CytoSorbents Corporation (NASDAQ: CTSO)
Q3 2017 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 Third 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, Monique Kosse. Please go ahead, Ms. Kosse.

Monique Kosse – Moderator:

Thank you and good afternoon. Welcome to CytoSorbents Third Quarter 2017 Operating and Financial Results Conference Call. Joining me today from the company are:

- Dr. Phillip Chan, Chief Executive Officer and President
- Kathleen Bloch, Chief Financial Officer
- Vincent Capponi, Chief Operating Officer
- Dr. Eric Mortensen, Chief Medical Officer
- Dr. Christian Steiner, VP of Sales and Marketing, 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 projections as to the Company's future performance represented by management include estimates today as of November 9, 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 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. Phillip Chan:

Thank you very much Monique, and good afternoon everyone.

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We are pleased to report record total revenue in the quarter of $3.8 million with $3.4 million in CytoSorb sales due to strong reorder rates with product gross margins of 69%.

During the quarter, we achieved a total of 31,000 cumulative CytoSorb treatments delivered, up from 17,000 a year ago. Looking forward to 2018, we see numerous revenue catalysts coming online including our co-marketing agreement with Fresenius Medical Care, which has now begun in five countries. The agreement is expected to roll out to all 44 of our countries, where possible, as we gain more experience with this mutually beneficial relationship. These initial 5 countries differ from the six countries where Fresenius has been already selling CytoSorb, and where they have exclusive distribution rights.

In addition, we are benefiting from the new reimbursement in Germany for CytoSorb and are already seeing the initial positive impact of that on our direct sales. During the quarter we also launched our CytoSorb Therapeutic ECMO™ kit which is designed to accelerate the use of CytoSorb in the application of extracorporeal membrane oxygenation where we have already logged in more than 1,000 treatments to date.

In addition, there has been a lot of new published and pending data out there, including studies published in the area of refractory shock, endocarditis, and the third analysis of our CytoSorb registry. There are also pending publications in the area of meningitis, the first case report on the use of CytoSorb in the treatment of acute exacerbations of autoimmune diseases like multiple sclerosis. There is also data pending on the use of CytoSorb to treat seven patients with H1N1 influenza, the deadly strain of the flu virus that caused the 2009 pandemic that is still circulating in the population, which is particularly timely and relevant given that we are entering into a new flu season. We also reported new animal data where the use of CytoSorb led to increased survival following traumatic brain injury and hemorrhagic shock, two of the major ways people die following a traumatic injury.

In addition, we announced that we have had a lot of different initiatives driving new innovation. We were awarded $1.7 million in grants and contracts to develop new polymers for the development of universal plasma for the blood transfusion industry and also new polymers for the treatment of severe burn injury. During the quarter, we also entered into a co-development deal with Aferetica for *ex vivo* solid organ rehabilitation, where we are looking to rehabilitate substandard donated organs for organ transplant that are often otherwise discarded because of their poor condition, using an *ex vivo* perfusion system with our sorbents to be able to improve their function so that they can be successfully transplanted into patients who need them.

In addition, there have been some new developments in the CAR-T Cell immunotherapy space with the approval of Kymriah by Novartis and Yescarta by Kite Pharma, now owned by Gilead, which should pave the way for European approval and, therefore, usage of CytoSorb to treat cytokine release syndrome in Europe and potential future usage of CytoSorb to treat cytokine release syndrome in the United States.

Slide 5:

As an update to REFRESH II, we met with the FDA and are in collaborative discussions with them, designed to drive final IDE application approval. The current trial remains focused on high risk valve replacement patients. Once we finalize our discussions with the FDA, we plan to have an update on the final design in the near future, and pending those FDA discussions, we anticipate the start of REFRESH II this quarter.

