CytoSorbents Corporation (NASDAQ: CTSO)
2017 Second Quarter 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 2017 Earnings Conference Call. At this time, all participants are in a listen-only mode. Following the formal remarks, we will open the call for your questions. Please be advised that the call will be recorded at the Company's request. At this time, I'd like to turn the call over to our moderator, Bob Yedid from LifeSci Advisors. Please go ahead, Mr. Yedid.

Bob Yedid:

Thank you, and good afternoon. Welcome to CytoSorbents Second Quarter 2017 operating and financial results conference call. Joining me today from the Company are:

- Dr. Phillip Chan, Chief Executive Officer and President
- Vince Capponi, Chief Operating Officer
- Kathleen Bloch, Chief Financial Officer
- Dr. Eric Mortensen, Chief Medical Officer
- Dr. Christian Steiner, Vice President of Sales and Marketing joining us from Germany and
- Chris Cramer, VP of Business Development.

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 projection as to the Company's future performance represented by Management include estimates today as of August 7, 2017, 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 second quarter by Dr. Chan and Ms. Bloch. Following that presentation, we'll open the line to your questions during the live Q&A session with the rest of the Management Team. With those prepared remarks, at this time, it's now my pleasure to turn the call over to Dr. Phillip Chan, CEO. Phil?

Phillip Chan:

Thank you very much, Bob, and good afternoon, everyone. We appreciate the opportunity to review our second quarter 2017 financials and provide you with an update on our progress and accomplishments so far. It has been a busy year and we are very proud here of our team and the tremendous growth in revenues that we achieved this quarter. Specifically, we achieved total revenue of $3.6 million and for the first time, we achieved $3 million in quarterly CytoSorb sales, on record direct and distributor sales. There have been a total of more than 27,000 CytoSorb treatments delivered to date, an increase from 14,000 a year ago, with continued strong re-order rates. We have also had excellent progress on German CytoSorb reimbursement rates in a survey of many key accounts, with new negotiated rates that cover both the device as well as the cost of the procedure. This is important as Germany is one of our largest contributors to revenue and we are pleased to see that Germany recognizes the benefits of our CytoSorb treatment. We are working to gain similar reimbursement outcomes in other countries. During the quarter, we also extended our partnership with Aferetica in Italy through 2021 with cumulative sales expected to exceed $10 million during that period for Italy alone. In addition, we plan to begin our co-marketing effort with Fresenius soon in five major countries. In addition, we expect that the imminent ECMO kit availability will also help catalyze sales.

In terms of guidance, we are expecting that the second half of 2017, in terms of CytoSorb sales, will exceed that of the first half of 2017 and we reiterate our guidance on achieving operating profitability in 2018.

On the clinical front, we thank Dr. Robert Bartlett, our former Chief Medical Officer who has retired, for his many years of support, guidance, and camaraderie. Although, it was difficult to do, we have found an exceptional replacement for Dr. Bartlett with the addition of Dr. Eric Mortensen, who started as our new Chief Medical Officer in June. Eric brings a wealth of experience in clinical and program development, having held positions in global development at Pfizer, Glaxo and Merck. He has also worked extensively with the FDA on regulatory approvals and will be leading our strategy. Eric is well-pedigreed with a degree in Biochemistry from Harvard College, a medical degree from Harvard University and the Massachusetts Institute of Technology Division of Health Sciences and Technology, and a PhD in Biophysics from the Harvard Graduate School of Arts and Sciences. He completed his internship and residency in Internal Medicine at the famed Massachusetts General Hospital in Boston and a fellowship in Gastroenterology at the University of Michigan Medical Center, Ann Arbor. We are very pleased to have him on board, guiding our program. We've also been very impressed by how quickly Eric has gotten up to speed, meeting with key opinion leaders and our European clinical team, and optimizing the REFRESH II trial design with the study expected to start later this year. He has also

created an overarching clinical trial and data strategy that he and his team will begin to execute upon in the near future. Our goal is to prioritize company-sponsored clinical trials and invest to make clinical development a core competency.

Meanwhile, data publication has been accelerating. Over the past 12 months, we have had two dozen peer-reviewed journal articles that have been published, highlighting the clinical usage of CytoSorb in a wide variety of indications. There are also now approximately 60 investigator-initiated studies in various stages of progress or planning with more data to come. In addition, an interim analysis on nearly 200 patients from the CytoSorb International Registry has been accepted for publication. We are pleased to continue the tradition of our Case of the Week reports, which many of our shareholders look forward to on a weekly basis and many presentations and posters at major conferences, highlighting ongoing treatment successes.

Finally, we have had some other good developments as well. As many of you know, we have been discussing CAR T-cell immunotherapy for some time and recently the CART-19 cancer immunotherapy program licensed by Novartis from the University of Pennsylvania, and pioneered by our Scientific Advisory Board member, Dr. Carl June, received unanimous recommendation by the FDA Review Committee for approval, with one of the review experts calling it, "the most exciting thing I've seen in my lifetime." Interestingly, cytokine release syndrome was the common adverse event, afflicting nearly 50% of patients. This may open up additional opportunities to fast-track CytoSorb approval in the United States for this indication.

