CytoSorbents Corporation (NASDAQ: CTSO)
Full Year 2017 and Q4 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 afternoon, and welcome to the CytoSorbents 2017 Financial and Operating Results 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, Jeremy Feffer. Please go ahead, Mr. Feffer.

Jeremy Feffer

Thank you, Sophie, and good afternoon. Welcome to CytoSorbents' 2017 Financial and Operating 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. Eric Mortensen, Chief Medical Officer
- Dr. Christian Steiner, VP of Sales and Marketing from Germany
- Chris Cramer, VP of Business Development

Slide 2:

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 March 8, 2018, 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 operating and financial highlights for 2017 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 my pleasure to turn the call over to Dr. Phillip Chan. Phil?

Phillip Chan

Slide 4:

Thank you very much, Jeremy. Good afternoon everyone and welcome to our earnings call. 2017 was an exceptional year for the Company. We had record 2017 total revenue of $15.1 million with $13.4 million in CytoSorb sales due to strong reorder rates. We also had 2017 blended product gross margins of 71%, mixing higher margin direct sales with lower margin distributor and partner sales, up from 67% a year ago. We also had 35,000 CytoSorb treatments delivered cumulatively, up from 20,000 a year ago, and ended the year with a healthy cash balance of $17.3 million.

We expect that 2018 will be a transformational year for the company with the achievement of key milestones. These were detailed in the press release issued earlier today but in brief they are: achieving operating profitability on a quarterly basis - excluding non-cash expenses and clinical trial costs, progress towards potential US regulatory approval for two products, generation of new clinical data, new and expanded strategic partnership, and greater market awareness for our company and life-saving technology. Certainly in the Q&A period, we can cover any of these items in detail.

Slide 5:

Just to give you an update on key clinical programs. On the U.S. REFRESH 2 Study, which is a pivotal 400-patient randomized controlled PMA multi-center trial targeting the reduction of post-operative acute kidney injury using CytoSorb during complex cardiac surgery, including valve replacement and aortic reconstruction with hypothermic cardiac arrest, we have obtained FDA IDE approval as announced in late December, central ethics committee approval, and now CMS (Centers for Medicare and Medicaid Services) approval. We have also strengthened the clinical team to execute upon the trial. The majority of REFRESH 1 clinical sites will be participating in this REFRESH 2 trial, with several coming online in the near term, one of which is already screening patients with the first patient to be enrolled very soon.

The German REMOVE Endocarditis Study is a 250-patient randomized, controlled trial evaluating the safety and efficacy of CytoSorb used intra-operatively during valve replacement surgery for infective endocarditis. The primary endpoint is a reduction in the SOFA score. Importantly, this is a study that is being fully funded by the German Federal Ministry of Education and Research. Their interest in funding this study is due to the growing numbers of people with infective endocarditis due to the opioid crisis and intravenous drug use with dirty needles that can lead to infective endocarditis. This study has now enrolled its first patient and is beginning to ramp.

Slide 6:

Finally, our HemoDefend in-line filter for packed red blood cells is nearing human clinical trials. We have been making very good progress with the generous support of the National Heart, Lung and Blood Institute (NHLBI), as well as US Special Operations Command, or USSOCOM. This is a product that targets the 100 million packed red blood cells (pRBC) that are transfused each year worldwide. You may be familiar with many companies that are targeting the decreased risk of blood-borne pathogens in transfused blood products. These are companies doing either nucleic acid testing for viruses or pathogen reduction like Cerus or Terumo-BCT. In contrast, HemoDefend is complementary to these pathogen reduction technologies. HemoDefend pRBC is a point-of-transfusion in-line filter focused on reducing non-infectious contaminants that can cause transfusion reactions ranging from relatively mild fever and allergic reaction, to very severe transfusion-related acute lung injury which is the leading reported cause of transfusion-related deaths that occurs in roughly 1 in 1,000 to 1 in 5,000 transfusions. The HemoDefend pRBC in-line filter reduces antibodies, cytokines, free hemoglobin, bioactive lipids, and many other substances that can cause transfusion reactions. We have talked to the FDA informally, and with the support of NHLBI, we expect to initiate a pivotal study within 12 months that is designed to lead to US approval for HemoDefend pRBC.