A corollary to the REFRESH II trial is a particular subgroup of valve replacement patients who have infective endocarditis. Infective endocarditis is a bacterial infection of the heart valve that occurs when bacteria seeds the heart valve. This can happen from a dental procedure in people who have a pre-existing heart murmur who do not take prophylactic antibiotics. Bacteria can get into the bloodstream from the mouth, and colonize the heart valve. But the incidence of endocarditis, and the severity of endocarditis, has been on the rise because of the opioid epidemic and IV drug abuse, like heroin, and the use of dirty needles. This type of endocarditis often involves the infection of the heart valve with very deadly skin bacteria. These types of infections can rapidly destroy the heart valve within days, leading to a patient who is not only very sick from the infection and who has sepsis, but also a patient whose heart valve is destroyed which can contribute to a state of heart failure, leading to a very unstable patient. When this happens, they require a valve replacement. However, these patients are often very difficult to manage both intraoperatively and postoperatively because of their blood pressure instability. They typically require vasopressors during the surgery and then vasopressors and mechanical support following the surgery, and typically have poor outcomes including a high risk of death.

Recently, Professor Karl Trager and his colleagues at the University of Ulm published the largest CytoSorb endocarditis case series to-date. This study involved 39 endocarditis patients where

CytoSorb was used during valve replacement surgery. All of these patients were very sick going into the surgery, and required emergent or urgent surgical valve replacement. Based upon their pre-operative risk assessment Euroscore II rating, these patients had a very high predicted mortality following cardiac surgery.

What was very interesting about this particular study was the comparison with endocarditis patients undergoing valve replacement surgery, but without CytoSorb, in another case series in France. This study, authored by Patrat-Delon and colleagues, was recently published in another journal, and evaluated the risk of death of their patients based on the Euroscore II. When they looked at the Euroscore II rating, which is a predictive algorithm for looking at mortality of patients undergoing cardiac surgery, they found that for those with a Euroscore II of less than 40, the observed mortality was 18%, while those with a Euroscore II of 20 to 40 had a mortality of 42%. A Euroscore II greater than 40 has an extremely high risk of death. In contrast, when you look at the Traeger study using CytoSorb during valve replacement surgery, the mortality of those with a Euroscore II of less than 40 had a mortality of 7%, and a mortality of only 17% when the Euroscore II was between 20 and 40. This study represents another subset of valve replacement patients where CytoSorb appears to be having a very important impact and a study area in the future, outside of the REFRESH II study.

Slide 6:

We were also very pleased to have reported broader industry accolades for our Company. During the third quarter, we announced that we had won the 2017 Global Frost & Sullivan Product Leadership Award in Blood Purification, and based on the press release that Frost & Sullivan had issued, “There were many factors that led to our selection of CytoSorb for this year’s Global Product Leadership Award,” said Frost & Sullivan Research Analyst Aish Vivek. “Among the most important was the recognition that this innovative product is surprisingly well-positioned to help solve two long-standing, difficult, and tightly linked fundamental problems with hospital medicine today. These include the high rates of death from common critical illnesses such as sepsis that have no approved treatment, and the resulting staggering costs and losses in critical care that are financially crippling hospital networks and healthcare systems throughout the world.”

We are also pleased to announce today that we have been listed to the 2017 Deloitte Technology Fast 500 as one of the fastest growing companies in North America. We logged in 293% revenue growth during the periods of 2013 to 2016, and in the Fast 500, we ranked 7th out of a total of 21 medical device companies in terms of growth. We also ranked 297th out of 500 companies in any industry overall. We are very pleased that our profile has been rising in the broader community and we hope that more such accolades will be forthcoming.

With that, let me hand it over to Kathy who will talk about the financial highlights for the quarter. Kathy?

Kathleen Bloch:

Slide 7:

Thanks, Phil, and good afternoon everyone. For today's call, I will provide an update regarding our third quarter 2017 financial results, product sales progress, and also an update around our working capital and cash runway.

Slide 8:

Total revenues, which include product sales and grant revenue, were approximately $3.8 million for the third quarter of 2017 as compared to approximately $2.4 million for the third quarter of 2016, which is an increase of approximately 59%. CytoSorb product sales for Q3 2017 were approximately $3.4 million which is our best quarterly product sales ever. This represents a 61% increase over product sales of approximately $2.1 million for Q3 2016.

