
CytoSorbents™

Working to Save Lives Through Blood Purification

# CytoSorbents Corporation (NASDAQ CM: CTSO)
# Q1 2015 Earnings and Operating Results Conference Call
# May 11, 2015 @ 4:15 pm Eastern

*This official company transcript has been edited for clarity and does not differ materially 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 First Quarter 2015 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, Lee Roth. Please go ahead.

**Lee Roth – Moderator:**

Thank you, Vicky and good afternoon. Welcome to CytoSorbents First Quarter 2015 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
- Dr. Christian Steiner, VP of Sales and Marketing from Germany, and
- Chris Cramer, VP of Business Development

Before I turn the call over to Dr. Chan, I'd like to remind listeners that during the call, management's prepared remarks may contain forward-looking statements which are subject to risks and uncertainties. Management may make additional forward-looking statements in response to your questions today. Therefore, the Company claims protection under Safe Harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. Actual results may differ from results discussed today and therefore, we refer you to a more detailed discussion of these risks and uncertainties in the Company's filings with the SEC. Any projections as to the Company's future performance represented by management include estimates today as of May 11, 2015 and we assume no obligation to update these projections in the future as market conditions change.

During today's call, we will have an overview presentation covering the financial and operating highlights for the 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, Lee, and thank you everyone for joining the call today. It's a pleasure to be here and welcome. For today's call and for the benefit of new shareholders and prospective investors, I will first start with a brief introduction of our company, then Kathy will go over financial results for the quarter and then we will discuss the factors that we believe will drive our growth in 2015. Then we will open the call up to a live Q&A period. An official transcript of today's call will be available in the next few days on our website at www.cytosorbents.com.

**Slide 4:** CytoSorbents is an emerging leader in critical care immunotherapy. We are leading the prevention or treatment of life-threatening inflammation in the ICU using CytoSorb blood purification.

**Slide 5:** What we are targeting is a $20 billion opportunity in critical care. Every year millions of people are admitted to the intensive care unit in hospitals around the world for deadly inflammatory conditions such sepsis, severe lung injury, burn injury, trauma, pancreatitis, influenza, complications of surgery, particularly cardiac surgery and many others.

And in these conditions, massive inflammation is often driven by a cytokine storm that causes cell death and organ failure. Nearly half of all deaths in the ICU are due to organ failure with no effective therapies. Because of the lack of effective therapies, approximately one out of every three patient dies and the cost can be staggering.

The lack of active therapies leads to patients lingering days to weeks at a time at a cost of $2,000 to $3,000 a day on average in the intensive care unit and it's not surprising that we spend nearly 1% of our gross domestic product, or $80 billion to $90 billion, on critical care medicine every year here in United States.

**Slide 6:** CytoSorb removes the fuel to the fire of inflammation and represents a powerful immunotherapy approach to control inflammation. It is approved in the European Union as the only specifically approved extracorporeal cytokine adsorber and is clinically proven to remove key cytokines in the blood of critically-ill patients. It is approved for any situation where cytokines are elevated. It has now been used in more than 5,500 human treatments safely and has been well-tolerated by patients.

**Slide 7:** The heart of our technology is a highly porous, very biocompatible polymer bead, roughly the size of a grain of salt, which acts like a tiny sponge to remove harmful substances from blood. This is a technology that is protected by 32 issued U.S. patents and multiple applications pending. We manufacture these beads from raw chemicals at our ISO 13485

certified facility in New Jersey. And it is one of the highest grade medical sorbents on the medical device market today.

**Slide 8:** The goal of our therapy is to prevent or treat organ failure, one of the biggest unmet medical needs in medicine today. Rather than let patients spiral down into this black hole of organ failure, where at the bottom we need to support them with life-support machines like mechanical ventilation and dialysis, we take a very different approach. Our goal is instead to treat unstable patients when they first come into the ICU, stabilize these patients, prevent them from developing organ failure, and get them out of the ICU faster, thereby helping improve their chances of survival, as well as significantly decreasing the cost of ICU and patient care. And because of this, we believe that CytoSorb is well-positioned to revolutionize critical care medicine.

**Slide 9:** Just to highlight how CytoSorb is being used currently, this is a recent case report study on drug-resistant pneumonia. This is a 46-year-old man who was hospitalized initially with fatigue, cough and breathing difficulty to a small hospital in northern Germany. He was subsequently diagnosed with pneumonia and severe sepsis, and was placed on broad-spectrum antibiotics. His blood cultures eventually grew out multi-drug resistant Acinetobacter baumannii. This is a bacteria that is often the cause of infection of many soldiers in the Gulf region and this is a very difficult bacteria to treat. This patient developed complications of rhabdomyolysis, a destruction of his muscle tissue that led to the release of myoglobin, which then led to kidney failure, and no urine output. This is a very dangerous situation particularly for someone with sepsis. In the meantime, he rapidly developed acute respiratory distress syndrome requiring mechanical ventilation, and his sputum grew out both Staph aureus, as well as Strep pyogenes, the cause of strep throat. And despite aggressive management with five days of dialysis, the patient had little improvement in myoglobin levels and little improvement in kidney function, and was transferred to a major outside hospital. Within the first day he underwent his first CytoSorb treatment, which reduced his plasma levels of myoglobin by 50% and after three treatments his organ failure had stabilized, his myoglobin levels were significantly reduced and very importantly, his renal function and urine production returned. So this was really a case where the kidneys were so overburdened by this myoglobin that they shut down. By removing myoglobin with CytoSorb, we were actually able to improve kidney function and this, we believe, helped the patient go on to survive. Eventually control of the infection was also achieved and the patient was discharged from the ICU on day ten. We talk about these case reports because they highlight how CytoSorb is being used in real-world activities every single day around the world and these positive outcomes motivate us greatly.

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

**Kathleen Bloch - CFO:**

Well, thank you, Phil, and good afternoon, everyone.

**Slide 10:** For today's call I will be providing an update regarding CytoSorbents' first quarter 2015 financial results, including product sales, as well as an update around our working capital and cash runway.