With that, allow me to turn it over to Kathy to talk about the financial highlights. Kathy?

Kathleen Bloch

Thank you, Phil, and good afternoon, everyone. For today's call, I'll be providing an update regarding our December 31, 2017 financial results, product sales progress, and around our working capital and cash runway.

Slide 8:

CytoSorb product sales for the year 2017 were $13.4 million, which is an increase of $5.2 million or 63% over 2016 product sales of approximately $8.2 million. Grants and other income grew 34% from $1.3 million in 2016 to $1.8 million in 2017, and total revenues, which includes product sales and grant income, increased by 59% to $15.1 million for the year 2017 as compared to $9.5 million for 2016. As Phil mentioned, we are very pleased that our 2017 annual product gross margins grew to 71%, and this is primarily a result of product cost reductions that were achieved during 2017, and as we look to 2018, we expect product gross margins to further improve as our new manufacturing facility comes online in the second quarter.

Slide 9:

If we look now at our graph of annual product sales growth, we note that our compound annual growth rate, or CAGR, was 62% over the past three years and we are, of course, observing a very positive trajectory here.

Slide 10:

Let's also look at our quarter-over-quarter product sales. Our fourth quarter 2017 product sales of approximately $4.3 million represented yet another record product sales quarter. This is an increase of 25% over the previous quarter and we are very pleased with the solid quarter-over-quarter growth

that we have been experiencing. We've guided that at a quarterly product run rate of approximately $5.5 million, we expect to achieve operating breakeven, which excludes non-cash expenditures and also clinical trial costs. With our track record of strong revenue growth and numerous catalysts expected to fuel future sales growth, we remain very confident that we will achieve this important milestone in 2018.

Slide 11:

Lastly, we'll take a quick look at our working capital position. At the end of 2017, we had a record $17.3 million in cash, which is expected to provide funding for our operations, including clinical trial activities, into 2019. In the fourth quarter of 2017, through our At-The-Market (ATM) equity facility with Cantor Fitzgerald, we sold approximately 267,000 shares of our common stock at an average price of $6.58 which generated net proceeds of about $1.8 million. In addition, in December, the Company received a net cash amount of $677,000 from the sale of the 2016 state NOL and research and development credits under the State of New Jersey Technology Business Tax Certificate Transfer Program. As of December 31, 2017, we had approximately 33.5 million common shares on a fully diluted basis.

With that, I'd like to turn the call back over to Phil.

Phillip Chan

Slide 12:

Thank you very much, Kathy. In terms of guidance, we have not historically provided guidance on quarterly results until the quarter has been completed. We continue to expect that Q1 2018 CytoSorb sales will exceed product sales in the first quarter of 2017 and we remain very optimistic about our growth opportunities. We reiterate our guidance on continued growth and achieving operating profitability in 2018 on a quarterly basis, less non-cash expenses and clinical trial costs. We anticipate expansion of blended product gross margins, currently at 71%, as we scale manufacturing and our new plant comes on-line, as Kathy mentioned, in the second quarter of this year.

That concludes our current prepared remarks. Moderator?

Question-and-Answer Session

Moderator

Thank you. As a reminder, if you do have a question, please press *1 on your touchtone phone. Please make sure your mute button is turned off to allow your signal to reach our equipment. In order to ensure all analysts have a chance to ask a question today, please limit your questions to one follow up and then you may signal back into the queue if you have any additional questions.

We'll take our first question today from Sean Lee with H.C. Wainwright. Please go ahead.