Our Q3 2017 annualized product sales run rate rose to $13.8 million compared to an annualized run rate of approximately $8.6 million one-year ago. Q3 2017 gross margins rose to approximately $2.3 million, an increase of approximately $860,000 as compared to gross margins of approximately $1.4 million for Q3 2016. Gross profit margins on our product sales were approximately 69% for Q3 2017 as compared to 68% for Q3 2016, primarily as a result of the mix of direct and distributor sales.

Slide 9:

Turning to our nine months financial results, total revenues were approximately $10.5 million for the first nine months of 2017 as compared to $6.4 million for the same period in 2016, which is an increase of approximately 63%. CytoSorb product sales for the first nine months of 2017 were approximately $9.1 million, which is a 62% increase over product sales of $5.6 million for the first nine months of 2016. Our grant revenue grew 67% from $850,000 for the first nine months of 2016 to $1.4 million for the first nine months of 2017, largely as a result of revenue from new grants.

Slide 10:

Next, we'll take a quick look at our quarter-over-quarter product sales. Q3 2017 sales of $3.4 million were significantly higher than Q2 sales of $3 million. That's a 13% quarter-over-quarter increase in sales, and the sales growth pace remains very strong.

Slide 11:

Next, let us take a look at our trailing 12 months product sales chart. We believe this chart best demonstrates the increasing trajectory we are experiencing with regard to our product sales. Our trailing 12 months product sales have climbed to $11.7 million for the 12 months ended

September 30, 2017, as compared to $7.1 million for the 12 months ended September 30, 2016, an increase of 65%. Phil has already discussed numerous catalysts which are expected to continue to fuel sales growth in the future.

Slide 12:

Now, with regards to working capital, as of September 30, 2017 we had approximately $15.4 million in cash and short-term investments. This includes the net proceeds of the $10.3 million received from our April 2017 equity financing, an additional $5 million received in June 2017 as a result of drawing down the second tranche of our debt facility with Bridge Bank, and an additional $1.5 million of cash from the sale of common stock using our at-the-market controlled equity offering during September 2017, and another $1.1 million in at-the-market equity sales occurred after September 30, 2017. We are pleased to report that we believe this will provide sufficient funding to support our operations into 2019.

Turning to our capital structure, as of September 30, 2017, we have approximately 33.4 million common shares on a fully diluted basis.

Slide 13:

Now for some guidance. We have not historically provided guidance on quarterly results until the quarter has officially been completed, but we do continue to guide that second half 2017 sales will exceed first half 2017 sales. Also, in light of the numerous catalysts expected to fuel growth in the future, we remain extremely confident that we will reach operating breakeven which excludes non-cash expenditures and excludes the cost associated with clinical trials, in 2018.

Finally, we expect that our new manufacturing facility will become operational during the first quarter of 2018, and with the ability to produce larger batches, we can expect to see further improvements in product gross margins during 2018 as well.

Now, I'd like to turn the call back to Phil. Phil?

Phillip Chan:

Thanks, Kathy. That ends our formal presentation. I would now like to open up the call for Q&A. Operator?

Operator:

Thank you. If you have a question press star, one on your touchtone phone. Please make sure your mute function is turned off to allow your signal to reach our equipment. We do ask that you please limit yourself to one question and one follow-up question.

We'll take our first question today from Josh Jennings with Cowen.

Joshua Jennings:

Hi, good evening. Thanks and congratulations on the record product revenue quarter. Hi Phil.

Phillip Chan:

Hi Josh. Thanks very much.

Joshua Jennings:

I understand you guys aren't giving a formal update on guidance and want to stay at a high level. But your current guidance of second half product sales being higher than the first half, gives a potentially really low number for Q4. From a high level, is there anything we should be thinking about in terms of our forecast, why the fourth quarter shouldn't be at Q3 levels from a product revenue standpoint or even sequentially higher?

