



**CytoSorbents Corporation (NASDAQ: CTSO)
Q3 2018 Earnings and Operating Results Conference Call
November 6, 2018 @ 4:45pm Eastern**

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 Third Quarter 2018 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.

Jeremy Feffer:

Thank you, Jessica and good afternoon. Welcome to CytoSorbents' Third Quarter 2018 Financial and Operating Results Conference Call.

Slide 2:

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, Vice President of Sales and Marketing
- Chris Cramer, Vice President of Business Development

Slide 3:

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 November 6, 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 the third 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.

Phillip Chan - CEO:

Thank you, Jeremy, and good afternoon everyone.

Slide 4:

We were pleased to have achieved more than 51,000 CytoSorbents treatments delivered cumulatively, up from 31,000 a year ago. We achieved record trailing 12-month total revenue of \$21.1 million, including record 12-month product sales of \$19.1 million, with a mix of strong direct, distributor, and partner sales in a total of 53 countries.

The Company is well-capitalized, with a healthy cash balance of \$24.9 million as of the end of the third quarter, providing sufficient working capital into the second half of 2020.

We had blended product gross margins of 72% that are expected to rise, now that full production in Q4 2019 is from the new manufacturing facility.

During the quarter, we also debuted the PerLife™ Organ Preservation System with our partner Aferetica for organ transplant, which uses CytoSorbents' proprietary sorbent technology, at the 27th International Congress of the Transplantation Society. We also received a CytoSorb procedure code in Switzerland that is currently pending payment designation.

Slide 5:

In terms of a clinical trial update, I am pleased to announce good progress on our U.S. REFRESH 2-AKI pivotal trial. As you recall, this is a 400-patient randomized controlled, PMA, multi-center adaptive trial, targeting reduction of postoperative acute kidney injury, using CytoSorb intra-operatively during complex cardiac surgery. The protocol amendment that we discussed on the previous earnings call was approved by the FDA in September, with subsequent approvals by the ethics committees at our clinical trial sites. The trial site feedback, based upon the modified enrollment criteria, has been that it is an easier protocol to enroll, with more eligible patients. I am pleased to announce that we have now enrolled 20 patients into the study, among 14 active

clinical trial sites, with a total of 25 sites to be active in the near future. Because of this, we are expecting enrollment to accelerate in this study.

In terms of the REMOVE endocarditis trial that is being funded by the German government – recall that this is a 250-patient randomized controlled trial that is evaluating the safety and efficacy of CytoSorb to improve organ dysfunction when used intra-operatively during valve replacement surgery for infective endocarditis. The first patient was enrolled in January, and now the trial has enrolled a total of 62 patients at nine clinical centers. There is a planned interim analysis on the first 50 patients, focused on the reduction of inflammatory mediators such as cytokines, that is planned for the next several months.

Last but not least, our HemoDefend pivotal trial. Recall that this is a point-of-care transfusion filter that removes noninfectious contaminants from transfused packed red blood cells. The U.S. pivotal trial is designed to support U.S. FDA approval of HemoDefend for packed red blood cells, and is expected to start in early 2019. We have been working closely with National Heart, Lung and Blood Institute (NHLBI), a division of National Institutes of Health (NIH), to fund and prepare this study.

With that, I will turn the call over to Kathy for our financial overview.

Kathleen Bloch - CFO:

Slide 6:

Thank you, Phil, and good afternoon, everyone. For today's call, I will provide an update regarding our third quarter 2018 financial results, including product sales, and in addition, I will provide an update around our working capital and cash runway.

Slide 7:

CytoSorb product sales for Q3 2018 were approximately \$5.1 million, which represents a 48% increase over product sales of approximately \$3.4 million for Q3 of 2017. This increase was driven by an increase in direct sales from both new customers and repeat orders from existing customers, along with an increase in distributor sales. The decline in the Euro had a negative impact on Q3 2018 sales, and I will discuss this in more detail in a few moments.

Total revenues, which includes product sales and grant revenue, were approximately \$5.7 million for the third quarter of 2018, as compared to approximately \$3.8 million for the third quarter of 2017, which is an increase of approximately 80%.

In Q3 2018, gross profit grew to approximately \$3.7 million, an increase of approximately \$1.4 million, a 61% increase over gross product profit of approximately \$2.3 million for Q3 2017.

Gross profit margins on product sales were approximately 72% for Q3 2018, which is up from 69% for Q3 2017, achieved primarily due to year-over-year reductions in the cost of devices manufactured as a result of production efficiencies.

