CytoSorbents Corporation (NASDAQ: CTSO)
Q4 2018 & Full Year 2018 Earnings and Operating Results Conference Call
March 7, 2019 @ 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 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 would like to turn the call over to our moderator, Jeremy Feffer. Please go ahead.

Jeremy Feffer:

Thank you and good afternoon. Welcome to CytoSorbents 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, Senior 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 would 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 7, 2019, 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 2018 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 is my pleasure to turn the call over to Dr. Phillip Chan.

Phillip Chan - CEO:

Thank you, Jeremy, and good afternoon everyone.

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Among the highlights from our earnings press release issued earlier today, we are pleased to report that we achieved greater than 56,000 CytoSorb treatments delivered cumulatively, up from 35,000 a year ago. We also recorded annual total revenue of $22.5 million and product sales of $20.3 million, with a mix of strong direct, distributor, and partner activity in a total of 53 countries. Just recently, we increased that number to 55 with the expansion of our partnership with Fresenius Medical Care to Mexico and South Korea.

We also achieved blended product gross margins of 74% for 2018, up 300 basis points from 71% in 2017. These blended gross margins are expected to rise to 80% on a quarterly basis later this year, propelled by the opening of our new manufacturing facility in June 2018. We are well-capitalized with a healthy cash balance of $22.4 million at the end of 2018, providing sufficient working capital into 2020.

Among other notable highlights, we were cited by the Deloitte 2018 Fast 500 as one of the fastest growing companies in North America for the second year in a row. Earlier in the year, we were added to the Russell 2000 Small Cap and Russell 3000 indexes.

Slide 5:

In terms of an update of our clinical trials, our U.S. REFRESH 2-AKI pivotal trial remains on track. This is a 400-patient, multi-center, randomized, controlled trial, targeting the reduction of post-operative acute kidney injury using CytoSorb during complex cardiac surgery. The trial has now enrolled 56 patients, with a recent increase to 21 initiated clinical trial sites with another eight undergoing startup activities. We are targeting 200 patients enrolled total in the next 12 months and an interim analysis for safety and futility shortly thereafter.

The REMOVE endocarditis investigator-initiated trial funded by the German government is also making very good progress. This is a 250-patient randomized, controlled trial evaluating the safety and efficacy of CytoSorb to improve organ dysfunction when used intraoperatively during valve replacement surgery for infective endocarditis. Recently, the independent Scientific Advisory Board and the Data Safety Monitoring Board recommended continuation of the trial following an interim analysis on the first 50 patients, focused on inflammatory mediators including cytokines. The trial recently passed the midway point, with 130 patients enrolled at 13 centers.

Finally, the HemoDefend pivotal trial will evaluate our HemoDefend-RBC point-of-transfusion filter that is designed to remove non-infectious contaminants from transfused packed red blood cells. This pivotal trial has been delayed due to the sale and loss of key technical personnel at our main parts supplier. However, we are working diligently with the new team at the supplier to reprioritize our project, and we plan to update investors on the timing of this trial soon.

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

Kathleen Bloch:

Thank you, Phil, and good afternoon, everyone.

Slide 6:

For today's call, I will provide an update regarding our full year and fourth quarter 2018 financial results, including product sales progress. In addition, I will provide an update around our working capital and cash runway.

Slide 7:

Starting with Q4 comparative revenue results, CytoSorb product sales for Q4 2018 were approximately $5.5 million, which represents a 27% increase over product sales of approximately $4.3 million for Q4 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 average euro to dollar exchange rate had a negative impact of approximately $189,000 on Q4 2018 sales.

Total revenues, which includes product sales and grant revenue, was approximately $6.1 million for Q4 2018 as compared to approximately $4.6 million for Q4 2017, an increase of approximately 31%. Q4 2018 gross profit grew from approximately $4.0 million, an increase of approximately 18% or roughly $600,000, over gross profit of approximately $3.4 million for Q4 2017. Our gross profit margins on product sales were 75% for Q4 2018, which is, in fact, the highest quarterly gross profit margin on product sales in our history. This compares to 72% for the fourth quarter of 2017. The improvement is primarily as a result of the manufacturing efficiencies that were achieved at our new production facility.