Phillip Chan:

No, I think that our guidance has been consistent with our policy on guidance that we've given in the past. I think that you can see clearly from the quarterly revenue growth that the momentum continues to proceed. We don't see anything in the near term that could potentially affect that but we don't intend to change our historical guidance practices at this time, so we're not offering more than that. But I think that investors should be comfortable that the business is proceeding as we have planned, and that not only do we anticipate this year to be a strong year but 2018 should be a very strong year as well.

Joshua Jennings:

Excellent. Thanks for that extra commentary. I also just wanted to check, you had such a strong product revenue quarter, I wanted to hear about any details. You had some tailwind in Germany with reimbursement, and I think German revenues have accounted for around 60% of total product sales over the last number of quarters but it also sounds like you had a pickup on the distributor side as well. Any further color in terms of the proportion of sales in Germany, and also the incremental success you're having on the distributor side of the business?

Phillip Chan:

Yes, I think what we said before is that Germany has benefited in a number of different ways. Not only is it a country that we initially began selling in, so it has about a year or more in terms of selling effort than most of our other countries, but this is a country where we have a tremendous amount of key opinion leader support, very strong support from multiple medical societies, a world class dedicated sales force, and now dedicated reimbursement that in some

cases is twice what hospitals were getting previously for CytoSorb. It remains a very strong country with a lot of good momentum where we are in most of the major public hospitals and university hospitals and a lot of the mid-tier hospitals as well. New accounts continue to grow in the country but our sales in the country are dominated by reorders. I think this is very important because it demonstrates that the device is being used again and again by clinicians where they have had success.

Germany will certainly continue to represent more than half of our revenue going forward, but what we do see is a lot of strength in a number of different countries and from different strategic partners where there is momentum in sales in many different applications, that we expect to continue. I think that we have some more work to do in terms of continuing to ensure that our international distribution runs the same path as our direct sales have done historically, but we are actively focused on that and look forward to that being a bigger driver of our sales growth in the future.

Operator:

We'll take our next question from Andrew D'Silva with B. Riley FBR Inc.

Andrew D'Silva:

Hey guys, thank you very much for taking my question. I have just a couple here. As far as REFRESH II goes, I know that you said that you met with the FDA. Are you getting any sort of sense on what the endpoints could be? Are they going to be more clinical in nature or do you think they could be fairly similar to what REFRESH I looked at?

Phillip Chan:

Yes, thanks Andy. Our goal is to make sure that we do a trial that is technically feasible but also results in a primary endpoint that can be used to help drive adoption and sales of CytoSorb in that market as well as reimbursement. There is a little bit of a play for what that endpoint should look like. I think that as a large, pivotal, registration trial, our focus is to demonstrate clinical benefit of the device, and although harder to show than a strict tool indication like a reduction in free hemoglobin that we focused on in the first study, I think that it will pay off in terms of the post-market usage of CytoSorb. We will discuss the actual primary endpoints once we finalize them with the FDA.

Andrew D'Silva:

Understandable, I was just trying to get a sense of where it was leaning at this point. Then I guess my last question is regarding Fresenius. The co-marketing agreement was supposed to rollout now, correct? Has that happened yet? Then if it has, are there any sort of data points that you can point to and how is it going so far?

Phillip Chan:

Yes, the co-marketing agreement has just rolled out. Even as of a few weeks ago, we were still putting the final touches on a lot of the preparations for doing this, but we having been rolling this out to five countries now. As I mentioned in my prepared remarks, these countries differ from the six countries (France, Poland, Denmark, Finland, Norway and Sweden) that Fresenius already has exclusive distribution rights to and has been selling to for more than a year. These are new countries where we either sell direct or through distributors or partners. With these five countries, our goal is to work out all the bugs and then roll this out more broadly.

Chris, did you have some additional commentary on that?

Chris Cramer:

Sure, thanks Phil. Hi, Andy. I think Phil hit the nail on the head. We can now see that the co-marketing activities have officially commenced. As a data point, we are conducting joint physician marketing activities this quarter in those five countries where either our direct sales team or our distributors will be working with the FMC Global in-country sales counterparts to introduce our product and get into or at least start talking to these FMC accounts that we don't have relationships with.