**Slide 11:** Turning to our financial results, the first quarter of 2015 product sales were approximately $704,000, which is a 24% increase over first quarter 2014 product sales of approximately $569,000. One factor negatively influencing first quarter product sales was the drop in the euro relative to the dollar. In the first quarter of 2015, the value of the euro averaged $1.13 as compared to the first quarter of 2014, when the euro value averaged $1.38. And this decrease in the value of the euro effectively reduced our first quarter 2015 sales by approximately $112,000 or 16% of total product sales. Grant income was insignificant for the first quarter of 2015 at approximately $19,000 as we are winding down several major grants. And then finally, we want to note that we were able to achieve growth product profit margins of approximately 59% in the first quarter of 2015 as compared to 61% for the first quarter of 2014, this despite the drop in the euro.

**Slide 12:** Next, we'll turn to our chart of products sales by quarter, which shows the decrease in sales in Q4 2014 and then again in Q1 2015. And this decrease in Q1 2015 sales is really attributable to three factors. The first is the decline in the value of the euro which I've just discussed. The second is the fact that there are no initial orders from new distributors in the first quarter of 2015, which is simply a matter of the timing of bringing new distributors on board. And third, it's the impact of the restructuring and rebuilding of the sales force. So given these three factors and looking forward to the future, there's really nothing we can do about the movement of the euro relative to the dollar. Although we do note that it has stabilized and it hasn't declined further from Q1. Regarding the second factor, we are in active discussions with new distributors with the intention of opening up new territories. And we continue to work with many of our existing distributors to attain regulatory approval, or reimbursement in our territories at which time we will see initial orders from these territories. In fact, of the 34 countries, in which we currently have distributors and/or strategic partners, we do not yet have approval to sell CytoSorb in a majority of these countries. When these countries obtain the necessary approvals, they will also contribute to increased sales. And third, as Phil will explain in some more detail later, the rebuilding of our sales force, we may have sacrificed some short term results but we believe this rebuilding will provide long-term benefits to our revenue stream and the effort is well underway already. So we've often advised our shareholders that quarterly results can be lumpy at these early stages of commercialization but that the overall trajectory remains strong.

**Slide 13:** So speaking of the overall trajectory, on the next slide, we'll take a look at our trailing 12 months of product sales. And while Q1 2015 is not increasing at a rate as great as the previous three measurement points, you can see from the trend line that the overall growth in sales is expected to remain strong going into the future.

**Slide 14:** And then finally, some notes on our working capital position and cash runway. In January of 2015, we completed a $10.3 million common stock offering, providing net proceeds to the company of $9.4 million and with these funds in hand as of March 31, 2015, we have approximately $13.4 million in cash and short-term investments. Our working capital excluding the warrant liability which is a non-cash item was approximately $13.7 million at the end of March. We believe we have adequate funding to meet our objectives into 2016. And turning to our capital structure, I just want to mention that on a fully diluted basis, we currently have 28.4 million common shares outstanding.

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

**Phillip Chan - CEO:**

Thanks very much Kathy.

**Slide 16:** Right now, I'd like to cover our catalysts for growth. As we've talked about in the past, one of the major catalysts is our core focus on CytoSorb sales. These are six of the important factors that will hopefully lead to our success in the marketplace. One is that we are working with major key opinion leaders worldwide. We've been fortunate to have the support and leadership of many key opinion leaders not just in our direct territories of Germany, Austria and Switzerland, but also in many countries around the world that are supporting the use of CytoSorb. This is very important because we look to not only sell to the key opinion leader, which is typically the head of the department, but also to get junior and senior physicians who are in the department to use the therapy. This could have a dramatic impact on our growth rate going forward. If you look at this picture here and just take the first six doctors sitting in the front row. If each one used CytoSorb on just one patient every week, that would result in a revenue opportunity for this ICU alone of approximately $1 million to $1.5 million. Now, when coupled with the fact that there are many ICUs in the hospital, not just a medical ICU but a surgical ICU, a cardiac ICU, a trauma ICU and others, the revenue opportunity here becomes very significant. Now to us, $1.5 million sounds like a lot of money, but when you think about what the operating budgets are for these hospitals, they are often hundreds of millions of dollars to more than a $1 billion every year with critical care accounting for anywhere from 10% to 20% of their operating budget. That could be tens to hundreds of millions of dollars and the amount of money that they would be spending here is really a drop in the bucket. But when we talk about the value-add that our therapy could have, it is really a win-win-win situation for hospitals, patients, and our company. Clearly, gaining these revenues would be great for our company. But importantly, our therapy is designed to try to improve the clinical outcomes of patients, decreasing the risk of death and improving their clinical outcomes. That would be a major win for patients. The third major win, of course is that we could potentially reduce the massive costs of healthcare by shaving days off of ICU stays, decreasing the acuity and severity of illness, etc.

In order to become standard of care in this field, we need data. And this is exactly what we've been going after. We now have 50 or more company-sponsored and post-market studies planned or enrolling where we are actively investigating the use of CytoSorb in many different applications. We believe that data coming from these studies will help support CytoSorb as standard of care medicine in these ICUs around the world. We will also talk about our direct sales team and about the importance of having the right people on board and the last part of the puzzle is reimbursement and the expansion of the distributor network. And we'll talk a little bit more about that in just a minute.

**Slide 17:** We believe that all of these factors will provide a multiplying effect on sales in the 2015 period and beyond.

