for Steve Brozak. How are you all doing?

Phillip Chan
Good Ahmad, how are you?

Ahmad Samad (for Steve Brozak)
Good. Just have a couple of quick questions, regarding your FMC partnerships, to what degree did your direct sales experience help inform their launch process there?

Phillip Chan
Fresenius has known about our technology for many, many years and has been following along with our commercial progress in Germany. As you know, Fresenius is based out of Germany. Their people have been watching how CytoSorb® has been rolling out. Obviously, they have key contacts with most of the major key opinion leaders throughout Germany and they've been hearing how CytoSorb® has been doing. I think that has contributed to the establishment of this partnership and contributed to their expectations of what CytoSorb® could do in their hands, in their countries.

But we clearly have not been leaving things to chance. Our goal is to make sure that we do whatever we need to do to ensure that they are successful. There has been an ongoing dialog and an ongoing transfer of information with our team and theirs to ensure they have what they need to be successful. This is also not the first time their sales people have heard about cytokine reduction to treat critical illnesses. Fresenius has a product called Ultraflux EMiC2, which is a high molecular weight cut off filter that they had introduced a number of years ago as a technology to try to remove cytokines. This is a very similar technology to SepteX by Gambro, but we have not seen SepteX much anymore in the critical care space, likely because, we believe, it was not felt to be effective. I think the Fresenius partnership with us is a nod to our technology as a potentially superior technology.

Ahmad Samad (for Steve Brozak)

Okay, thank you for that. I'm going to go back to something that was stated earlier in the presentation. You mentioned that Fresenius was in attendance at the last CytoSorb Users conference that you had. Can you tell us a little bit about the Users conference, because the success of the buy in and the roll out to Fresenius' customers is going to contingent upon feedback from users and physicians? So it would be interesting to hear about the conference that you guys just hosted. Then any discussions you've had with FMC on how to expand the conference? Or how they can contribute or help to promote the conference in more detail?

Phillip Chan

Sure, we held our third International CytoSorb® Users Meeting in Brussels at the ISICEM (International Symposium of Intensive Care and Emergency Medicine) Conference in March earlier this year. That was a third Users meeting in roughly a year and half. This particular conference brought in approximately 107 people from 23 countries from around the world to discuss their experiences with CytoSorb® and to share information on how best to treat. Fresenius sent 18 representatives to that conference. As a working conference, there is a lot of open discussion and presentations of data. I think Fresenius' people got a good feel on how CytoSorb® is being used today.

Only a fraction of the more than 14,000 human treatments that have now been performed with CytoSorb® were presented at this Users meeting. There is always more to learn, more to teach. I think we expect Fresenius to be active participants going forward in those conferences. However, what I would also note is that we have been participants at their conferences in critical care meetings as well. For example, at their invitation, our key opinion leaders and our people have been present there, and have been participants in their booth with our device to help support their marketing efforts. To date, there has been a good give and take between Fresenius and CytoSorbents. We expect that to continue.

Ahmad Samad (for Steve Brozak)

Okay. Well, thank you for taking my call.

Phillip Chan
Sure. Absolutely. Thank you.

Operator
At this time, I'd like to turn it back to management for any additional or closing remarks.

Phillip Chan
Thank you very much everyone for taking the time today to get on the call. We certainly appreciate your participation. If you do have any other questions, as usual please feel free to reach out to Amy Vogel at avogel@cytosorbents.com and we will try to get answers to your questions where possible. Thank you very much everyone, and have a good evening. Good night.

Operator
Thank you. That concludes our conference for today. I would like to thank everyone for their participation. Have a lovely evening.