I think the other thing that Phil had mentioned is that, we'll be monitoring these initial countries in the roll out of this co-marketing program very closely just to make sure that we can resolve any issues or complications. There is nothing that we are concerned about right now and we are anticipating a smooth initial roll out. We look to scale this up and begin rolling it out to the remainder of our countries starting sometime in the first half of next year.

Operator:

We'll take our next question from Sean Lee with H.C. Wainwright.

Sean Lee:

Good afternoon guys, congratulations on a great quarter.

Phillip Chan:

Thanks Sean.

Sean Lee:

I've seen that your gross margins have been improving steadily over the last couple of quarters. Could you give us a bit more color on the pushes and pulls on that?

Phillip Chan:

Sure. Kathy would you want to take that, and then Vince maybe if you could add some color?

Kathleen Bloch:

Yes. The product gross margins move around a little bit and is mainly driven to date by the mix of distributor and direct sales. This past quarter we had product gross margins of 69%, which was very good, but does not yet reflect major reductions in our standard costs. We are still operating at the existing plant. What we do see going forward Sean, is real measurable improvements to those gross margins, especially once our new manufacturing plant starts up, which is expected to occur in the first quarter of Q1 2018. Then in early 2018, I think we will start to see blended gross margins in the 70%+ range and then growing from there.

Sean Lee:

Great. In terms of capacity, how much is the new plant going to help you?

Phillip Chan:

Vince, do you want to take that?

Vincent Capponi:

Sure, Sean. The plant is going to be capable of taking us well through operating cash flow breakeven. Right now with the first phase, we'll be able to do about $35-40 million worth of business out of it and then we have the ability to do some additional modifications to take us up to roughly $70-80 million in sales annually. The new plant is about 80% complete right now and we have already notified our regulatory authorities about the expansion with the goal of putting everything in place to bring the plant online in the first half of 2018.

Sean Lee:

Okay, that's great to hear. That's all I have, thank you again for taking my question.

Phillip Chan:

Thank you, Sean.

Operator:

Again, if you would like to ask a question please signal by pressing star, one.

We'll take our next question from Joanne Lee with Maxim Group.

Joanne Lee:

Hi guys, this is Joanne Lee speaking for Jason Kolbert for Maxim Group. The first question is related to the upcoming REFRESH II trial. Could you walk us through what the trial design might look like based on the data reported in REFRESH I, demonstrating the reduction in plasma free hemoglobin over several hours? What do regulators consider to be a clinically meaningful reduction and over what period of time to support regulatory approval?

Phillip Chan:

Previously I had mentioned that we would be looking at improvement in clinical outcomes that could include a wide variety of different measures of organ function. Kidney injury is common in complex cardiac surgery, but other complications such as the failure to wean off of mechanical ventilation, a drop in the blood pressure requiring the use of vasopressors, and other organ dysfunction are things that we will be looking at in a large pivotal registration study that is designed to drive U.S. approval for CytoSorb in the area of cardiac surgery.

Plasma free hemoglobin, activated complement, cytokines, and other inflammatory mediators are just some of the causative factors that can drive organ dysfunction. There have been a number of studies that have documented ranges of these substances, particularly free hemoglobin, that were associated with organ dysfunction such as acute kidney injury. But no one has been able to reduce these factors in a reproducible way in the past, so we are breaking new ground. Based upon what we saw in REFRESH I, we feel pretty good that the levels of reduction of these inflammatory mediators that we observed with CytoSorb gives us a good chance at impacting organ injury and dysfunction.

Joanne Lee:

Okay, thank you. The second question is related to CAR-T cancer immunotherapy. With Kymriah and Yescarta now approved, training programs and treatment protocols are being development and implemented which include the management of cytokine release syndrome (CRS). What are CytoSorbents plans in CAR-T going forward? Could we see CytoSorb emerge as part of the CRS treatment paradigm sooner than later with CAR-T now in the market?