Slide 8:

Now let us look at our comparative annual revenue results. Product sales for 2018 were approximately $20.3 million, a 51% increase over product sales of $13.4 million for 2017.

Increases in both direct and distributor sales were the major contributors to our year-over-year product revenue growth. Also, approximately $792,000 of this growth in product sales was due to an increase in the average euro to U.S. dollar exchange rate for 2018 versus 2017.

Our grant revenue was approximately $2.3 million for 2018, which is an increase of 27% over grant revenue of $1.8 million for 2017, and our total revenues, including product sales and grant revenue, were approximately $22.5 million for 2018 as compared to total revenue of $15.2 million for 2017, an increase of approximately 49%. Our gross profit was approximately $15 million, an increase of $5.4 million, or 56%, over gross profit of $9.6 million in 2017, and our overall gross profit margins on product sales for the year were approximately 74% as compared to 71% for 2017. As I mentioned, this is a result of the production efficiencies that are being achieved.

Slide 9:

Next, we will look at our quarter-over-quarter product sales. Q4 2018 product sales of $5.5 million were a new record in quarterly product sales, and as I mentioned earlier, the fourth quarter 2018 reported sales would have been even higher if not for a negative impact from the decline in the average euro-to-dollar exchange rate. That being said, our track record of 26 consecutive quarters of year-over-year sales increases continues.

Slide 10:

Next, let us look at our trailing 12 months product sales, which we have always stated provides the best representation of our overall sales growth. Note that over the past three years, the Company has achieved a 71% compound annual growth rate, and overall, as you can see when you look at the chart, annual product sales exhibit a very strong growth trajectory that we expect to continue into the future.

I also want to say a few words about the achievement of operating breakeven on a quarterly basis, which we have defined as operating results excluding non-cash expenses and clinical trial costs. We came very close last year, with a couple of quarters missing by only a few hundred thousand dollars. The point of talking about operating breakeven was to demonstrate just how profitable our business could be at a relatively low revenue number. In Q4 2018, however, we began to shift to a more aggressive growth mode because we believe, with faster top line growth and the high gross profit margins we are experiencing, which are expected to further improve in 2019, we can expect improvements in operating results and increased generation of cash. One such example of this investment strategy was our recent expansion of our direct sales territories from 5 to 10 countries, with the addition of the direct sale territories of Poland, the Nordics and the Netherlands. Please be assured, however, that we will continue to manage our spend in a very responsible and deliberate manner.

Slide 11:

Finally, turning to working capital and our cap table, as of the end of 2018, we remain very well-capitalized, with approximately $22.4 million in cash, which we believe provides a solid foundation for the Company. During 2018, we were able to generate capital through the use of our At-The-Market equity facility with Cantor Fitzgerald. We sold approximately 1.5 million shares at an average sales price of $9.61, with net proceeds generated of approximately $14.1 million.

The ATM provides an efficient and cost-effective way for us to raise funds for the Company. We believe that this existing cash runway will allow us to meet our operating and clinical needs into 2020. And just briefly on our capital structure, as of December 31, 2018, we have approximately 36 million common shares on a fully-diluted basis.

That concludes my report. I would like to turn things back to Phil at this time. Phil?

Dr. Phillip Chan:

Thank you very much, Kathy.

Slide 12:

Historically, we have not given specific financial guidance on quarterly results until the quarter has been completed. However, in the short term, we expect that Q1 2019 product sales will exceed Q1 2018 product sales, and in 2019, we expect to achieve blended product gross margins of 80% on a quarterly basis. Longer term, we are targeting significant and sustained sales growth and GAAP profitability.

As we continue to see the massive unmet medical needs in critical care and cardiac surgery, we strongly believe that we are in the right place with the right therapy at the right time to make it happen and we appreciate your continued support.

That concludes our current prepared remarks, and I would now like to open it up for a live Q&A session.