Our new manufacturing facility is in the build-out phase and is on schedule to come online in the first quarter of 2018, which will increase our manufacturing capacity, with some modification, to approximately $80 million in sales.

Finally, we engaged with LifeSci Advisors as our Investor Relations firm to expand our investor network and shareholder base in both the U.S. as well as internationally. We plan to be visible at multiple investor and industry conferences such as the European Society of Intensive Care Medicine (ESICM) Conference and the European Association of Cardiothoracic Surgery (EACTS) in Vienna, Austria, as well as the pending Military Health System Research Symposium (MHSRS), also known as the Combat Casualty Care Conference, later this month in Florida. With that, I'll turn the call over to Kathy for our financial overview. Kathy?

Kathleen Bloch:

Thank you, Phil, and good afternoon, everyone. For today's call, I will provide an update regarding CytoSorbents second quarter 2017 financial results, including product sales progress, and also provide an update around our working capital and cash runway. Our total revenues, which includes product sales and grant revenue, were a record $3.6 million for the second quarter of 2017 as compared to approximately $2.2 million for the second quarter of 2016, an increase of approximately 60%. CytoSorb product sales for the second quarter of 2017 were approximately $3 million which was our best quarterly product sales ever. This represents a 64% increase over product sales of approximately $1.9 million for Q2 2016. Our Q2 2017, annualized

product sales run rate rose to $12.2 million compared to our annualized run rate of approximately $7.4 million, one year ago. Q2 2017 gross margins rose to approximately $2.1 million, an increase of approximately $735,000, as compared to gross margins of approximately $1.3 million for Q2 2016, and our gross profit margins on product sales were approximately 65% in Q2 2017, as compared to 68% for Q2 2016. This was primarily as a result of the mix of direct and distributor sales.

Turning to our six month's financial results; CytoSorb product sales for first half of 2017 were approximately $5.6 million, which is a 63% increase over product sales of $3.5 million for the first half of 2016. Grant revenue grew 79% from $582,000 for the first half of 2016 to $1 million for the first half of 2017, largely as a result of incremental revenue from new grants. Total revenues, which of course includes product sales and grant revenue, were approximately $6.7 million for the first half of 2017 as compared to $4 million for the same period in 2016, an increase of approximately 66%.

Let us just look quickly at our quarter-over-quarter product sales. Q2 2017 sales of $3 million were significantly higher than Q1 2017 sales of $2.6 million. That is a 17% quarter-over-quarter increase in sales and we saw increases in both direct and distributor sales during the quarter. In fact, they were both at record levels. The sales growth pace that we saw in the first half is continuing to track to the positive growth patterns that we have seen over the past two years.

Next, we will take a look at our trailing 12-month product sales chart and here we can clearly see the increasing trajectory that we are experiencing with regard to our product sales. Our trailing 12-month product sales have climbed to $10.4 million for the 12 months ended June 30, 2017, as compared to $6 million for the 12 months ended June 30, 2016, which is an increase of 73%. Our three-year compound annual growth rate, or CAGR, was 81%, and the underlying drivers of revenue growth remain unchanged and Management expects that the second half of 2017 product sales will continue to climb and that they will, in fact, exceed first half 2017 product sales.

Finally, we have guided that we expect to reach operating breakeven, which excludes non-cash expenditures such as stock option expense and also excludes the cost of clinical trials, at approximately $20 million in annual revenue. We remain confident that we can achieve this important milestone in 2018. Now, as of June 30, 2017, we had approximately $16.4 million in cash and cash equivalents. This includes the net proceeds of our $10.3 million financing in April of 2017 and also includes the $5 million received in June as a result of drawing down the second tranche of our debt facility with Bridge Bank. Management believes that this will provide sufficient funding to support our operations through at least the end of the year 2018.

Turning briefly to our capital structure, as of June 30, 2017, we have approximately 33.2 million common shares on a fully-diluted basis, and now I'd like to turn the call back to Phil. Phil?

Phillip Chan:

Thank you very much, Kathy. Recently, we have had a lot of shareholder interest in our plans for sepsis and I wanted to take a moment to explain our strategy. As most of you know, sepsis remains a top ten killer worldwide. It is a result of an overzealous immune response to an infection and is driven by cytokine storm. Based on recent estimates, it afflicts approximately 30 million people worldwide every single year and is growing due to the aging baby boomer population who are very susceptible to getting infections and sepsis, as well as the increase in drug resistant bacteria. Today, severe sepsis kills approximately one in every three people despite the best medical treatment, that includes antibiotics, and it kills more people in the U.S. than either heart attacks, strokes, or any single type of cancer. There are no approved therapies to treat it with only a handful of therapies in Phase 3 clinical studies. At an average cost of more than $45,000 to treat, and with inadequate reimbursement, hospitals are losing significant amounts of money annually.