**Slide 18:** This is a picture of our current direct sales infrastructure in Germany. This is led by Dr. Christian Steiner, our Vice President of Sales and Marketing, who is also Managing Director along with me, of our CytoSorbents Europe GmbH operating subsidiary. And here you see the people that we have here. We spend a great deal of time trying to select and cultivate the people in our company and try to ensure that we have the best people trying to sell CytoSorb in

the marketplace. This is our International Sales Director, Stefan Baudis. Our Business Export Manager is Alex Bojan. Our European Medical Director is Dr. Joerg Scheier, who many of you have heard about in our recent press release. Head of Scientific Marketing is Dr. Rainer Kosanke. Head of Product Management is Dominik Gutzler. Our Application Specialist is Eva Weschler. Our Sales Assistant and Customer Support people are Ilona Otto and Petra Hoffman. And on the right-hand side are our sales people. As you can see here, we have four existing sales people that are in the marketplace today. We've made significant progress in terms of rebuilding our sales force. We now have signed two sales people. Both of them will start in early Q3. One of them will cover Northeast Germany and the other one will cover Northwest Germany. We are currently now screening for two additional representatives, as well as a medical science liaison, that will help our sales people out there in the marketplace. I think it's very important to note that we've gone a tremendous way in terms of rebuilding our sales force and we think that the addition of the people that we just added will add significantly to our growth starting in the third quarter and going forward.

**Slide 19:** Now in terms of our progress on registration. We are actively selling the product in the EU in Germany, Italy, the UK, Austria, Switzerland, Romania, the Netherlands, as well as outside the EU in countries like Turkey and India. And I am pleased to say that we are now registered in France, the second largest medical device market in the European Union, which paves the way for both Fresenius as well as our cardiac surgery partner to begin sales in France. We are currently registered in Saudi Arabia and we're waiting for Saudi FDA approval that can hopefully be leveraged rapidly across all seven countries around the Gulf Cooperation Council nations including the UAE, Kuwait, Qatar and others. We are also registered in Australia through the Therapeutic Goods Administration, and including New Zealand, are now in the final stages of negotiations with our distribution partner there. We are also in the final stages of registration in Russia and we expect that to occur in Q1 2016, if not sooner. We've also met the requirements to add Canadian registration to our ISO 13485 certification and this will allow CytoSorb to be registered in Canada once all Health Canada requirements have been met. Last but not least we continue to work on establishing distribution in many other countries around the world and we will hopefully have more to announce on that in the months to come.

**Slide 20:** But I think all of these things that we've talked about really get to this graph on slide 20. Our growth is basically being driven by three major drivers: direct sales, distributor sales, and partner sales. And what you can see here in this graph is the theoretical revenue growth based on layering of all of these different stakeholders. Direct sales in Germany, Austria and Switzerland is the very bottom component, followed by current distributors, followed by our three partners, then followed by the Middle East, Australia, Asia, North America, South America, as well as Africa. Some of these inflections take into account the development of clinical data that may help accelerate the adoption and usage of CytoSorb in these various markets. But I think what you can see here is that a lot of these things have been put into place already, and are expected to turn on either in 2015 or 2016. I think this has the potential to dramatically increase our sales growth for the company. Just to note, this graph does not represent revenue guidance or forecasts, but is meant to demonstrate the concept of this revenue layering concept and how we anticipate to grow our sales moving forward.

**Slide 21:** A second major catalyst is targeting U.S. FDA approval which we've talked about this in the past. In terms of cardiac surgery, we are pursuing the REFRESH cardiac surgery trial here in the United States where we are looking to reduce a number of inflammatory mediators

during surgery in order to try to prevent postoperative complications. And on the sepsis side and on the critical illness side, where most of our sales are being generated today, we are looking to develop the pivotal studies designed to make CytoSorb a standard of care in these various applications.

**Slide 22:** Now an update on the REFRESH study. As we had mentioned last time, the FDA has approved our IDE for our REFRESH feasibility study in cardiac surgery. This trial is a 20-patient multicenter feasibility study evaluating the safety of CytoSorb when used intra-operatively in a bypass circuit in a heart-lung machine during complex cardiac surgery. The goal is to try to reduce levels of free hemoglobin and other inflammatory mediators that, if left unabated, can cause post-operative complications such as kidney failure and a failure to wean from the ventilator. The trial is on target to commence mid-year and is expected to be completed before year-end. It's very important to note that this is a much different trial than a critical care trial. The only intervention is using CytoSorb in a bypass circuit during the three to five hours of the cardiac surgery. It's one and done. After the surgery, all that is required of the study nurse and the clinical team is to take blood draws every day and to evaluate the patient clinically, until the patient leaves the intensive care unit. This is a study that can be done very rapidly and is the reason why we have more than 300 intra-operative cardiac surgery treatments already in Germany and in Austria. And so, we believe that we can complete this trial very expeditiously. Following discussions with the FDA, we plan to file a pivotal trial IDE shortly thereafter, to support U.S. regulatory approval.

**Slide 23:** Switching gears slightly to critical illnesses and sepsis. One of the things I wanted to discuss today is the Expedited Access Pathway. I mentioned this in our shareholder letter, but it was something that I thought we should cover on the call today and answer questions if needed. The FDA has issued formal guidance on the Expedited Access Pathway, or EAP, program that will facilitate the approval of medical devices that treat life-threatening conditions that meet the following criteria: One is that you have to have a technology that treats a life-threatening or irreversibly debilitating disease. That is something that we do. The second is that there are no approved alternative treatments that exist for that particular disease. This we also meet, given that there are no approved treatments for most of the diseases that we treat in the ICU today. And third, the sponsor, which would be us, needs to submit an acceptable data development plan that would outline the pre-market and post-market data collection that would be needed to get this product approved early. This is a very relevant program to us because CytoSorb targets the treatment of many life-threatening conditions such as sepsis, acute respiratory distress syndrome, severe acute pancreatitis, trauma and many others that do not have viable treatment alternatives.