Slide 8:

Turning now to our nine months ended September 30, 2018 financial results, product sales for 2018 were approximately \$14.8 million, which is a 63% increase over product sales of \$9.1 million for the same period of 2017. Increases in direct and distributor sales were the major contributors to revenue growth, also aided by a stronger Euro to U.S. dollar average exchange rate. Grant revenue was approximately \$1.6 million for the nine months ended September 30, 2018, an increase of 16% over grant revenues of \$1.4 million for the same period of 2017. Total revenues, which includes product sales and grant revenues, were approximately \$16.4 million for the nine-month period of 2018 as compared to total revenue of approximately \$10.5 million for the nine-month period of 2017, which is an increase of approximately 56%.

Slide 9:

Now let us take a closer look at our quarter-over-quarter product sales. Q3 2018 product sales of \$5.1 million were slightly below Q2 2018 product sales. There were a number of factors underlying this slight reduction in quarter-over-quarter sales. First, Q3 2018 sales were negatively impacted by a decrease in the euro to dollar exchange rate, which reduced Q3 2018 reported sales by approximately \$178,000. In other words, if the exchange rate had remained unchanged from the second quarter of the year, Q3 2018 sales would have been approximately \$5.28 million, or an increase of \$35,000 over Q2 2018. In addition, in the third quarter of 2018, despite record CytoSorb unit shipments, we had a higher percentage of distributor sales, which have lower margins and lower selling prices than direct sales, than in the second quarter of 2018.

Finally, many European businesses slow down in the third quarter due to summer vacations, not only by workers but also customers, in July and August especially. Given the concentration of our business in Europe, we were surprised that this was really the first year in which we have seen this slowdown affect our financial results to this magnitude. That being said, our track record of 25 consecutive quarters of year-over-year sales increases remains intact. Most significantly, we believe the underlying drivers of revenue growth remain strong and that our year-over-year growth pattern will remain consistent and strengthen in the future.

Slide 10:

Turning to our trailing 12-month year-over-year product sales chart, over the past three years, the Company has experienced a 77% compound annual growth rate, and overall, our annual product sales growth exhibits a very strong growth trajectory, and we expect that to continue into the future.

Slide 11:

Now turning to working capital and our cap table; as of September 30, 2018, we remained very well-capitalized with approximately \$24.9 million in cash, which provides a solid foundation for the Company. In the third quarter of 2018, we did utilize our at-the-market ATM equity facility with Cantor Fitzgerald. We sold approximately 48,000 shares at an average price of \$12.60, which generated net proceeds of approximately \$605,000. As we've said before, we believe the ATM provides an efficient and cost-effective way for us to raise funds for the Company. We believe

that the existing cash runway will allow us to meet our operating and clinical trial needs well into the second half of 2020.

Turning to our capital structure, as of September 30, 2018, we have approximately 36.4 million common shares on a fully diluted basis.

With that, I would like to turn the call back to Phil.

Phillip Chan - CEO:

Slide 12:

Thank you very much, Kathy.

In addition to our prior guidance that second half product sales will be greater than first half product sales, we have additionally refined our guidance and expect that Q4 2018 product sales will exceed Q3 2018 product sales.

We also continue to expect solid growth and achievement of operating profitability in 2018 on a quarterly basis, less non-cash expenses and clinical trial costs this quarter. We were again very close to achieving this objective in the third quarter of 2018, with an operating loss, as defined, of approximately \$380,000.

We anticipate expansion in blended product gross margins, currently at 72%, as we scale up production from our new manufacturing facility.

That concludes our prepared remarks. Operator, please open up the call for the Q&A session.

Slide 13:

Question-and-Answer Session

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. Please limit to one question and one follow-up. If you'd like to ask another question, please queue up again.

We will go first to Andrew D'Silva with B. Riley FBR.

Andrew D'Silva:

Good afternoon. Do you have any updates related to any of your investigator-initiated studies? You had about a dozen or so a couple quarters ago that were expected to publish, and I was wondering if you knew how the pipeline looks right now from that standpoint.

Phillip P. Chan:

Hi Andy. The investigator-initiated studies continue, and in fact, we are starting new ones all of the time. If you look at the pace of publications, you will see many studies that are currently being published. These range from case reports, case series, and small randomized controlled studies. Some of these were started years ago, and only are getting published now as those studies have been recently completed. But the pipeline of investigator-initiated studies continues to be robust, and we continue to support those with scientific and clinical input from our clinical team.