The sepsis crisis is now. In May 2017, the World Health Organization, or WHO, mandated sepsis as a "Global Health Priority," and in July 2017, Bloomberg news declared that, "America has a $27 billion sepsis crisis". As you can see from the chart from Bloomberg on the right-hand side, the incidence of sepsis continues to rise and although standards of medical care continue to improve, helping reduce the overall mortality of sepsis, the numbers of patients with sepsis, and who die of sepsis, continues to grow. There is no question that sepsis will remain an equal opportunity killer and it is not going away any time soon.

Sepsis has defied pretty much any solution. There have been more than a hundred Phase 2 and Phase 3 clinical trials exploring the potential of different interventional strategies on sepsis. All of these strategies on the right-hand side have included standard of care treatment including antibiotics. This table was from an article in 2014 and we can add several more strategies to the list now. But as you can see here, with the exception of the PROWESS Xigris trial, all of these have failed, and even Xigris was subsequently taken off the market after a failed PROWESS SHOCK trial.

Currently, there are no approved therapies to treat sepsis and no one, not even us, has pivotal data demonstrating efficacy of any therapy. But that said, there have been many attempts to try to improve this. What I would like to impress upon you today is why we, as a broad spectrum therapy, believe we are at the forefront of the treatment of sepsis.

There have been many promising early sepsis studies that have focused on one aspect of sepsis, but history has taught us that these should be viewed with caution. One well-publicized strategy was early goal-directed therapy (EGDT). The goal of the EGDT therapy was to use a protocolized-based process to try to improve hemodynamics and oxygenation in sepsis patients in the emergency room before they were admitted to the intensive care unit, to try to prevent organ failure and to improve survival – a reasonable strategy. There was a very promising 263-patient single-center randomized control trial between patients with severe sepsis or septic shock that either received protocol-based hemodynamic resuscitation or standard of care therapy, and

mortality was 30.5% in the treatment arm versus 46.5% in the control arm, with a p-value <0.01. The problem was that in large scale, multi-center studies including the ProCESS trial, the ARISE trial, the ProMISe trial, as well as the PRISMA meta analyses which studied 3,723 patients from 138 countries, that early goal-directed therapy showed no benefit in 90-day mortality.

A second promising early study used an orally-administered agent called talactoferrin. Talactoferrin, or lactoferrin, is a substance found in breast milk that was presumed to have an immunotherapy-type effect by acting on the gut, protecting infants against sepsis – another plausible strategy. There was a very promising, 190-patient Phase 2 randomized controlled study demonstrating that orally-administered talactoferrin versus placebo led to a reduction in mortality in patients without shock from 22.6% to 2.6% mortality with a p-value=0.03, and when you considered all patients and their mortality, it reduced it from 26.6% to approximately 15% with the p-value=0.04. The problem is that, subsequently in a Phase 2/3 study in 77 centers in 10 countries, this large study was terminated after enrollment of 305 patients because of futility and safety concerns.

Now, there has also been a lot of publicity about steroids in sepsis and unfortunately those studies, although initially very promising, have not panned out in large-scale clinical studies either, including the HYPRESS trial in 2016 that evaluated the prevention of shock in 380 patients with severe sepsis, but no shock. These patients were given approximately 200 milligrams per day for 5 days and then tapered out to day 11, but it showed no effect on the progression of shock and no improvement on 28-day (8.8% treatment vs 8.2% control) or 90-day mortality. Subsequently, the CORTICUS trial, evaluated approximately 500 patients with septic shock, with a similar steroid regimen as HYPRESS. What the CORTICUS trial showed was that although there was a shorter time to reversal of shock, there was no change in 28-day mortality which was roughly the same in both arms, but that the treatment group had more new incidences of sepsis and super infection. For this reason, steroids are not routinely recommended in the treatment of sepsis today.

Along these lines, there now has been a very widely publicized study called the Vitamin C trial earlier this year that uses a cocktail of Vitamin C, hydrocortisone and thiamine to treat septic patients. In this retrospective single-center 47 consecutive patient trial, patients with severe sepsis or septic shock that were given daily treatments of 6 grams of IV Vitamin C, 200 milligrams of hydrocortisone IV for seven days - so very similar steroid regimens as the CORTICUS and HYPRESS trials - and 400 milligrams of IV thiamine each day, and they compared this against a same-center 47 consecutive patient historical control. What they found was that hospital mortality was roughly 40% in the control versus 8.5% in the treated, and if you go back to the HYPRESS trial, the 8.5% was roughly the overall 28-day mortality that they saw in septic patients with no shock.

Although this is interesting data supported by a real mechanism of action, it is limited by the fact that it is a single-center, non-randomized controlled study and when you look at the patients, they're very different from the patients that are typically in septic trials. For example, in most of our trials that we do, patients typically have multi-organ failure, on mechanical ventilation, many

are on dialysis, and most of them have septic shock. But in this particular study, they had a relatively low severity of illness with only about 22% in each group having septic shock requiring vasopressors, with most only requiring a very short duration of vasopressor usage, approximately two days, even in the control group. In addition, only about a quarter of the patients required mechanical ventilation. Also, most patients had evidence of only modest blood perfusion defects, with a lactate level of about 3 mmol per liter, in both the treatment and control groups. On top of that, there was a very short ICU stay, roughly a mean ICU stay of about four days in both groups. In most trials in severe sepsis and septic shock, particularly septic shock, patients are in the ICU for an average of 12 to 18 days. So the fact that the control group left the ICU after four days, even without the benefit of treatment, again suggested they were relatively not very sick.