Slide 13:

Operator:

Thank you. We will now be conducting a question-and-answer session. If you would like to ask a question, please press *1 on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press *2 if you would like to remove your question from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys. One moment, please, while we poll for questions.

Thank you. Our first question comes from the line of Josh Jennings with Cowen & Company. Please proceed.

Joshua Jennings:

Hi, good afternoon.

Dr. Phillip Chan:

Hi, Josh.

Joshua Jennings:

Congratulations on the 2018 results - quite a year. Thanks for the guidance for 2019 on the gross margin line. I was hoping to better understand where gross margins can ultimately get to. If 80% is the target for 2019, how should we think about the longer-term gross margin trajectory?

Dr. Phillip Chan:

Thank you, Josh. Just to be clear, that 80% is a blended gross margin between higher margin direct sales and lower margin distributor and partner sales, which implies that the direct gross margin will be significantly higher than 80%. That said, let me turn it over to Vince to give a little more color on why we feel confident about achieving this objective this year and also what are some of the levers that can be pushed to be able to drive us potentially even higher.

Vincent Capponi:

Hi, Josh. We believe we can exceed the blended 80% gross margin and there are a number of things that will factor into that. Obviously, it is dependent on product mix between direct and distributor sales, as Phil mentioned, but a major driver of the increase in gross margin is a reduction in cost of goods sold, which in turn is being driven by scale such as volume manufacturing, improved utilization of our current plant and labor, bulk raw material ordering, and efficiencies in shipping. These, and many other things we are doing, are expected to drive product gross margins even beyond where we are now. That said, the next big jump in product gross margins will be with the next scale of manufacturing beyond $80M in sales. Does that help?

Joshua Jennings:

Thanks Vince, that does. Phil, as a follow-up, thinking about the Switzerland procedure code and the reimbursement value assignment process, have you seen any impact there yet, and how are you thinking about the impact in 2019? Also, have you seen any impact yet from the EU label expansion that now includes reduction of bilirubin and myoglobin? How we should be thinking about this in 2019?

Dr. Phillip Chan:

In terms of the Switzerland procedure code, just like the German code, we are waiting for an assignment of value to that procedure code. That can take anywhere from six to 12 months to obtain. But it is in an active process right now, so when we know, we will definitely make that public, but the impact on 2019 revenue targets is currently unclear. That said, sales continue in Switzerland even without that reimbursement designation, but we will just have to see how 2019 turns out.

In terms of the label expansion that included the removal of bilirubin for the treatment of acute liver disease, as well as the reduction in myoglobin for the treatment of severe trauma, the value is primarily on reimbursement and marketing. That said, we have seen a lot of interest in the use of CytoSorb as a next generation liver dialysis therapy. Unlike existing liver dialysis therapies that typically just remove bilirubin, bile acids, and other liver toxins, CytoSorb is very unique because it not only removes these toxins, but it also removes cytokines and other inflammatory mediators

that are often the root cause of acute exacerbations of chronic liver disease. These occur with increasing frequency as patients and their chronic liver disease worsen. In terms of 2019 sales, it is too soon to say, but there certainly is a lot of interest, a lot of people looking to use this in substitution of other types of liver dialysis therapies, and we will hopefully have more visibility on that later this year.

Joshua Jennings:

Thanks for that. Then my last question, congrats on the progress in enrolling REFRESH 2, but I wanted to ask about the REMOVE trial. Could those results get you an indication in Europe? Then if you could talk about how you are thinking about the endocarditis indication and just sizing up that potential opportunity? Thanks a lot for taking all the questions.

Dr. Phillip Chan:

Absolutely. In Europe, we are already approved as an extracorporeal cytokine adsorber, that is indicated for any clinical situation where cytokines are elevated. Because of this, the use in patients undergoing cardiac surgery for infective endocarditis and other conditions, is already on-label. That being said, if the REMOVE trial is successful, we anticipate that it will drive usage as standard of care in these types of surgeries across all of our territories.