Sean Lee

Good afternoon, Phil and Kathy, and thank you for taking my questions. Congratulations on a good year. I have two questions. One is on your projections for 2018. Why the conservatism in the first

quarter numbers? To hit the operational profitability, I would expect your quarterly numbers released by the end of the year to be quite a bit higher than what you achieved in 2017. What are some of the reasons or concerns that could cause seasonal fluctuations?

Phillip Chan

Thanks Sean. In the past, we've historically guided that our results would be improved year-over-year rather than quarter-over-quarter. With today's guidance, we are continuing that historical practice.

Sean Lee

Okay. It's not anything specific you've seen so far that's causing the conservatism in your guidance?

Phillip Chan

That is correct. From our quarterly results graph, you can see the trends that we have observed in the past, quarter-to-quarter. That said, results from Q4 2017 was the 22nd quarter of year-over-year increases in quarterly sales that we have seen. We expect that trend to continue.

Sean Lee

Okay, good to hear. Second, on the German Endocarditis study, could you provide a little more color on that since I don't think we've heard much about it previously?

Phillip Chan

Endocarditis is an infection of a heart valve. It is typically caused by bacteria getting into the blood in some way and then seeding the heart valve. In the past, many cases of infective endocarditis occurred in people with heart murmurs who did not take prophylactic antibiotics before dental work. Disruption of the gums can lead to bacteria spilling over into the bloodstream, ultimately settling on a faulty heart valve and causing an infection. The bacteria in the mouth are relatively benign and often cause a subacute bacterial endocarditis that can be treated with long term antibiotics. However a more acute infective endocarditis occurs when skin bacteria, such as Staphylococcus aureus or MRSA, or methicillin resistant Staph. aureus, infect the heart valve. This is much more common now because of the opiate crisis and the use of dirty needles and failure to clean the skin with IV heroin and other IV drug abuse. Staph aureus is a very dangerous and aggressive bacteria that replicates quickly, forms biofilms that protect it from antibiotics, and produces a lot of toxins that are very destructive. Staph aureus can destroy a heart valve in days, leading to patients presenting to hospital emergency rooms because they are septic from the infection, but also have elements of acute heart failure due to the destroyed heart valve.

What we have seen in many different cardiac surgery centers around the world is that infective endocarditis represents a very difficult disease to manage, both intraoperatively and postoperatively, particularly in patients that have aggressive infections. They often require the use of vasopressors during and after the surgery, may also require mechanical support such as extracorporeal membrane oxygenation (ECMO) after surgery, and stay in the ICU for a long time.

The German Endocarditis trial is a 250 patient randomized controlled trial that is looking at the ability of CytoSorb, when used intraoperatively during valve replacement surgery for endocarditis, to potentially reduce hemodynamic instability and improve clinical outcomes based on an improvement in the SOFA score, or Sequential Organ Failure Assessment score, which is the primary endpoint of the study. SOFA score is a commonly used endpoint that looks at a composite of organ function over time. The study is being fully funded by the German Federal Ministry of Education and Health and is being managed by the University of Jena, one of the clinical trial centers of excellence in Germany. The principal investigator fof the trial is Prof Dr. med Frank Brunkhorst.

One quick note. The opiate crisis and the heroin addiction crisis is not just in the United States. It is also in major countries, and westernized countries. I think the German government is funding this trial because they have recognized the potential of endocarditis to become a major scourge for their hospitals. Just as in the U.S., patients with infective endocarditis are in the hospital for long periods of time, consume a lot of hospital resources, and are very difficult to manage and expensive to treat. IV drug abusers also have the potential to get repeat infections, and when this happens to a prosthetic heart valve, they are often sicker than those coming in the first time, and have very difficult surgeries.

Sean Lee

I see. That sounds like a very promising indication for you. Do you have a rough estimate of the timeline for the study and also would you think that, if the study is positive, it will be sufficient to support a new indication for CytoSorb?

Phillip Chan

We believe that the REMOVE trial will enroll over two years, following a similar timeframe to REFRESH 2. It is interesting. REFRESH 2 focuses on elective, non-emergent, non-infected valve replacement surgery patients, as well as aortic reconstruction and hypothermic cardiac arrest. REMOVE focuses on infective endocarditis. Together, they form the spectrum of patients that are undergoing valve replacement surgery.