I think that although this is very interesting data and that it certainly justifies a larger multi-center randomized controlled trial, we view this as a technology that is potentially complementary to our technology, but certainly nothing that they have shown to-date would make our technology redundant or obsolete. So, why do we believe that? It is because CytoSorb attacks sepsis broadly, which is unlike the more targeted approach that many of these other therapies have tried to take. For example, the proposed value of steroids and Vitamin C is to try to help maintain the capillary endothelial barrier and to prevent capillary leak syndrome, while restoring vasomotor tone and allowing blood vessels to respond to vasopressors, which is one of the things that is missing in patients with septic shock. Early goal-directed therapy tries to restore intravascular volume and cardiac output to ensure that tissues are receiving adequate amounts of blood as well as oxygen. As with many of the failed therapies in the mechanism of action table I just presented, these are worthy goals, but only focuses on one or two of many problems that are going wrong in these patients. But when you look at a sepsis patient, it is typically many, many things that are going wrong at the same time. It is kind of a system crashing all at once and one of the benefits of CytoSorb is that we attack sepsis broadly.

For example, we have very good data that CytoSorb reduces inflammatory cytokines and other factors that are perpetuating a hyper-inflammatory response that can lead to organ failure and death. We also have now interesting data that CytoSorb can establish immune responsiveness in hypo-immune septic patients. This is still very early data but it is very interesting data from a mechanistic standpoint, most likely through the reduction of immunosuppressive cytokines. And one thing that all these other technologies do not do is the removal of bacterial toxins. Why is this important? Well, all of us have heard of MRSA, or methicillin-resistant Staphylococcus aureus, the leading cause of hospital acquired infections in the country. One of the reasons MRSA is so deadly is not because it is antibiotic (specifically methicillin) resistant. In fact, we have about a dozen antibiotics that will kill MRSA. But the reason why MRSA is so deadly is because it produces a wide variety of toxins that will activate the immune response and cause hyper-inflammation, as well as destroy tissues directly. We have very good data through our work with DARPA that we can remove these toxins. In addition, through the work of Dr. John Kellum at University of Pittsburgh Medical Center, we know that we can make activated white blood cells go to the site of infection and avoid otherwise healthy tissues that could be damaged by proteolytic enzymes and dangerous reactive oxygen radicals that these white blood cells produce

to combat infection. In addition, we have seen over and over again that we improve hemodynamics and, like what they are seeing in Vitamin C and steroids, we also reduce capillary leak syndrome. We believe we are at the forefront of sepsis research because no other single therapy has demonstrated this broad range of activity.

Our strategy in sepsis is to try to play it smart, and with Eric leading our clinical trial program, we have confidence that we will be able to do so. Our goals are to avoid the heterogeneity inherent to most large scale pivotal trials in sepsis; to take advantage of the unique mechanistic aspects of CytoSorb such as bacterial toxin removal; benefit from the ever-expanding clinical experience with CytoSorb; and focus on subgroups where CytoSorb works well and reproducibly. Instead of doing the very large-scale "all-comers" trial, our goal instead is to focus on validating randomized control trials, but ones where the effect of CytoSorb can be seen with a smaller number of patients. Through this strategy, we believe that these studies will add to the widening body of clinical evidence of CytoSorb and help drive the therapy as standard of care.

With that, let me end our formal remarks and, Operator, if you would, please open it up to questions.

Operator:

Thank you, and if you do have a question, please press *1 on your touchtone phone. Please make sure that your mute button is turned off to allow your signal to reach our equipment.

We will take our first question from Josh Jennings with Cowen & Company. Please go ahead.

Josh Jennings:

Hi. Good evening. Thanks for taking the questions and congratulations on the progress. I just wanted to ask Phil about German reimbursement. Is the issue about German hospitals and their negotiation of reimbursement for the new procedure code for CytoSorb now in the rear view mirror? How should we think about that German reimbursement benefiting CytoSorb in the back half of the year?

Phillip Chan:

Hi Josh. Yes, I think that for those familiar with that reimbursement system, hospitals typically negotiate their entire operating budgets with the central reimbursement agency, at different points throughout the year, with all decisions retroactive to January 1st of that year. Many negotiate in the first half of the year and that is one of the reasons why we have had a lot of feedback from many of our key accounts. But some negotiate in the second half of year as well. I think that on a go-forward basis, certainly the progress that we have had in the first half of the year will definitely help the second half of the year and as we progress through the second half of the year, adoption and usage at those German hospitals that have established their reimbursement will continue to accelerate.

Josh Jennings:

Great, and I wanted to follow up with a question on the ECMO kit launch. Can you give us a little bit more of a download on the opportunity there and any more specifics around timing, when that can get into the market place?