As we have discussed a number of times before, valve replacement surgery for infective endocarditis is very complex, has a high expected mortality of approximately 15% to 20%, and is associated with a host of problems, including hemodynamic instability during and after the procedure, and other adverse events that can be fatal. With the growing opiate crisis, this issue has become significantly more relevant. In the United States, the historical incidence of infective endocarditis has been 10,000 to 15,000 cases a year. However, with the opiate crisis, it has become a growing epidemic, with many major hospital centers doing 100 to 250 of these surgeries every year, and it is only becoming more and more of a problem. In fact, The New York Times did an article on this exact problem of infective endocarditis and the recidivism that often occurs in patients who get one valve replacement surgery for endocarditis but then continue abusing intravenous drugs and get a second infection on a prosthetic heart valve, where the mortality is even higher than for a native valve. The article quotes an expert who estimates the cost per endocarditis case, all in, could easily exceed $150,000 per case. Using a product that is several thousand dollars to try to reduce a lot of the costly complications of this illness could well be worth it. For that reason, we believe that if the trial is successful, CytoSorb can become standard-of-care therapy in this application relatively quickly.

Joshua Jennings:

Great. Thanks again, and thanks for the clarification that use of CytoSorb during valve replacement surgery for endocarditis is on-label.

Dr. Phillip Chan:

Thanks Josh.

Operator:

Thank you. Our next question comes from the line of Jason McCarthy with Maxim Group. Please proceed.

Jason McCarthy:

Hey guys, thanks for taking the question. Related to the Fresenius collaboration expansion, could you please provide some additional clarity on the timelines for launch in those countries, and then also what kind of market opportunity do those two countries represent, given the large combined population of over 180 million?

Dr. Phillip Chan:

Thanks, Jason. Chris, would you like to take this one?

Christopher Cramer:

Yes, sure thing, Phil. Hi, Jason, this is Chris Cramer. Thanks for the question. For the first question about market clearance, I think you are referring to our expansion to Mexico and South Korea with our partner Fresenius (FMC)?

Jason McCarthy:

Yes, you are correct.

Christopher Cramer:

Each country has its own health authority process and timelines for registration, and currently, our regulatory experts have started to compile the registration dossier in collaboration with the FMC regulatory teams. The other thing I would say is that the review time by the health authorities can be variable, but we expect to have more feedback after the submission of these dossiers, which is currently in process.

In terms of the opportunity, Korea and Mexico are large and strategically important markets for CytoSorb, and together, they represent about 181 million people with about 129 million in Mexico and 52 million in Korea. In each of these countries, there is a large unmet need and burden of disease. Hundreds of thousands of lives are lost from hyperinflammatory conditions due to lack of effective therapies each year in both of these countries. As such, we believe there is a critical role for CytoSorb. In particular, we see a growing demand for blood purification treatments for acute kidney injury and cytokine removal in acute care.

On top of that, FMC has a very strong and motivated commercial organization in both countries, with sales, marketing, and medical affairs resources to introduce new therapies. The partnership itself is fully backed by senior leadership at the highest levels in both the FMC Mexico and FMC Korea organization, and this will help to ensure that the CytoSorb sales and marketing efforts are appropriately resourced and supported. We have also assigned dedicated international sales

resources to support the market launches. We feel very confident that following product registration, we will see a strong market launch coming from the FMC sales teams in both countries.

Jason McCarthy:

Thank you. Then just as a quick follow up, I would like to see if you could talk about some of the regulatory pathways and your development strategy for expanding the use cases for CytoSorb. I know that the label in Europe is pretty broad for pretty much any situation where cytokines are elevated, so I am wondering how you would position CytoSorb as a treatment for something like cytokine release syndrome (CRS) and CAR-T. Would you look at additional trials to prove its usefulness in that indication, or would this be more of a marketing effort?

Dr. Phillip Chan:

Yes, I think in terms of that particular application, we are seeing a lot of strong interest, both in the United States amongst leading investigators in the CAR-T cell immunotherapy space to demonstrate the potential utility of CytoSorb in treating cytokine release syndrome. Also, with the approvals of Kymriah and Yescarta in the European Union, we have been in close contact with some of the leading centers that were involved in those approvals in Europe where there is also a very strong interest to evaluate the therapy. At the moment, our experience is limited in the treatment of cytokine release syndrome specifically, although we have mentioned before that we have more than a dozen cases treating secondary HLH, or hemophagocytic lymphohistiocytosis, which is very similar to CRS.