**Slide 24:** Our first step is to submit an application to the FDA to request EAP designation, and if it is successful, it has a number of advantages. First of all, CytoSorb would be given priority status and we would be assigned a manager from the FDA who would facilitate all of our future discussions with the FDA. We'd essentially be on a fast-track with the FDA. The designation is good for both the Pre-Market Approval (PMA) and De Novo 510(k) regulatory approval paths for medical devices. And importantly, based on associated guidance from the FDA, it would shift the pre-market data collection to the post-market setting with the appropriate safeguards for safety. What does that mean? Right now if CytoSorb was going to be entered into a clinical trial for the treatment of sepsis, the de facto primary endpoint would be 28-day all-cause mortality. But this is a very difficult endpoint for most companies to meet, which is why there are no

approved therapies for sepsis. All companies and their technologies have failed to demonstrate 28-day all-cause mortality. We believe that we can ultimately show 28-day mortality. But to make that a requisite for approval, it could potentially be a very high bar, making a trial very expensive to conduct with many, many patients. If the FDA would allow us to do an approval trial with a less stringent endpoint, that could allow the trial to be much smaller. It would allow us to potentially have less risk in achieving the endpoint, and would potentially allow us to get to market faster, and expedite our therapy to help patients in need. We would be required, however, to demonstrate a benefit on 28-day all-cause mortality in the post-market period to stay in the marketplace. But that is a trade-off that we are more than willing to accept. So once we submit for EAP designation, it is a 30-day review of the application and then we hope to hear back from the FDA about having CytoSorb labeled as an EAP designated product. That is the same as having a biologic or a drug designated with "breakthrough" status. It does not mean approval but it now puts us on the fast track so that we can do a clinical trial that will enable us to get approval more quickly. Again this program is designed to facilitate earlier and faster U.S. regulatory approval of potentially life-saving devices. We believe this squarely applies to the core of our critical care strategy at CytoSorbents. And as we move forward with our cardiac surgery trial, we plan to pursue this EAP opportunity aggressively for critical care applications and foster open discussion and collaboration with the FDA.

**Slide 25:** A third major catalyst is a generation of clinical data. With the funds that we've raised in the past 12 months, we are not only looking to get into the U.S. market for cardiac surgery, but we are also looking to support our number one application for the company which is sepsis. We plan to launch a number of company-sponsored sepsis studies both here in the United States as well as in Europe in addition to the large number of other studies that we are either conducting or helping to supervise or support. In the United States, we are running our cardiac surgery REFRESH trial that is hopefully the first step to U.S. approval. We will be running a small sepsis study here that is currently in the planning phase. And we are also running a U.S. Air Force funded, 30 patient randomized controlled trial to treat patients with trauma and rhabdomyolysis. And in Europe, we have more than 50 investigator initiated studies being planned with many enrolling, our European registry, many case reports, studies ongoing in sepsis and additional ones being planned.

**Slide 26:** A fourth major catalyst is strategic partnerships, and this is a slide outlines just part of the universe of companies that could potentially be partners for us in the marketplace either in cardiac surgery, renal dialysis, blood transfusion, biotech and immunotherapy or other areas.

**Slide 27:** As a quick strategic partner update, Biocon has been a fantastic partner to date. And they are now moving forward with the design and funding of four investigator-initiated or proof-of-concept studies and a focused effort to collect and publish clinical data from the field. Biocon is also planning to expand to Sri Lanka, a country of 20 million people. They have developed a dedicated sales force for CytoSorb and are targeting 15 people to cover India as well as a medical director. Biocon remains extremely committed and continues to be a very good customer and partner of ours. Fresenius is also working to complete the necessary start-up activities and training needed to launch CytoSorb in France, Norway, Sweden, Finland, Denmark and Poland. And as I mentioned before, we have now achieved registration in France and we are very close to a launch and hope to have more information about this soon. And in terms of our cardiac surgery partner, we are currently in the process of the market evaluation with a leading cardiac surgery center in France. Our partner has also made an initial order of CytoSorb devices

to help support this process. And again just like our own clinical trial in the United States, we expect this market evaluation process to go quickly. We spent the past several months building up to this clinical evaluation and hopefully a successful outcome here will pave the way for a much broader partnership.

**Slide 28:** We believe that new opportunities represent another major catalyst for growth. Many of you who follow the biotech space know about cancer immunotherapies or have heard about companies pursuing either activated T-cell therapies or CAR T-cell therapies. One of the things I wanted to talk about today is cytokine release syndrome in cancer immunotherapy. This area of activated T-cell immunotherapies is one of the most promising and exciting areas of cancer research. In this approach, the patient's blood cells are taken out of their body, specifically their T cells, and then a gene encoding a chimeric antigen receptor is put into the cell that now enables the T-cell to proliferate, recognize, hunt and kill cancer cells. Although this is an experimental immunotherapy, it has led to the remission or cure of refractory leukemias and other cancers in a number of studies. But one of the issues with this therapy is that, by trying to kill cancer cells by stimulating the immune response, it can lead to a massive immune response and an expected flu-like syndrome in patients characterized by very high levels of cytokines. When the production of cytokines gets out of hand, it is called a cytokine release syndrome, or CRS. This is essentially the same as cytokine storm. CRS can spiral rapidly out of control despite the use of prophylactic measures like tocilizumab, leading rapidly to multiple organ failure and death.

**Slide 30**: This whole area of cancer immunotherapy has been a very lucrative place for deals as well as market values. On the left hand side is a chart taken from a recent issue of The Scientist talking about the different companies in this space and the major partnerships that they've collaborated on with major players in the pharmaceutical industry. And on the right hand side, you can see what their market caps look like today. This is clearly a very hot area of clinical research.

**Slide 31:** But one of the things that is limiting the excitement in this area is the concern over safety. This was an inset in the article from The Scientist where they talk about the challenges of cytokine release syndrome and though they're trying many different ways to try to mitigate this effect, there are no highly effective therapies to do so today.