Phillip Chan:

Yes, of course. ECMO stands for "extracorporeal membrane oxygenation" and it refers to a machine that can oxygenate blood outside of the body when the lungs cannot. It has been used predominantly in the past as a rescue therapy when mechanical ventilation fails. When a patient's lungs are so filled with fluid, mucus, blood, or debris, even piping in 100% oxygen, there is often very little gas exchange that occurs into the blood. These patients will develop refractory respiratory failure and severe hypoxia - lack of oxygen throughout the body - and die. Our former Chief Medical Officer, Dr. Robert Bartlett, had pioneered ECMO as a way to provide gas exchange outside of the body like you would do in open heart surgery, for example. I think there has been a resurgence in the interest in ECMO away from being just strictly a rescue therapy, but now being used as a primary therapy for not only gas exchange but also for hemodynamic support because of a new mode called veno-arterial ECMO, which takes blood out of the veins and pumps it directly into the arteries and provides blood pressure support in doing so.

As we disclosed last quarter, we have had more than 1,000 ECMO treatments where CytoSorb has been used in conjunction with ECMO to help reduce the inflammatory toxins that are wreaking havoc around the body, particularly in the lungs. Again, ECMO is used for gas exchange and hemodynamic support but does nothing to reduce the toxic inflammatory burden that is common in patients with life-threatening illnesses in sepsis, burn injury, trauma, pancreatitis, and many other illnesses. But with our therapy, we are adding removal of inflammatory toxins and control of the inflammatory response to the solution. We have seen clinicians have good success in helping stabilize their patients with this solution. We are by far the leader in this field. We feel this is a very important growth area for us and this ECMO kit allows us to be able to swap out the device on a daily basis without causing any undue risk to the patient on ECMO.

Josh Jennings:

Thanks, and my last question is just on the clinical development program in the U.S., the REFRESH trials. Congratulations on the hiring of Dr. Mortensen. Is there any timeline that you can provide? I understand that there may be not a specific timeline, but just in terms of the IDE submission for REFRESH 2, are you still on track to begin enrollment by the end of the year? And then lastly, should we be expecting publication of REFRESH 1 sometime in 2017? Thanks for taking the questions.

Phillip Chan:

Sure. Before I turn it over to Eric to comment on our timeline for REFRESH 2, the REFRESH 1 study has been submitted for publication. The investigators are responding to reviewer comments and will be resubmitting that back very shortly. That is planned for this month and so our hope is that it is accepted and published this year, but we will have to wait and see on that. Eric, would you like to try to comment on the timing of our submission and whether or not we are on track with REFRESH 2?

Eric Mortensen:

Sure, Phil. Just first before I answer the question, I want to thank you for the extraordinarily gracious introduction. I am happy to be coming on board and just note that I hope to be able to satisfy the very high expectations you provided. It has been fantastic being on board the past 67 days, at this point in time.

Getting back to the question, currently, we expect the REFRESH 2 study initiation to happen this year. We are planning for success at this point, and we are well underway and working with contract research organizations to have resources in place to support the study initiation later this year. Now, of course, that is subject to a successful conclusion of our discussions with the FDA and for that reason we are working very diligently to ensure that the study design incorporates prior discussions with the agency as well as recent experience in clinical trials in this therapeutic area, in order to be able to accelerate towards both an IDE approval as well as the study initiation.

Josh Jennings:

Great. Thanks, again.

Operator:

Moving on, from B. Riley, we have Andrew D'Silva.

Andrew D'Silva:

Hey, guys. Thanks for taking my call, just a couple of quick questions. First off, as you start thinking about growth, particularly in Germany, now that you have established this reimbursement code where the device and procedure are covered, is the same growth rate going forward plausible compared to what you have seen historically, even though your revenue base in Germany is larger than it has been in previous years?

Phillip Chan:

Hi Andy, thanks. Yes. I think that we are just scratching the surface of the market in Germany, but we have laid the foundation for growth. We have strong key opinion leader support from throughout the country. We have strong support from major medical societies, ranging from the German Sepsis Society, to the Society of Nephrology, the Cardiothoracic Surgery Society and others. We have a strong direct sales team. And we think that with this increased reimbursement, it will relieve a major bottleneck on CytoSorb sales in Germany where we expect to see an acceleration of CytoSorb growth and usage going forward. As we mentioned last year, we achieved $1 million in CytoSorb sales from a single hospital account, and we think that is very easily plausible in many of our existing accounts on a go-forward basis, and hope to be able to show that to you in the coming quarters.

Andrew D'Silva:

Great, and just touching on that $1 million hospital, is there particular indications that they're seeing or utilizing CytoSorb more in or having success in, and are they fully integrated throughout various divisions of the hospital or just particularly one segment?

Phillip Chan:

We have strong usage in both critical care as well as in cardiac surgery at that account. I think it helps to validate the focus on these two verticals.

Andrew D'Silva:

Great. Fantastic. Just a couple more quick questions for you; you've been spending a little bit of time with the U.S. military in various capacities. Is there anything new going on there? Obviously, they don't need to go through the full approval process domestically to start placing orders in case of emergencies and things of that nature. Can you give any color on how discussions are going or what opportunity might be lying ahead?