Phillip Chan:

Yes. The benefit that we have in this field is that we are approved in the European Union for the reduction of cytokines and the treatment of cytokine storm, of which cytokine release syndrome is a subset. We have previously discussed the treatment of a dozen cases of a very similar disease entity called secondary hemophagocytic lymphohistiocytosis, or secondary HLH. Secondary HLH is characterized by a massive cytokine storm that is typically trigged by a viral infection. The interesting thing about secondary HLH is that is has a very similar clinical presentation to cytokine release syndrome seen in CAR-T Cell immunotherapy.

We have had a lot of success in treating secondary HLH, which is why we feel very confident that CytoSorb could help treat cytokine release syndrome in CAR-T Cell immunotherapy patients. We envision that CytoSorb can be used after tocilizumab, which is typically first line therapy to treat cytokine release syndrome, but before steroids which has been reported to be used on three quarters of the patients who get severe CRS. The problem with steroids is that it can kill or damage the very expensive CAR-T immunotherapy that costs between $300,000 to $500,000 per treatment. That would obviously be a bad thing.

In terms of usage in Europe, we benefit from the fact that we have had this clinical experience in HLH and are approved to treat cytokine release syndrome and cytokine storm in Europe and other countries where we are selling CytoSorb such as Russia, India, Vietnam, and many other countries. We think that once the approvals for Kymriah and Yescarta spread abroad, we will likely get some fairly rapid usage, particularly in Germany where we have a very strong footprint among most of the major hospitals that would be doing this type of therapy.

In the United States, we would look to try to do some clinical studies, looking at the ability of CytoSorb to treat cytokine release syndrome here. We have been fortunate to have had a lot of interest from a number of different cancer immunotherapy companies as well as critical care physicians at major cancer centers that have been involved in the clinical trials for CAR-T. Also, we were fortunate to have welcomed Dr. Carl June, the pioneer of CAR-T immunotherapy to our scientific advisory board early this year. We will give an update when we have more news.

Operator:

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

Brian Marckx:

Hi Phil, nice quarter, congrats on the product sales number, it looks great.

Phillip Chan:

Hi Brian, thanks.

Brian Marckx:

On your meeting with the FDA regarding REFRESH II, I know in REFRESH I there may have been a question about the drop in platelets in the CytoSorb arm versus a control arm. Is there anything about that relative to your meeting with FDA, and whether there was any concerns around that?

Phillip Chan:

I think that we have addressed any of those concerns appropriately, which also includes potential risk mitigation steps based upon an analysis of our data.

Brian Marckx:

Okay. Based on your expectations to start the study by the end of the year – the next seven or eight weeks – it sounds like you expect to hear back from the FDA relatively soon? Also, is your understanding that this will be sufficient as a pivotal study? Are those both fair assumptions?

Phillip Chan:

Yes, I think so. Although it is a tight timeline to get the study started by year end, we benefit from significant redundancy from REFRESH I and have been working in parallel to make sure we can stay on track. For example, we benefit from the fact that REFRESH I and REFRESH II are very similar type protocols where we are treating with CytoSorb intraoperatively. Also, in REFRESH II, we are looking at a subset of patients from REFRESH I, so we are actually narrowing the focus of the study. This will hopefully make it easier for the ethics committees to approve the protocol that will be similar to the one they approved for REFRESH I. We will also be starting in several of the clinical centers that conducted the REFRESH I trial, so the teams are already familiar with how to use CytoSorb. Finally, we have already negotiated the clinical trial agreements with many of our sites prior to REFRESH I, and would not expect the need for significant changes in the language. Because we have been working in parallel, we think that we are on track to get the study off the ground before the end of this year. We are certainly going to try.

Operator:

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

Phillip Chan:

Thank you everyone for joining the call. If you have any additional questions that were not addressed today, please feel free to reach out to Monique Kosse at Monique@lifesciadvisors.com and we will try to get back to you where possible. In the meantime, we look forward to the next earnings call and wish everyone a safe and healthy holiday season. Thank you very much everyone. Good night.

Operator:

Thank you. That concludes our call for today. I'd like to thank everyone for their participation.