We believe that REMOVE is very well designed and a high-quality study. If positive, we believe that it may lead to an expanded approval of CytoSorb in the United States. We would still need to discuss the data with the FDA and whether or not we would need to do a repeat study in the U.S. But if we can get approved under the REFRESH 2 study for valve replacement and we present good, quality randomized controlled data from an endocarditis trial in Germany, it may potentially enable the FDA to fast track that particular indication, given that it represents a major unmet medical need.

Sean Lee

Just to clarify on that a little bit, in Germany, would this support an additional indication or reimbursement approval, for example?

Phillip Chan

In Germany, the use in infective endocarditis actually falls under the current dedicated reimbursement that was awarded in late 2016. In fact, most of the CytoSorb applications that are being performed in

Germany are on label given that CytoSorb is current indicated for use as an extracorporeal cytokine filter in diseases where cytokines are elevated.

Sean Lee
I see. Thank you for the additional color. That's all I had.

Phillip Chan

Sure. Thank you, Sean.

Operator

Next, we'll go to Andrew D'Silva with B. Riley FBR.

Andrew D'Silva

Good afternoon. Thanks for taking my questions. First, just a couple on the P&L, back of the envelope, am I correct in assuming that gross margins for the fourth quarter for products were close to 80%? On the R&D line, I am getting about $2.6 million, is that accurate and should that kind of be where we assume R&D to be at going forward?

Kathleen Bloch

I'll take that Andy. Yes, the grant income was about $1.768 million for the year and yes, the product gross margins were approaching 80% in Q4 2017.

Andrew D'Silva

Great. That's impressive. Thank you.

Operator

Next, we'll go to Jason Kolbert with Maxim.

Jason Kolbert

Hi, Phil, A couple of questions, can you talk about what it's going to take to start seeing revenues really breakout independent of a launch in the US, and can we talk a little bit about what's going on with the REFRESH study and what has to happen for that to get underway? Thanks.

Phillip Chan

Sure. A couple of years ago we talked about our business approaching the inflection point and when you look at product sales on an s-shaped curve, we believe that we are, in fact, beyond that point and actually entering into a potential phase of rapid growth. Now, quarter-to-quarter, year-to-year, that's all variable but we do believe that enough catalysts exist that will lead to very strong growth in the near future, potentially exceeding the pace of growth that we have seen to date. In terms of REFRESH

2, maybe let me have Dr. Eric Mortensen, our Chief Medical Officer, comment on his thoughts there. Eric?

Eric Mortensen

Sure, Phil. We are encouraged with where we are. Following a positive engagement with the FDA, at the end of December 2017, we had our IDE approved for REFRESH 2 with a one cycle review and approval of the protocol. Because of this, we were optimistic that we might be able to accelerate the next step of study start-up faster than what was traditionally possible. However, CMS approval of the protocol proved to be a bottleneck, which was an absolute requirement for trial sites before they could move forward with the serial steps of contract review and IRB review. That said, we now have CMS approval and are moving to aggressively bring on our initial clinical trial sites.

At this point, we now have one center that is already up and running and screening patients for enrollment. That was the one center that was actually willing to go a little bit faster and work in parallel in anticipation of CMS approval. The majority of other REFRESH 1 centers are coming on board and we have intentionally scheduled a staggered study and review. I have found over my career in clinical development that when you have a large number of centers, you really want to make sure that you are running smoothly. You want to battle test the protocol and understand the issues at these initial sites to make sure that you really have things going well before rapidly expanding to other sites.

We are already starting our protocol feasibility and contracting with additional centers and are planning to have those come on board after the WAVE 1 sites have gone through their initial start-up. We are very enthusiastic. As Phil said, we are hoping to have the first patient enrolled shortly and then continue on with those factors we have discussed to complete enrollment within a two-year time frame, potentially sooner.