**Slide 32:** One of the deals that has just been recently announced was the deal between Juno Therapeutics and Fate Therapeutics. Juno recently announced the strategic partnership with Fate for the screening and development of small molecules that can modulate the biologic activities of activated T-cells. The goal of this program is essentially to act as a kill switch. If cytokine release syndrome is starting to occur, they want to try to turn off the T-cells. But this is a pre-clinical program that involves small molecules that are specific to Juno's CAR T-cell constructs. And it is very unclear whether or not turning off these activated T-cells will help mitigate cytokine release syndrome because what happens in the body is that once the immune system gets going, it is not just the CAR T-cells that are producing cytokines. Rather, they trigger the activation of the entire immune system, and other cells as well, that results in an upward spiral of cytokine storm. We will see what happens under this development program, but the terms of the deal were very interesting. There was a $5 million upfront payment to Fate. There was a purchase of a million shares at $8 per share at 75% premium to the current share price. It involved an up to four-year research term, where Juno would pay all costs of development. And

for each Juno CAR T-cell program that was developed using Fate technology, Fate would receive $50 million in milestones plus low-single-digit royalties on net sales. Also included in this deal, was the ability to extend the term by two years with a $10 million stock purchase. The reason that I am talking about this particular deal is to 1) emphasize the immediate need for strategies to control cytokine release syndrome and 2) to talk about what partnership deals look like in this space.

**Slide 33:** CytoSorb was specifically designed to control cytokine storm and cytokine release syndrome by reducing a broad range of inflammatory mediators that are driving the systemic inflammatory response syndrome. We believe that CytoSorb represents a unique and easy to administer rescue therapy, not just for CAR T-cell immunotherapies, but also for other activated T-cell therapies as well. It is agnostic to the T-cell activation approach and could potentially be used as a broad spectrum solution across the technologies of all companies in this space. And although we are still very early in this space, we currently have multiple initiatives in this area that we are exploring. Again, this area of cancer immunotherapy is not a tangent application for our therapy. We are squarely focused on cytokine release syndrome and cytokine storm every single day in ICUs all over the world with demonstrated activity in many different cases.

**Slide 34:** So last but not least, our goal is to increase investor awareness of our company. In the very near future, we will be meeting with institutional investors in major cities across the country to increase awareness of our company and the technology. Although we are a NASDAQ company, we are still predominantly a retail-owned stock and if you talk to institutional investors outside the metropolitan region here in New York City, very few know our story. But when we talk to institutional investors, to analysts, to bankers, and to doctors, everyone is extremely excited about our approach because it just makes sense. We believe there will be a lot of benefit to increasing the awareness amongst investors across the country of our technology and our company.

**Slide 35:** We also continue to have positive analyst coverage and investor outreach from six investment banks with a number of analysts from other banks also following our progress. And we are working with our PR firm to increase our media coverage and hopefully we will have more to talk about there.

**Slide 36:** On our CytoSorb website, and on our Facebook page, we have videos that have been done recently. One of them was filmed at the University of Rostock. It's unfortunately in German, but we will be translating that video soon and will hopefully make that available to our shareholders, investors and physicians. But this is really an exciting piece for us for a number of reasons, but one of them is that we did not sponsor the production. This was actually done by NDR.de, a well-known television station in Germany. In the video, they highlighted the sudden and unexpected deterioration of a woman who almost died from a massive viral infection and how CytoSorb was used to stabilize her so that she could go on to have a life-saving operation. This is really a great piece for us, because it is the first time that investors have seen an actual human patient who was saved by our therapy. We hope to have more of these exciting stories in the future.

**Slide 37:** We believe that CytoSorbents has tremendous potential and may revolutionize critical care medicine by saving lives and reducing costs. Again, this is such a massive market. We have a product that is generating revenue with good margins. We continue geographic expansion

throughout the world. We are pursuing U.S. approval through either a Cardiac Surgery Pathway or the EAP pathway for critical illnesses here in United States. We are looking to expand our existing strategic partnerships which we believe can be very substantial to our overall business. And we look to leverage our NASDAQ Capital Market listing with institutional investors and other investors all over the country.

This ends our current prepared remarks and now I'd like to open up for a live Q&A session. Lee?

**Lee Roth - Moderator:**

Operator, we are ready to poll for questions.

**Operator:**

Yes. Thank you. And, as a reminder, if you do have a question, press star one on your touchtone phone. And, please make sure your mute button is turned off to allow your signal to reach our equipment. And we will take our first question today from Andrew D'Silva with Merriman Capital. Please go ahead.

**Andrew D'Silva - Merriman Capital:**

Good afternoon, guys. Thanks for taking my call. Just a couple quick questions for you. I guess, in your prepared remarks you said something about an initial order with one of your strategic partners. Could you elaborate on which partner that was, was it Fresenius or another one? And then, when do you expect their sales teams to actually start pounding the table in France and distributing the product within their network?

**Phillip Chan - CEO:**

Yes. So the initial order was actually by our cardiac surgery partner in France in order to support the initial market evaluation. It was not a big order, but it was certainly a good start and we are looking for more sales from this partner in the future. I think in terms of setting the expectation for sales, although the major activity should be viewed as starting in Q3 for both cardiac surgery and Fresenius, there may be some upside to that timing but that would be our expectation.

**Andrew D'Silva - Merriman Capital:**

And the order that you mentioned, is that going to be a Q2 event or was that in Q1?

**Phillip Chan - CEO:**

That is a Q2 event.

**Andrew D'Silva - Merriman Capital:**

Okay. And then moving over to your FDA approval process, do you have any sense on the timing and the regulatory path of the REFRESH trial? Is this going to be a PMA or 510(k) approval or anything else in between there?

**Phillip Chan - CEO:**

In our discussions with the FDA, the FDA has kept the door open to a potential De Novo 510(k) application or a PMA application. There are potential advantages to both. The De Novo 510(k) path would potentially be for a biomarker reduction application, specifically, a reduction in free hemoglobin. And that could potentially be a very small and very fast trial and something that would be relatively low cost. The PMA trial would be focused more on clinical outcomes, such as the prevention of acute kidney injury or the reduction in ventilator days. That would be a larger trial but currently we're waiting for the completion of the REFRESH feasibility study where we are collecting a lot of biomarker data, as well as clinical outcomes data, and are waiting for a follow-up discussion with the FDA to determine which path we are going to take.

**Andrew D'Silva - Merriman Capital:**

Is there a substantial cost difference between the two regulatory pathways?

**Phillip Chan - CEO:**

Yes. The De Novo 510(k) path would be much less expensive - on the order of millions of dollars less expensive.