Phillip Chan:

Well, we are very much looking forward to the Military Health System Research Symposium (MHSRS), formerly known as the Combat Casualty Care Conference, later this month. We have been selected to present a number of posters and we will have quite a few meetings lined up to talk about some of the very exciting new data that we have in our R&D programs that are funded by the military, as well as some others that are external collaborations with some other universities. We hope to be able to share those exciting data in the future but I think that based on what we see, there is a lot of opportunity here to help support the brave men and women in our military in the future.

Andrew D'Silva:

Thank you. Last question, just as it relates to Novartis, Dr. June, Penn, and the CAR-T recommendation by the FDA review committee, could you maybe explain a little bit of how those dynamics work there? I know that Novartis has a global collaboration agreement with Penn and Dr. June is the head of that division at Penn but is Penn still highly involved with Novartis and if so, what is their solution right now for Cytokine Release Syndrome and how do you think things will progress with you guys going forward?

Phillip Chan:

I can't really speak to the strategy at either Novartis or Penn and would be out of place to do so. But that being said, I think that when you look at most of the CAR-T cell immunotherapy studies, you will find that Cytokine Release Syndrome is the primary adverse event that happens in these illnesses. Whether or not it's a traditional cytokine storm leading to organ failure and potentially death, or it's the encephalitis that occurs from on-target but off-tumor effects for the CAR-T cell immunotherapy in the brain and others, we think there is a role for CytoSorb in the treatment of those types of excessive inflammatory reactions. Today, the first line therapy is to use tocilizumab, which is an anti-IL-6 receptor antagonist, to try to control the Cytokine Release Syndrome. But if you talk to many in the industry, it sometimes works and sometimes works very well, but in many cases does not work, and forces clinicians to turn to high-dose steroids as a means to basically just shut off the immune response. But the problem with high-dose steroids is that it can trigger apoptosis, or death, in the CAR-T cell immunotherapy and if you look at some of the published reports that are out there where one therapy for one patient could cost north of a quarter million dollars, what you do not want to do is potentially jeopardize that immunotherapy. What you want to do is just bring the inflammation under control so that the modified T-cells can then hunt and seek out the cancer and kill those cancer cells. We think that CytoSorb represents a good intervening strategy, a strategy between tocilizumab and steroids as a way to treat cytokine release syndrome.

Andrew D'Silva:

Great. Thank you very much. Good luck going forward and good job this quarter.

Phillip Chan:

Great. Thanks a lot, Andy.

Operator:

Moving on, from Aegis Capital we have Evan Wang.

Evan Wang:

Hi. Thanks for taking the question. First of all, regarding sepsis, I know you guys are getting more and more data from patients in Europe, and was just wondering if you can give some update on your thoughts on what you guys need before you initiate a large U.S. trial for sepsis?

Phillip Chan:

Thanks Evan. I think, as we tried to outline in the presentation, the goal is not to do the big large-scale, all-inclusive study. I think that has been one of the failings of most clinical trials in sepsis. There is too much heterogeneity that comes with taking all patients from all walks of infection and walks of life. That is not the way to do these clinical studies. We believe that the smarter strategy is to focus on those subgroups where CytoSorb has worked very well and very reproducibly, and to conduct initial validating studies in those areas, and then pivotal studies to either obtain approval or expand the label for CytoSorb in the United States and elsewhere. We think that in many of these subgroups, the effect size has been observed to be so large that potentially, even the pivotal trials may be not need to be very large at all, and therefore be a very good use of our resources. That is sort of where we stand at the moment and I think, again, with the leadership of Dr. Eric Mortensen, we plan to execute upon that strategy.

Evan Wang:

Okay. Thanks for clarifying, and could you provide any kind of timeline for that?

Phillip Chan:

We have been going over many different trial designs for many different areas of where we have seen CytoSorb work very well. We are looking to try to get a study going on in the United States as well as studies abroad as well, and we will have more detail on that as the clinical team finalizes those plans.

Evan Wang:

Okay, thanks, and just a question, do you guys happen to break out the direct and the distributor proportions of product sales?

Phillip Chan:

We've not done direct versus distributor, but we have done Germany versus the rest of the world. Kathy, would you want to comment on that?

Kathleen Bloch:

Yes, I think I can give you some color on that. Germany represented about 67% of our total sales for the first half of 2017. While we haven't revealed the contribution of the other direct countries, I can just tell you that it is small – somewhere between 0% and 10% compared to Germany. We also just got started in Belgium and Luxembourg, so we have not had a meaningful contribution from them yet.

Evan Wang:

Okay, and I guess going forward, should we expect product gross margins to stay around the 65% range, or will lower-margin distributor or partner sales from groups like Fresenius and Terumo cause gross margins to decline?

Kathleen Bloch:

It will vary by quarter depending on the mix of direct and distributor sales. But I would say between 65% and 70% product gross margins is what we can expect in the near term and then I think it will improve once we move over and begin volume production when the new manufacturing facility is up and running.

Operator:

Moving on, from Zacks Investment Research we have Brian Marckx.

Brian Marckx:

Good afternoon, everybody. Congratulations on the quarter.

Phillip Chan:

Thank you Brian.