Jason Kolbert

Thank you so much for the update.

Operator

Next, we'll go to Josh Jennings with Cowen and Company.

Brian Kennedy

Hi, guys. This is Brian here for Josh. Thanks for taking the question.

Phillip Chan

Sure. Hi, Brian.

Brian Kennedy

Hi. Can you provide an update on where you are in Germany, just in terms of establishing awareness of the favorable reimbursement terms you received there as of December 2016? Are most of your existing hospital customers aware of this now, and has it been a driver of new accounts for you?

Phillip Chan

Yes. This has been a key point that our sales reps are making on their sales visits, that this new reimbursement is established and that the hospital can leverage this new higher reimbursement code. Christian, maybe if you could comment on what you are seeing in Germany and how you think things are going?

Christian Steiner

Yes. Thank you, Phil. I can confirm what you just said, that the sales reps are visiting with the hospital administration in procurement, in addition to visiting the doctors and the departments who are performing the treatments, in both our existing customers, but also potential customers as well. Hospitals typically negotiate their operating budget and reimbursement once a year for the whole year. This can even be after the year has finished. That means sometimes hospitals need to start to treat without knowing exactly what the reimbursement will be. They can collect data from their own patients which supports the negotiations but they still don't know exactly what they will get in terms of reimbursement. Altogether, we believe the new reimbursement code helps a lot. The users and the hospitals see that the therapy, at least for the time being, is accepted by the payers and there are no problems like we had in the past with the older codes, so that hospitals can be sure that they get their money.

Brian Kennedy

Okay. Great. That's helpful. I wanted to ask about the manufacturing facility. What are the remaining operational steps needed to get the facility online next quarter and, specifically, is there anything to do from a regulatory perspective?

Vincent Capponi

This is Vince Capponi. I'll answer that question for you. Basically, what remains is qualification of the plant. We have loaded all the equipment in there and we have actually started to do all the test batches that are required for qualification of the facility. We expect it will be fully operational by Q2 2018 as we finish shaking out each of the individual processes. We have already scheduled, for the end of March, a regulatory review with our Notified Body. It is required that our Notified body come in and evaluate the manufacturing facility, as well as all of the systems, support systems, documentation, and other things, and confirm that we are meeting all of the ISO 13485 quality system requirements. We are well into that process which will not only lead to the increased capacity, but also to what we believe will be significantly higher gross margins once that capacity is brought online.

Operator

Once again, that is *1 on your touchtone phone if you have a question. We will go next to Brian Marckx with Zacks Investment Research.

Brian Marckx

Hi, everybody, and congrats on another great quarter and another great year. I know you guys get this just about every quarter but I think this warrants the same question. Given the fact that product sales were so strong, was there anything in product sales in Q4 that was, I guess, kind of unusual, stocking order or anything else that's noteworthy, I guess?

Phillip Chan

Thanks Brian. Nothing out of the ordinary. This is typical organic growth for us. We do typically see strong ordering at the end of the year as hospitals use up some of the extra money in their budget but I think that, in general, the order patterns that we have seen are very typical of what we have seen in the past.

Brian Marckx

Okay, and then, Phil, relative to REFRESH 2 and the design of the study and enrollment inclusion and exclusion criteria, can you give us kind of a ballpark in terms of what the size of the patient—the overall US patient population would be that would fit that enrollment criteria? I am just trying to get a sense of the opportunity for a related indication here in the US.

Phillip Chan

Sure. Eric, do you want to answer that? I can follow up with that if necessary.