Andrew D'Silva:

Okay, great. Out of the 53 countries where you distribute today, how many have established product registrations thus far and are able to actually sell the product?

Phillip P. Chan:

Let me let turn that over to Vince to talk about product registrations. Vince, can you please give a little color on that.

Vincent Capponi:

Hi Andy. On the product registrations, CytoSorb is registered in approximately 90% of those countries. Right now, we are also working on bringing new countries and distributors up to speed, with training and other support.

Andrew D'Silva:

Then out of the 20 patients that you have enrolled in REFRESH 2, how many were enrolled after the protocols changed and the sites upped to 14?

Phillip P. Chan:

I think the majority of the enrollments have been after the protocol amendment has been submitted and approved. We had mentioned last time that a lot of the clinical trial sites wanted to wait until the FDA actually approved the protocol amendment before aggressively enrolling. We did have one clinical trial site that was enrolling ahead of that using the new protocol guidelines, but they had already worked that through their system. We expect that enrollment to accelerate now that all 14 sites have gotten the final protocol approved, and as we expand to 25 sites total.

Operator:

We'll take our next question from Josh Jennings with Cowen and Company.

Brian Kennedy for Josh Jennings:

This is Brian for Josh. Hi Phil, how are you?

Phillip P. Chan:

Hi Brian, good thanks.

Brian Kennedy for Josh Jennings:

I want to start with product sales. I understand the impact of the Euro and the greater percentage of distributor sales, but can you discuss the reason you are confident that you are facing a modest amount of seasonality rather than something more company-specific in Europe?

Phillip P. Chan:

Yes. Let me turn it over to Christian to give some color on that. Christian?

Christian Steiner:

Thank you, Phil. Hi Brian.

I think business during the summer vacation time is normally always a little bit slower. For this year, I think we have seen the first time that our business has been affected by this, to this extent. For example, a lot of elective cardiac surgery has been postponed because doctors and surgeons go on vacation, but patients also want to enjoy the summer with their families. Also, many physicians have told us that they were not seeing a lot of septic patients, perhaps because of the good weather and hot summer in Central Europe.

We have talked to many of our customers and do not believe it is anything company or product specific. In addition, I think other companies with significant European operations have seen a similar slow down this quarter.

Brian Kennedy for Josh Jennings:

Okay, thank you. For a follow-up, on REFRESH 2, the entries on clinicaltrials.gov suggest there were just two amendments made to the protocol, including the removal of the age cap that you discussed last quarter. My question is, does the approved protocol now reflect everything you were looking to do? Or were there elements that were not approved by the FDA?

Phillip P. Chan:

Yes, it fully reflects what we wanted to change. But let me turn it over to Eric to give some more color on that. Eric?

Eric Mortensen:

Sure, Phil. This is actually Amendment D, but prior amendments were more administrative than clinical. In this last amendment, we removed an age cap to allow enrollment of patients greater than 80 years old, and allowed the inclusion of obesity (body mass index or BMI greater than 30) which is a known risk factor for AKI. These two changes have made a significant difference in the rate of enrollment, allowing study coordinators to rapidly identify eligible patients.

We are hearing positive feedback on these changes, where sites have gone from few to no qualified patients during pre-screening, to seeing a majority of the scheduled cases now meeting our inclusion criteria. We have been able to recruit 12 patients in just about a month and a half and expect that enrollment will accelerate from here.

Operator:

We will now take our next question from Jason McCarthy with Maxim Group.

Jason McCarthy:

Hi, thanks for taking my question.

First, I would just like to see if you can provide a bit of an update with regards to May's CytoSorb label expansion to now include myoglobin and bilirubin reduction. Specifically, is there any update related to progress or uptake in those indications? More broadly, which therapeutic areas do you consider the most important for driving growth in CytoSorb revenues going forward?

Phillip P. Chan:

The two major indications that we have currently are in sepsis, which dominates our critical care applications, and cardiac surgery, which represents about a quarter of all of our cases. Within cardiac surgery, CytoSorb is being used in various indications including: 1) preemptively to help stabilize patients going into surgery 2) during surgery to help stabilize patients intra-operatively - for example patients undergoing valve replacement surgery for endocarditis, and 3) postoperatively in patients who have developed postoperative inflammation or post-op SIRS (systemic inflammatory response syndrome).