Brian Marckx:

First, was there anything lumpy in the quarter? I know you get this question all the time and haven't heard it yet, so I'll take the reins this time. Was there anything lumpy in this quarter in terms of revenue, such as stocking orders or such, that may make sequential revenue growth into Q3 challenging?

Phillip Chan:

I think there was pretty much strength across the board. We are seeing very good strength in direct sales but also a lot of the distributors have been moving forward as well. We are looking

forward to, as we said earlier, a strong second half of this year that is expected to exceed the first half.

Brian Marckx:

Okay, great. In terms of the potential CAR T-cell immunotherapy opportunity, what does the near term looks like in terms of next steps for CytoSorbents and then can you expand on the broader view…is this something down the road where you think there might be a potential collaboration opportunity, assuming the Novartis's candidate is eventually FDA-approved, that you could potentially collaborate with Novartis?

Phillip Chan:

What I would say is that we've been invited by many of the leading cancer centers that have been conducting these cancer immunotherapy trials to give a talk on our therapy and I think there was strong interest across the board to try the therapy. But at the time, mixing in a product that was not yet approved in the United States with another product that was not yet approved in the United States, just could not be done. I think one of the reasons why we are so excited by the pending likely approval of the Novartis program is that there has been some wide speculation that this could happen by the end of the year. If that happens, then we could potentially be used in post-market studies in the treatment of Cytokine Release Syndrome, on an approved product. Again, I think there is a lot of interest to do so, just the timing in the past hasn't been right, but I think on a go-forward basis, that represents a good opportunity for us.

Now, from a collaboration standpoint with the cancer immunotherapy players, I think most actually know who we are and know our technology but, again, in the past, the timing wasn't right. We hope that on a go-forward basis with Novartis and then likely Kite getting the next approval, there may be opportunities for us there and certainly our association with Dr. June as a scientific advisor is very helpful.

Brian Marckx:

Okay, and then in terms of REFRESH 1 and potentially moving into REFRESH 2, is there anything that you can talk about relative to your recent discussions with FDA and any feedback that they have given you? In particular, are there any concerns relative to the safety profile that you saw in REFRESH 1 with getting IDE approved for REFRESH 2?

Phillip Chan:

We will have an update on REFRESH 2. With Eric coming on board, I think we've delayed the submission to the FDA a little bit because we wanted him to make sure that he was up to speed on all the data analysis and up to speed on the clinical trial strategy. I think he's done a fantastic job in terms of optimizing the protocol to try to increase the chances of both technical as well as clinical success, and we'll have an update for you when appropriate.

Brian Marckx:

Okay. Perfect. Thanks, Phil. Appreciate it.

Phillip Chan:

Sure. Thanks Brian.

Operator:

Once again, folks, that is *1 for any questions.

Next from Maxim Group, we have Jason Kolbert.

Jason Kolbert:

Hi, guys. Jason here with Gabrielle Zhou. I see the star building but I think it would be really helpful for us to step back a little bit and say, what does it take to get to critical mass for sales and what would your target for critical mass be? That's the first part. Yes, we're very excited about CAR-T and about the prospects in the U.S. of the REFRESH 2 clinical trial. What I'm trying to understand is, given the week-to-week driving effort by the sales force around the globe, what's it going to take to hit some more significant numbers?

Phillip Chan:

I think that what you are seeing already is a very nice upward trend on a year-over-year basis in terms of sales growth. I think that is reflecting the progress that we are seeing, both in our direct territories but also in our international sales, and we expect that our partners and their progress will be a further catalyst to that growth. I think that what you are not seeing is plain, linear growth. If you go back to that 12-month trailing revenue chart, you can see there is a very nice acceleration of growth. Now, our interim target is to get to operating profitability. We think that will be a very important inflection point for our business and will significantly cut down on the cash needs of the company, and also make our company much more attractive to a wide variety of different interested groups.

We are guiding that we will hit that breakeven point, at approximately $20 million in product sales in 2018, representing a doubling of trailing 12-month sales from this point. That's nice growth. I think that if you track the sales growth of other medical device companies or other companies in general, that growth has led to significant increases in market awareness and ownership of those stocks across the board.

Gabrielle Zhou:

Hi, it's Gabrielle here. I do have a follow-up question in terms of increasing sales. If you can deploy more resources, do you think it makes sense for you to add more sales people to drive the revenue growth?

Phillip Chan: ***[This section has been elaborated upon]***

What we are trying to do is have a balance of strong growth but also the ability to achieve operating profitability. Growth obviously is our primary concern, but it is not growth at all costs.

I think that you may have seen the news today that Fresenius will acquire NxStage Medical for $2 billion. NxStage Medical is a dialysis machine and disposables company that sells its System One dialysis machine. This is a small footprint machine that has become popular in the U.S. and other countries, particularly in critical care and home dialysis because of its relative ease of use. It uses cassettes that are simply inserted into the machine, and requires less user technical know-how than other dialysis machines. This is a good company, with good products. We know them, having collaborated with them in DARPA and in one of our clinical studies. NxStage has grown at a tremendous rate over the years. However, with about $380 million in sales, they are just nearing profitability, with about $5 million in losses. On the verge of profitability, they were acquired for roughly five to six times sales.