Also, recently in December, there was a young 13-year old patient with refractory acute lymphocytic leukemia, who was not on CAR-T cell immunotherapy but was being treated with standard therapy and developed a cytokine storm - essentially a cytokine release syndrome. This cytokine storm persisted for two weeks with an IL-6 of greater than 200,000 pg/mL, and precipitated multi-organ failure. To put that into perspective, all of us on the phone should have an IL-6 of less than 10 pg/mL. This was true cytokine storm, and in fact, with several CytoSorb treatments, they were able to bring her rapidly out of cytokine release syndrome and she went on to recover. We feel very confident that this is a true application for us, and as that market develops, we hope to simultaneously gain further experience and be able to report that publicly.

Jason McCarthy:

Okay. Thank you very much for taking the questions, and congratulations on the quarter.

Dr. Phillip Chan:

Great, thank you very much Jason.

Operator:

Thank you. Our next question comes from the line of Brian Marckx with Zacks Investment Research. Please proceed.

Brian Marckx:

Hi Phil. Congrats on the quarter and the year. Relative to HemoDefend, I think you had previously mentioned that you thought you could start a pivotal study this year in Q2. Can you talk about how the manufacturing delays may impact that timeline?

Dr. Phillip Chan:

Thanks Brian. Vince, would you like to take that question?

Vincent Capponi:

Sure. Hi Brian, this is Vince. Here is what happened. Over the last several months, we have been experiencing delays from our key parts supplier because they were recently acquired by another company. As happens in many acquisitions, a number of the key personnel at our supplier that were working on the product were let go, which has impacted the timeline. In revising our forecast, we are looking for a second half FDA IDE submission. I have been in constant contact with the company and just talked to one of the senior engineers today. We are hopeful that we will receive the parts and move this project forward. The polymer is ready.

Brian Marckx:

Okay. Then in terms of your direct sales efforts in Poland, the Nordics, and the Netherlands, has that already launched, or is that in process of launching? Do you have a sense of how many people you need to add to service those territories?

Dr. Phillip Chan:

Christian, would you like to take that one?

Dr. Christian Steiner:

Yes, sure Phil. We have added a number of direct sale territories, and as usual, we start with a relatively small number of direct sales reps, build our KOL relationships, and then will add as needed. In all the countries except Poland, we have started our sales and marketing activities, which have already begun to have a positive impact on our results. In Poland, we already have the team and will start in Q2. I hope this answers your question.

Brian Marckx:

Yes, it does. Thanks. That is all I had.

Dr. Christian Steiner:

All right, thank you.

Dr. Phillip Chan:

Great, thanks Brian.

Operator:

Thank you. Again, if you would like to ask a question, please press *1 on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press *2 if you would like to remove your question from the queue, and for participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys.

Thank you. Our next question comes from the line of Sean Lee with H.C. Wainwright. Please proceed.

Sean Lee:

Hi, guys. Congratulations on a great year, and thank you for taking my questions.

Dr. Phillip Chan:

Thank you Sean.

Sean Lee:

My first question is on the REFRESH study. In the opening remarks, you said that you expect to reach 200 patients enrolled in the next 12 months, which would trigger an interim analysis, so could you provide a little more color on what this interim analysis would comprise of? Is it just a DSMB decision, or do we get any data releases, and would they look at just safety or both safety and efficacy?

Dr. Phillip Chan:

Thanks, Sean. Eric, would you like to take that one?