Eric Mortensen

Yes. The part of the question I will answer is in terms of the study design. Phil will then discuss the U.S. opportunity in terms of market size. The study is designed to enroll up to approximately 400 patients, evenly randomized between active and control populations. We are using a design which has been proven effective in recent cardiac surgery studies in enriching for AKI. In REFRESH 2, we are using pre-operative screening criteria to enrich for those patients undergoing cardiac surgery who will have a higher risk of AKI. Specifically, those undergoing either valve replacement without hypothermic cardiac arrest, or aortic surgery with hypothermic cardiac arrest. Those populations, when enriched for cofactors associated with AKI, have a significantly increased frequency of acute kidney injury. We believe this adds to the power of the study to be able to detect a treatment effect and we believe, after our discussion with the FDA, this will represent a very clinically meaningful improvement if we are able to demonstrate a treatment effect and reduce the incidence or severity of AKI in these populations.

Does that answer the question that you have with regard to the study design? I was going to then let Phil speak to the commercial opportunity.

Brian Marckx

Yes. It does. Yes, I appreciate that.

Phillip Chan

In terms of market size, there is an estimated 100,000 to 150,000 valve replacement surgeries a year in the U.S., split primarily between aortic valve and mitral valve replacements but other valve replacements as well. When we look at the enrichment criteria that we are using, and when we look back at our REFRESH 1 trial and look at the valve replacement patients, roughly 20% of those that we had screened in REFRESH 1 would potentially meet our new criteria in REFRESH 2. It is a more selective patient population. However, by enriching for risk of AKI with such screening criteria as a history of diabetes, hypertension, hyperlipidemia, and other risk factors that would predispose them to having some element of chronic kidney injury going into the trial, we believe the higher event rate and the fact that even a small hit may trigger AKI will make it easier to demonstrate a benefit of CytoSorb in AKI and may increase the probability of a successful trial.

Given that valve replacement surgery is one of the most common complex cardiac surgeries that are performed in the United States, and that the incidence of heart valve disease is expected to grow as valve disease is common in the elderly, and the baby boomer generation continues to age, we expect a healthy market if the REFRESH 2 trial is successful.

Brian Marckx

Thanks, Phil. It sounds like you enriched to make sure that this is going to be successful. I don't expect an answer from that but I think that that is good, too. I appreciate that. Thanks a lot.

Phillip Chan

Thanks Brian.

Operator

Next, we'll come back to Andrew D'Silva with B. Riley FBR.

Andrew D'Silva

Hi. My apologies. I am not sure if we got cut off originally or not but I had a two-part question on the P&L. As far as R&D goes, it was meaningfully higher sequentially than the third quarter. I was wondering if that was the new run rate we should expect going forward and if you were potentially looking at any new indications that would have resulted in that? Then I have one more question after you answer that. Thank you.

Kathleen Bloch

Yes. Andy, for your modeling, I think that the higher costs observed in Q4 are to be expected going forward, given that Eric has been building his team and as we ramp clinical programs throughout the world.

Andrew D'Silva

Wonderful. Thank you for that, and then you've previously noted that, in Germany, you had a hospital running at about a million dollars a year, which, for your revenue run rate, is quite meaningful. Has there been any other health systems that have approached that number at this point? Or, any color that you have on that data point would be very valuable.

Phillip Chan

Based on our disclosures in the 10-K, there is no reliance on any one customer. What I would say is the customer that we disclosed in 2016 continues to grow and others continue to grow along the same trajectory as the usage increases in both cardiac surgery as well as intensive care medicine. Although we haven't publicly disclosed those data, we believe that the million-dollar revenue number per hospital is a very realistic number.

Andrew D'Silva

Wonderful. Okay, thank you very much and good luck going forward this year.

Phillip Chan

Thanks very much.

Operator

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

Phillip Chan

Great. Thank you everyone for taking the time today to join us on this earnings call. We greatly appreciate your participation. If you do have any other questions, please feel free to reach out to Jeremy Feffer at jeremy@lifesciadvisors.com, and we will try to reply to your questions where possible. Thank you very much everyone, and have a good evening.

Operator

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

Analysts

Sean Lee, *HC Wainwright*
Andrew D'Silva, *B.Riley FBR*
Jason Kolbert, *Maxim*
Brian Kennedy, *Cowen & Company*
Brian Marckx, *Zacks Investment Research*