This is an acquisition that makes a lot of sense for Fresenius. It immediately gives them a leading market share in critical care in the U.S. and adds new growth opportunities in home dialysis. This is in addition to the Xenios AG acquisition last year, which added extracorporeal lung (Novalung) and hemodynamic support devices to its machine offerings. In particular, Novalung is an extracorporeal membrane oxygenation (ECMO) machine that can also remove carbon dioxide. What can be seen from both acquisitions is the longer term strategy of being a dominant player in the critical care market and their commitment to this space.

In our case, we are optimistic about our partnership with Fresenius because CytoSorb represents the high margin disposable that can be used across Fresenius' new and legacy machines in the ICU. This represents a future area of high potential growth opportunities for our company.

In addition, you can see from this acquisition that a significant premium is paid for accretive businesses that are profitable or will be in the near future. As a company that expects to get to operating profitability next year, after which $0.50 on every dollar is expected to drop to the bottom line, CytoSorbents has the ability to be a very profitable company. We think that the market will recognize the fact that we are an enabling, life-saving technology that is highly strategic to multiple international device companies in critical care and cardiac surgery, with tremendous profitability characteristics. Whether this is reflected in the stock price or through M&A interest, we think this is a major positive for our shareholders.

So we are trying to achieve that right balance between growth and profitability, but are certainly adding headcount in key areas that we think will accelerate future growth. We are not afraid to make those investments and we have been doing so.

Gabrielle Zhou:

Great. Thank you, and again, congratulations on a great quarter.

Phillip Chan:

Thank you very much Gabrielle.

Operator:

Moving on, from H.C. Wainwright, we'll hear from Sean Lee.

Sean Lee:

Hi, guys. Congratulations on the quarter. Most of my questions have been answered. I just have a quick one. You mentioned that Fresenius is planning to start co-marketing CytoSorb in five additional countries soon. Could you provide a little more color on the relationship, like how has this helped your revenues or at least helped CytoSorb with the visibility it brings?

Phillip Chan:

Sure Sean. Before I turn it over to Chris for some color commentary, it is kind of very interesting when you look at the Fresenius acquisition of NxStage Medical that was announced today. It fits very much in line with the overall strategy, speaking just strictly from what has been publicly announced, that Fresenius wants to grow in both the critical care and home dialysis markets. It is also not well known that NxStage is actually a leader in critical care dialysis in the United States. It is one of the top-two players next to Baxter in the U.S. and their market share was actually very large. We, I think, also fit in that strategy, where we are the high margin disposable that fits into that whole game plan. That being said, let me have Chris provide some color on where we are with that co-marketing agreement.

Chris Cramer:

Sure. Thanks, Phil. The co-marketing work has made some significant strides in Q2. The generic process which we had worked out with FMC, things like the set up requirements and sales process roles and responsibilities, has been nailed down and we are now working with the local in-country FMC sales managements, as well as our distributors, to coordinate the implementation for each country, and this will move on a country-by-country basis. This is something that involves support from our sales team in Germany who are working closely to make this happen, along with our distributors. As Phil mentioned, we are planning to start with five countries right now that are

all active with our product and the plan is to roll it out, perfect the model, and then scale it to other countries. We just want to make sure we have worked out all of the bugs in the co-marketing model as we take it broader beyond that. That is where we stand right now, so I think we'll see it move relatively quickly as we finish out the rest of the year.

Sean Lee:

Thank you for the clarity on that. My second question is on reimbursement, and from the looks of it, it has been a major driver in the growth in German revenues over the last two quarters. Is the Company or any of your distributor partners looking to expand the reimbursement in other countries as well?

Phillip Chan:

Absolutely. CytoSorb is being reimbursed or paid for through a variety of different mechanisms in different countries but we certainly have the resources focused on trying to achieve reimbursement or enhanced reimbursement in major countries that are strategic to our overall growth. I think that those plans are moving along and I think with the addition of additional clinical data, we will be making progressive improvements in reimbursement across the board. I think it just takes time, these things are not fast. They actually require a lot of resources, but it is one of the priorities of our commercialization efforts.

Sean Lee:

Thank you for taking my questions.

Phillip Chan:

Sure.

Operator:

Ladies and gentlemen, that does conclude our question-and-answer session for today. I'd like to turn the floor back to Management for any additional or closing remarks.

Phillip Chan:

Thank you very much everyone. I'd just like to add that I'm very proud of the CytoSorbents team and the work they have done to help us achieve the success we have had to date. In addition, all of us here at CytoSorbents extend a sincere thanks to our Board of Directors, as well as all of you, our loyal Shareholders, for your ongoing support. Looking forward, we will have several updates on our ongoing programs and look forward to providing regular updates on our quarterly calls. Thanks everyone for taking the time for this update call. We appreciate your participation and if

you have any additional questions, please reach out to Bob Yedid, at bob@lifesciadvisors.com, and we will try to get to you answers to your question where possible. Thanks very much.

Operator:

Thank you. That does conclude our conference for today. I'd like to thank everyone for their participation.