Dr. Eric Mortensen:

Sure. Sean, thank you for the question. First, the DSMB is continuously looking at safety throughout the program. We also have a Clinical Events Committee because we want to make sure that we are getting, as much as possible, a uniform blinded assessment to events to minimize the potential risk of bias that may come from sites. With regard to what will be examined in the interim analysis, the DSMB will be looking at both safety and efficacy. We do not expect a release of any efficacy data to avoid potentially contaminating the study's conduct, since, for example, it obviously becomes very difficult if you are seeing a positive result to justify putting patients in the control arm. The trial may be stopped early for futility. Alternatively, depending on the strength of the results, the trial could also be terminated for a very positive result, but that would require a very strong p-value and a discussion with the DSMB on whether or not this would be appropriate. Does that answer your question?

Sean Lee:

Yes, that is great. Thanks for the additional color. My second question is on the split between distributor and direct sales and how each part is growing. Could you provide more color on that? What percentage of your sales came from direct sales last year versus distributors, and how does that compare to 2017?

Dr. Phillip Chan:

Sure. Kathy, would you like to take that one?

Kathleen Bloch:

Yes, sure Phil. Sean, in our Form 10-K, we have a very robust revenue disclosure that breaks down the direct sales from the distributor sales, so you can use that to exactly answer your question. I will say that we have had a double digit increase in both direct and distributor sales.

Sean Lee:

I see. Were there any territories that were going particularly well, or are there any that you think could definitely do a bit better in 2019?

Dr. Phillip Chan:

Hi Sean, just to add to Kathy's comments, I think what you will see is that direct sales accounts for roughly 72% of our total product sales and the balance is from international distributors and partners. That has remained fairly constant over the past couple of years. It has been roughly three to one, three quarters of our sales are direct and a quarter is distributors, and the fact that this ratio has been stable suggests that both direct sales as well as international sales are growing at roughly the same rate. That being said, there is always more work to do, and we certainly have a lot of countries that are outperforming and doing very well and we certainly have others that could use some help. Part of the growth strategy in 2019 is to invest the time, resources, and effort to ensure that all the drivers of our revenue are working well. We remain very committed to this hybrid sales model where we are mixing direct and indirect sales and hope to demonstrate how our efforts are improving results in 2019.

Sean Lee:

I see. Thanks for the helpful response. That is all I have and thank you for taking my questions.

Dr. Phillip Chan:

Thanks Sean.

Operator:

Thank you. Our next question comes from the line of Andrew D'Silva with B. Riley FBR. Please proceed.

Andrew D'Silva:

Hey, good afternoon. Thanks for taking my questions. For the first question, as far as the total distributors that you are currently working with and countries you are in, I know you have historically had two numbers, one being the number of countries that you are actually selling into and the other being countries that you have established distribution in, but are not actually selling product yet in. Can you give me the breakout of what that is?

Dr. Phillip Chan:

We have not broken that out for a while, Andy, and we do not have that number handy. However, I would say that the majority of our distributors have been contributing to revenue. We have certain countries where we are still working on registration, for example Israel and, of course, the new territories of Mexico and South Korea. But I would say that the majority of the countries have been moving along and we have strong expectations for them in 2019.

Andrew D'Silva:

Okay, got it. Just looking at the history between direct sales and indirect sales, the bulk of the countries are assigned to distributors and partners, yet the majority of your sales are through direct territories, mainly Germany and the others. How do you bridge that gap so that the other countries are able fill in or get somewhat closer to the direct sales countries in terms of sales? Is it related to more data or is it just a situation where it is never really going to get there all the way? Are you more likely just to start investing in new direct sales opportunities across different regions, similar to what you announced earlier in the week?

Dr. Phillip Chan:

Direct sales benefit from the fact that we, as a company, have a singular focus, which is the sale of CytoSorb. We have a lot of resources and a lot of experience from our direct sales territories to bring to bear on those markets, have strong relationships with key opinion leaders, and of course, the margins are significantly higher in our direct sales territories than they are in our distributor and partner territories. That said, we benefit from distributors by leveraging their infrastructure, their expertise, and their contacts within various countries. Of course, we give up some margin for that benefit, have to deal with the fact that we do not have direct contact with the customers, and these distributors often have multiple products that they are also trying to sell and do not have the singular focus that we benefit from in direct sales.