**Andrew D'Silva - Merriman Capital:**

Okay. Last question for you. In terms of the revenues that you're generating now and in the first quarter. Could you maybe give us a sense of where they're coming from, are they repeat orders from hospitals and ICUs that you had to establish relationships with in Germany and so forth or is it more related to new distributors and strategic partners filling up their funnel, if you could give a little bit of context. Obviously all revenue isn't created equal.

**Phillip Chan - CEO:**

The vast majority of our orders are reorders from existing customers or distributors. It is where we have been seeing a lot of traction. And I think that has been a very positive thing. Interestingly, however, we are seeing a lot of new orders as well. One of our strategies going to marketplace was to focus on the largest university and public hospitals and gaining key opinion leader support from them. The interesting consequence of doing that is that there has been a lot of excitement, a lot of chatter, and a lot of discussions with colleagues around the country. In Germany, there are 2,100 acute care hospitals. There are 400 with more than 400 beds in the hospital. We've been targeting the top 400. But we're now seeing a lot of interest from small hospitals that are hearing about the technology and hearing about the successes from the larger hospitals, and are very receptive to starting their CytoSorb treatment experience with us. So I would say that you need both reorders as well as new orders in order to build the market. And I think that we have a very nice balance currently.

**Andrew D'Silva - Merriman Capital:**

Okay. Got it. Thanks for taking my questions…

**Phillip Chan - CEO:**

Thanks a lot, Andy. We appreciate it.

**Operator:**

And we're going to a question from R.K. with HC Wainwright. Please go ahead.

**R.K. - HC Wainwright:**

Good evening, Phil. Good evening, Kathy.

**Phillip Chan - CEO:**

Hi RK.

**R.K. - HC Wainwright:**

Looking at the revenues and COGs, just to start up from the top. Not taking into account the drop in the Euro, how did you do sequentially compared to the fourth quarter 2014. And the second part of that question is, with the rebuilding of the sales force and not considering the euro exchange issue, when would we start seeing that number go up again?

**Phillip Chan - CEO:**

Kathy, would you like to take the first part of that question?

**Kathleen Bloch - Chief Financial Officer:**

Sure, Phil. Hi, R.K. So the real number for the Q1 sales is the $704,000 that we reported and as we stated, the impact of the reduction caused by the decline in the euro was about $112,000. So, I'd say the comparable number for Q1 2015 is about $816,000. And also I want to just comment a little bit on what you can expect going forward. The euro has sort of stabilized, so we are happy to see that. But surely another decline in the euro would have a further negative impact on our sales. But this impact is somewhat mitigated by a fact that almost one-half of our sales are in U.S. dollars. So, a say, 10% drop in the euro would have approximately a 5% decline in product sales. And then just looking the other side of the coin, because we are funding our German subsidiary in U.S. dollars, the decreases in the euro to some extent reduce the expenses associated with funding that operation. I hope I answered your question.

**Phillip Chan - CEO:**

For Q4 2014, we did about $871,000 in product sales and adjusting for the steep drop in the euro at the beginning of Q1 of this year, that number on a comparable basis would've been approximately $816,000. So it's roughly comparable. I would call it flat. But clearly, our goal is to be working on all three cylinders of revenue generation, where direct sales are a major part. The two other engines of growth are distributor sales as well as potential partner sales. So in terms of your second question about the sales force, our goal is to have the team rebuilt by the end of Q2. Because of the labor laws in Germany, there's typically a waiting period before they can actually start. But the two that we have already signed with, will start at the beginning of Q3 and the other two may, depending on their ability to get out of their current employment situations, would potentially be more variable from a timing standpoint. But I think while we continue to rebuild the sales force, we are not stopping with the effort on distributor sales as well as partner sales and those will continue. As we mentioned, we expect Q3 to be good conservative timing for the initial launch of the product by Fresenius, though it could be sooner but Q3 is what we are targeting, and then for the cardiac surgery company, we expect the market evaluation to take up the remainder of Q2 but hopefully be in a position for a larger partnership in Q3.

**R.K. - HC Wainwright:**

Just as a follow-up to those questions, we also saw the gross margin drop. Was the decline in the euro a factor there also?

**Phillip Chan - CEO:**

In calculating gross margins, we are converting sales in Europe from the euro to the dollar. Then in the United States, the COGS are built around dollars. And so any drop in the ASPs because of the conversion of euros into dollars will result in a decrease in our gross margins. That being said, in terms of our COGS, we have a path to continue to reduce our cost of goods sold that will culminate ultimately with the expansion of our manufacturing facility where we hope to benefit from the economies of scale of this larger facility. So again, we are not sitting still in terms of our gross margins. We continue to believe that we can drive our gross margins higher as we gain economies of scale and drive down the cost of goods sold, and that may be helped by stabilization, if not rebound, of the euro.

**R.K. - HC Wainwright:**

Okay. Another question on these German accounts. Are the German accounts normally renegotiated every year or do you have German accounts which run over multiple years? If so, will not having a fully staffed sales force over the next three to six months hinder in the negotiation or re-signing of any of these contracts and have a long-term impact on direct sales?

**Phillip Chan - CEO:**

Our direct sales are not based on contracts. In other parts of the world like the Middle East, or even Turkey, they do work on large tender offers that get filled over time. In Germany, it is still very much a quarter-to-quarter direct sale. There are no long-term contracts in Germany yet. But as we are used more, as we start being used as a standard-of-care for different therapeutic

indications, the potential for contracts exist, but currently right now it's a quarter-to-quarter direct sale.

**R.K. - HC Wainwright:**

Okay. A couple more questions. The French cardiac surgery partner, have they started the evaluation period? I think I heard that you're expecting revenues in Q3.

**Phillip Chan - CEO:**

Yes. They are just about to start but let me turn this over to Chris to talk about the activities that have led up to this point, because we certainly have not been standing still with this partnership. I think both sides have been pretty motivated to get this off the ground. But as with all things, there is a process involved. Chris, could you please comment?