The label expansion for myoglobin and bilirubin were done in response to physicians wanting to use our therapy on label for these particular indications. The addition of bilirubin removal added the ability to treat patients with liver disease or liver failure, specifically as a liver dialysis therapy, on label. The addition of myoglobin allowed physicians to use CytoSorb to help treat patients with severe crush injury and rhabdomyolysis, which releases toxic myoglobin into the bloodstream that can then accumulate in the kidneys and cause kidney failure – an independent risk factor for death in severe trauma.

We are seeing some initial good uptake in those fields, but the real effect on our sales growth is not yet being felt. These are still developing areas, but areas where we believe have tremendous opportunity for the Company and for our CytoSorb technology.

Chronic liver disease alone is a massive problem worldwide; with approximately 850 million people affected, of which an estimated 300 million people are in China alone. Many of these patients will be admitted to the hospital with acute exacerbations of their chronic liver disease. Many others develop acute hepatitis from alcoholism or other acute toxicity. So, you can see these markets are very big. We believe these applications will be additive and complementary to the current applications where CytoSorb is already being used.

Jason McCarthy:

Okay. Thank you. Then just one more related to CAR-T. I would like to see if you could go into more detail on your plans for positioning CytoSorb in these patients with regards to cytokine release syndrome (CRS). Then, in terms of label expansion, could you leverage data from REFRESH 2 in the U.S., and then only require small label expansion studies rather than full trials?

Phillip P. Chan:

CAR-T cell immunotherapy is a high-profile application where a lot of money is being spent and where there is a lot of optimism over the new treatments coming to market and the ones already approved on the market. Both Kymriah by Novartis and Yescarta by Gilead, are now approved in the United States as well as in the European Union. We have already been approached by a number of cancer centers in Europe whose hospitals have had prior experience using our product in critical illnesses. They are asking to now collaborate with us on using CytoSorb to treat cytokine release syndrome. We also have an active outreach program in Europe where we are looking to position CytoSorb for use in various clinical studies for the treatment of cytokine release syndrome, as a potential alternative to steroids, when first line treatment with tocilizumab – an IL-6 receptor antagonist – fails. Steroids have the potential to cause apoptosis to the CAR-T cell immunotherapy cells, potentially impacting long-term complete and partial response rates.

We believe that CytoSorb represents a superior alternative to steroids, and that is how we are currently positioning CytoSorb today in the European Union for this application. In the United States, we will hopefully have an update on our activities in the future.

Operator:

Once again, ladies and gentlemen, as a reminder, it is star, one to ask a question. We'll go next to Sean Lee with H.C. Wainwright.

Sean Lee:

Good afternoon, guys. I just have a quick question on the dedicated procedure code for Switzerland. Would you provide a little bit more color on how that is different from what is available now? Although I know you guys do not break out the per country results, but how important is Switzerland for your direct sales operations? Do you expect this approval to make a material impact to your overall sales?

Phillip P. Chan:

Thanks Sean. Germany, Austria and Switzerland represent our top direct sales territories, Germany obviously being number one, but Austria and Switzerland also are very strong.

The prior reimbursement in Switzerland was based upon a more generic code, with incomplete reimbursement. The new procedure code has the potential to allow for full reimbursement of CytoSorb and the procedure itself, as well as any ancillary products.

Switzerland is widely regarded in Europe as having one of the best health care systems, providing their citizens with top-of-the-line medical therapies. Getting reimbursement in Switzerland is very important, not only from a revenue generation standpoint, where we do believe that it can become material over time, but also from a perception issue, given the high-profile nature of Swiss medicine.

Sean Lee:

Thank you.

Operator:

It appears there are no further questions at this time. I'd like to turn the conference back to Management for any additional or closing remarks.

Phillip P. Chan:

Thank you very much, everyone, for your participation today. If you do have any other questions, please feel free to reach out to Jeremy Feffer, jeremy@lifesciadvisors.com, and we will try to reply to your questions where possible. Also, if any of the analysts had additional questions or comments, we are available for a follow-up conference call.

We look forward to our next quarterly call. Good night.

Operator:

Thank you. That concludes our conference for today.

Analysts

Brian Kennedy for Joshua Jennings, Cowen and Company, LLC

Andrew D'Silva, B. Riley FBR, Inc.

Sean Lee, H.C. Wainwright & Co, LLC.

Jason McCarthy, Maxim Group