That said, we are actively working to make sure that the indirect channel is humming along, and we do a lot of training. We have a lot of communication with these distributors and we work actively to make sure that the data that we have is available to them for their sales process. We do not ever expect them to perform the same way as our direct sales territories, but it is a way to blanket the world so to speak – we are now in 55 countries around the world – without incurring the massive infrastructure costs that are associated with that type of coverage.

Andrew D'Silva:

Okay, got it. Just a couple more questions for me. Just from the competitive landscape, Baxter's oXiris product fairly recently got approval for cytokines as well. I was curious as to how you are viewing the competition, and has there been any sort of a material impact that you have noticed through that? If so, what are you doing to counter it?

Dr. Phillip Chan:

Of the various competitive threats out there, Baxter, as the one of the leading dialysis players in the world in critical care, is probably the most relevant. Of course, we are partnered with Fresenius Medical Care, the largest dialysis company in the world and the number one or number two player next to Baxter in critical care globally. Baxter acquired Gambro, which was the second leading dialysis player in the world, in 2013 and inherited their acute care product line, which included oXiris, Septex, and a number of other acute care products.

oXiris was launched by Gambro back in 2009, initially as an endotoxin filter for the treatment of Gram negative septic shock. At the same time, Gambro launched and marketed another product called Septex as a high molecular weight cut off filter to reduce cytokines. But Septex had limited success and is not being actively marketed anymore, while oXiris also had limited success and remained in the shadow of another product called Toraymyxin which was, and likely still is, the leading endotoxin removal filter out there. However, Toraymyxin has had its own issues because of a number of failed pivotal studies demonstrating no mortality benefit of endotoxin removal. That said, recently Baxter expanded the E.U. label of oXiris to include cytokines, citing some *in vitro* data in serum. However, just because oXiris has a label to reduce cytokines, does not mean that it will be effective in treating critical illnesses. The fact that oXiris has not really taken off as a therapy in its 10 years on the market, may be a reflection of its efficacy. In the short-term, this marketing push by Baxter creates some market confusion, but I think that as it plays out, we will demonstrate the superiority of CytoSorb.

Andrew D'Silva:

Okay, great and thank you for that color. Last question: Kymriah and Yescarta are still new therapies in Europe with, I think, only a handful of patients treated. How are you positioned to be utilized alongside them for CRS? Are you partnered with any of the hospitals or health centers that are actually capable at this point of providing CytoSorb treatment to patients yet?

Dr. Phillip Chan:

The short answer to that is yes. There is a lot of interest to collaborate with us on clinical studies to evaluate CytoSorb as a treatment of cytokine release syndrome, particularly as a rescue therapy when standard treatments, such as tocilizumab and steroids, fail. It is not clear whether or not steroids could potentially be harmful in patients undergoing CAR T-cell immunotherapy, both for the CAR T-cell immunotherapy itself but also potentially for the patient. At the end of the day, we seek to evaluate CytoSorb in the clinical trial setting as a way to establish the value of this therapy in treating CRS. There are a lot of reasons why we believe this could be successful.

Andrew D'Silva:

Okay, but are some of your hospital customers actually hospitals that are able to provide CAR-T therapy to patients? Because I know there is an issue with a lot of facilities not actually being properly equipped, certified, or registered to be able to actually provide that service.

Dr. Phillip Chan:

Yes, that is correct.

Andrew D'Silva:

Okay, wonderful. Thank you so much for answering my questions, and best of luck going forward in 2019.

Dr. Phillip Chan:

Great, thank you Andy.

Operator:

Thank you. At this time, I would like to turn it back over to Management for additional or closing remarks.

Dr. Phillip Chan:

Thank you everyone for participating in today's call. If you have any questions, please 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 night.

Operator:

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

Analysts

Joshua Jennings, *Cowen and Company, LLC*
Andrew D'Silva, *B. Riley FBR, Inc.*
Sean Lee, *H.C. Wainwright & Co, LLC.*
Jason McCarthy, *Maxim Group*
Brian Marckx, *Zacks Investment Research*