**Chris Cramer - VP, Business Development:**

Sure. Thanks, Phil. Hi, RK. So for the cardiac partnership, there are really two phases to the market evaluation. One is procedural and administrative, and then the second is clinical usage. The majority of the heavy lifting takes place during the first phase. This is where you're getting everything set up. It includes matters such as registration, getting set up in the partners' purchasing system, trainings and other activities, and typically it takes longer than the clinical evaluation. So I am pleased to say that we are finished with this first set-up phase. Our cardiac surgery partner has now ordered and received the product for this initial market evaluation, and we are very close to starting the actual clinical usage phase. They will begin by identifying patients to receive CytoSorb therapy. Once underway, the goal will be to treat 10 to 12 patients which we believe can be accomplished over the next two to three months. And so ultimately, this evaluation will give us the information needed to potentially expand to additional sites within France and to possibly negotiate a larger partnership with this partner. So that's where we currently stand. Hopefully that answered your question.

**R.K. - HC Wainwright:**

Yes. Thanks. So after the evaluation period, you don't expect a long time to formalize this relationship, you expect these things to be done quickly, is that…

**Chris Cramer - VP, Business Development:**

I'm hoping that's the case. We're assuming that the evaluation goes well and that we can quickly move to formalize something like that.

**R.K. - HC Wainwright:**

Got you. Fantastic. Thank you, folks. Thank you for taking all the questions.

**Phillip Chan - CEO:**

Sure, R.K. Thank you very much.

**Operator:**

Before we move on to the next question, I'd like to give everyone a reminder, if you do have a question, press star one on your touchtone phone. And we'll now go to Thomas Yip with MLV & Company. Please go ahead.

**Thomas Yip - MLV & Company:**

Hey, guys. Thank you for taking my questions. Ram sends his regards.

**Phillip Chan - CEO:**

Hi, Thomas.

**Thomas Yip - MLV & Company:**

Just a couple of quick questions. I guess, we'll go back to your European sales force ramp up and reorganization. What do you see to be the near-term impact of that on the topline for rest of this year in those areas?

**Phillip Chan - CEO:**

It's hard to quantitate the impact of the sales force. I think, certainly in the first half of the year, particularly in Q1, without having the sales people on the ground, we saw a decrease in direct sales because we just did not have people in the territories, knocking on doors and driving those sales. I think it's really important to note that when it comes to selling, it is not just about getting the key opinion leader or the Head of the Department or your champion to say yes and agree to buy the product. It is really a process of getting everybody on board. This includes the five or six stakeholders in the hospital: the head of the department, the hospital administrator, the person who handles reimbursement, the formulary person, and others who are involved in the decision-making process. We actually see a tremendous amount of interest and demand from the end-user physician. But sometimes it requires a lot of effort on the part of our salespeople to push through these orders through the hospital administration. So, we expect that our sales force will be back to full force in the second half of this year. The majority of the sales force will be up and running in early Q3. The people that we've signed for the Northeast and Northwest territories in Germany that will start in early Q3 are well-known to our sales team in Germany. And we believe that they will be able to start up very quickly. They are ICU salespeople that have an established network of ICU doctors that overlaps in a good part with our current ICU network but also adds additional contacts, which I think is great. Because of this, I think the new sales people can begin to generate revenue relatively quickly. That being said, just to set expectations, when someone starts it does take time to get up to speed. You are learning the ropes. You are getting trained. There are a lot of start-up type activities. So, we expect them to be in full force in Q4. In Q3, we certainly expect them to contribute and take up where some of the other salespeople have left off. As for Q2, what we have said previously is that we expect direct sales to be flat with the growth being driven predominantly by distributors and partners.

**Thomas Yip - MLV & Company:**

Sure. To me, it sounds like 2015 will be important time to rebuild the sales force, get all the people on the ground for a more meaningful 2016, I think. So, I guess we can move on to the EAP Expedited Access Pathway in the U.S. that you talked about earlier.

**Phillip Chan - CEO:**

Sure. Maybe before we go there, just a couple other things to note. In Germany, we're looking creatively about how we address two markets in Germany in our direct sales territories. One is clearly the ICU. The other is in cardiac surgery. Those are two different kinds of markets. Today we've been effective in terms of being able to detail both of those. But there are ways to potentially leverage our current sales force and do so rapidly. This represents a potential upside in the near term, if we are successful in our efforts to do that. I know that's a little vague, but we will detail that in the future when things progress. Sorry, you have a question about the EAP?

**Thomas Yip - MLV & Company:**

No, it's okay. Yes. So regarding EAP, it sounds like there are a pretty large number of both regulatory and financial incentives for the EAP. So when do you expect to file that application and when do you expect to get a response from the FDA?

**Phillip Chan - CEO:**

So working backwards, contractually just like the 510(k) process and other processes, it's a 30-day turnaround from when you submit the application to when you expect to hear back from the FDA. Our goal is to submit a very well-thought out and detailed application. The application is not a simple one. It involves not only a determination of why you meet the criteria of being a medical device that addresses a major unmet medical need. But you also have to propose a preliminary data designation plan where you are proposing what you plan to do, from a clinical trial perspective, to get early market approval and then what you plan to do in terms of clinical studies in the post-market period. Once you get EAP designation, then you really go into high gear with the FDA and begin negotiating these points in detail. But that said, we are aggressively pursuing this and hope to have something to submit in the near future.

**Thomas Yip - MLV & Company:**

Sure. That's understood. So you need to prepare it as fast as possible. So I guess we can move on to the cytokine release syndrome indication that you mentioned CytoSorb could potentially expand into. You also mentioned some initiatives regarding this CRS indication. Can you expand a little bit more on what these initiatives are?

**Phillip Chan - CEO:**

Well, currently we can't discuss that right now, but I think that when we make progress in those areas, we will plan to talk to shareholders about it. Some of the things that we are working on are very exciting and I think will provide us with the necessary background information to be

able to go and demonstrate the potential of our therapy in this space. Again, cytokine release syndrome is akin to cytokine storm. Cancer immunotherapy is just yet another cause of cytokine storm that is right in line with things like sepsis and burn injury, trauma, pancreatitis, lung injury and other things. We don't necessarily have to be connected to clinical studies to be used as a rescue therapy for this or any other complication of cancer immunotherapy, whether it is CAR T-cell therapy or any other type of therapy. I think that's very important. We believe there are certainly potential strategic partnership and alliance opportunities in the CAR T-cell arena and activated T-cell arena with companies in these areas. But if nothing else, we are firmly embedded in this space already. And CytoSorb could be used today in Europe if patients had complications of CAR T-cell therapy there. So it's a very exciting area for us, and is very much right up our alley, so to speak.

**Thomas Yip - MLV & Company:**

Sure. Understood that. Thanks for the clarification. One last question regarding REFRESH, I just want to clarify that you expect to start enrolling beginning in mid-2015. And can you remind us what some of the future catalysts are?

**Phillip Chan - CEO:**

What was that last part, Thomas?

**Thomas Yip - MLV & Company:**

For the REFRESH study, can you please remind us some of the expected data readout date though or enrollment target date etc.?

**Phillip Chan - CEO:**

As we mentioned before, we are on target to begin the trial mid-year - sometime around summer time. Again, this should hopefully be a relatively short trial based of what my comments were before in terms of the ability to enroll patients very rapidly, the limited treatment with CytoSorb just during the surgery, and the minimal work needed in the follow-up period which just involves blood draws and ongoing clinical evaluation. So we expect that the enrollment to occur very rapidly. And we are working with number of major centers in the country that are well-known to our clinical team. Hopefully we will have that study done before the end of the year with the goal of meeting with the FDA and looking to file an IDE for a pivotal study hopefully thereafter, once the clinical development path has been clearly defined.

**Thomas Yip - MLV & Company:**

Okay. Sounds good. Thank you again for taking my questions.

**Phillip Chan - CEO:**

Okay, sure. Thanks very much.

**Operator:**

And we'll now go to the Jan Wald with Benchmark Company. Please go ahead.

**Jan Wald - Benchmark Company:**

Good afternoon. And thanks for taking my questions.

**Phillip Chan - CEO:**

Hi Jan.

**Jan Wald - Benchmark Company:**

Hi. I guess, a couple of more clarifications than anything else. I just want to make sure when you were talking about the sales people and bringing them up to let's called a full productivity. You said it may take a quarter to do that, is that right?

**Phillip Chan - CEO:**

Yes. What I was saying is that, these sales people are well-known to our team. They are very experienced in the area of ICU sales and but whenever you transfer over to a new product, it's getting up to speed and making sure that you know how to address the questions and how to pitch the product. So I think there will be a bit of a learning curve, but again these are entities that are well-known to the company which I think gives us a lot of confidence that they will be able to get up to speed very quickly. And we do expect them to contribute in Q3.

**Jan Wald - Benchmark Company:**

Okay. And on the Sepsis Trial, in case you don't get the expedited review. Is the only fall back to the 28-day all-cause mortality endpoint or are there other ways to approach the FDA?

**Phillip Chan - CEO:**

Our original strategy for sepsis in United States was to pursue a large randomized controlled study in sepsis where we are not relying on the outcome for approval. And so that's one of the reasons why we went to a cardiac surgery trial in United States, because it would be a much faster trial, the endpoints were not mortality but easier endpoints to hit for regulatory approval, such as biomarker reduction or an improvement in other clinical outcomes, and the market was still substantial. If we do not qualify for the EAP pathway, we would fall back to the original strategy of getting CytoSorb approved initially in the United States for cardiac surgery. And then conduct a large randomized controlled sepsis study using 28-day all-cause mortality as an endpoint either in Europe where we're already approved or here in the United States. We would then use that data to expand the label for CytoSorb here in the United States. So that would be the case if we did not achieve EAP designation. But, we'll see what will happen, because we do believe, based on the analysis of the FDA guidance, that CytoSorb is a very good candidate for EAP designation.

**Jan Wald - Benchmark Company:**

I just was wondering what would happen if what you expected didn't happen. And I guess, just my last question - there are a lot of investigator trials that are going on. It's a great strategy but just a question - how many of them are single centered and how many of them are randomized? What will you be able to bring from Europe to the United States as part of the data package to support U.S. approval?

**Phillip Chan - CEO:**

The investigator initiated studies are a mix of different types of trial designs. Many of them are randomized controlled studies and some of them are retrospective studies using an active treatment arm against a retrospective or historical control. For example, we have two cardiac surgery trials, one at the University of Hamburg and one at Medical University of Vienna, that are randomized control trials and have actually completed enrollment. And so we're hoping to see some data coming out of those studies in the near future. We believe that positive data would not only help to support our discussions with the FDA, but will also help to support clinical usage around the world.

Now the reason why we're doing the REFRESH feasibility study, is that the FDA is looking specifically for safety data in the United States and hopefully, we'll get that done. And they've indicated that depending on the outcome of this study that they are very open to having a discussion about a potential pivotal study in the United States. So I think the U.S. regulatory path is not predicated on any kind of studies outside of the U.S. It is a very self-contained study. That being said, we hope to have safety data, cytokine and biomarker reduction data, and other things that we can bring to the FDA that will hopefully help support our case. There has also been some recent guidance from the FDA where they are looking more favorably on ex-U.S. clinical data. We will hopefully have a lot of different studies when we approach the FDA for different applications.

**Jan Wald - Benchmark Company:**

Okay. Thank you very much for taking the question.

**Phillip Chan - CEO:**

Sure. Absolutely. Thank you, Jan.

**Operator:**

And at this time, I would like to turn it back to management for any additional or closing remarks.

**Phillip Chan - CEO:**

Thank you everyone for taking the time today to get on this call. We certainly appreciate your participation. If you have any other questions, please feel free to reach out to Amy Vogel at

avogel@cytosorbents.com and we'll try to get you answers to some of your questions as needed. In the meantime, we look forward to the next update on the next quarterly call. Thank you very much.

**Operator:**

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