

# CytoSorbents Corporation (NASDAQ:CTSO) Q1 2018 Earnings and Operating Results Conference Call May 8, 2018 @ 4:45 PM 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 First 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 and good afternoon. Welcome to CytoSorbents' First 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 (from Germany)
- 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 May 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 the first quarter by Dr. Chan and Ms. Bloch. Following that presentation, we will open the lines of your questions during the live Q&A session with the rest of the Management Team.

At this time, it is now my pleasure to turn the call over to Dr Phillip Chan.

# Dr. Phillip Chan

Thank you very much Jeremy, and good afternoon, everyone.

#### Slide 4:

Coming off a seasonally strong Q4, we had a solid start to the year. During the quarter, we achieved 40,000 CytoSorb® treatments delivered, up from 23,000 a year ago. We also had record trailing 12-month total revenue of \$17 million, including 12-month product sales of \$15.2 million with a mix of strong direct, distributor, and partner activity. At the end of the quarter, we were well-capitalized with a healthy cash balance of \$21.1 million and we are currently preparing for more growth. We have a new manufacturing plant nearing final validation and certification and expect it to come online this quarter. We expect that blended gross margins should approach or exceed 80% over time with volume manufacturing, blending higher margin direct sales with lower margin distributor and partner sales.

Meanwhile, users of CytoSorb continue to demonstrate the clinical benefit of CytoSorb in a wide range of critical illnesses, now easily searchable in a <u>new literature database</u> at www.cytosorb.com, with new published articles and peer-reviewed journals and the successful completion of our 5<sup>th</sup> International CytoSorb Users Meeting at the 38th International Symposium of Intensive Care and Emergency Medicine Conference in Brussels, Belgium. During the quarter, we also expanded our distribution to Malaysia with our partner Biocon.

#### Slide 5:

On the clinical side, our U.S. REFRESH 2 pivotal trial, which is a 400-patient randomized-controlled PMA trial, targeting the reduction of post-operative acute kidney injury using CytoSorb during complex cardiac surgery in patients undergoing valve replacement and/or aortic reconstruction with hypothermic cardiac arrest. We recently enrolled our first patient into the trial with more expected soon. Several REFRESH 1 sites are expected to come online soon with a total of 26 sites in various stages of evaluation, qualification and initiation. We are targeting a total of 20 active sites for the study.

Meanwhile, the REMOVE endocarditis trial which is being funded by the German government, continues to make excellent progress. This is a 250-patient randomized controlled trial evaluating the safety and efficacy of CytoSorb in improving organ dysfunction when used intra-operatively during valve replacement surgery for infective endocarditis. The first patient in this trial was enrolled in January. Now the trial has 22 patients enrolled at three centers with three more starting very shortly.

Last but not least, the HemoDefend pivotal trial that we discussed last quarter. This is a point of care filter that removes non-infectious contaminants like cytokines, bioactive lipids, antibodies, free hemoglobin, and others from transfused packed red blood cells. The commercial-grade tooling for clinical device parts is nearing completion ahead of the human trial, which is expected to begin sometime in the next 9 to 12 months.

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

# **Kathleen Bloch**

#### Slide 6 & 7:

Thank you, Phil, and good afternoon everyone. For today's call, I will be providing an update regarding CytoSorbents' First Quarter financial results and an update around our working capital and cash runway.

Product sales for the first quarter of 2018 were approximately \$4.4 million, which is an increase of \$1.8 million or 71% over Q1 2017 product sales of approximately \$2.6 million. This increase was primarily driven by an increase in direct sales from both new customers and repeat orders from existing customers, and increase in distributor sales, and a benefit of a stronger Euro.

Grant and other income was \$491,000 in Q1 2018 as compared to \$517,000 in Q1 2017, and our total revenues, which includes products sales and grant income, increased by 58% to \$4.9 million for Q1 2018 as compared to \$3.1 million for Q1 2017.

We are also very pleased to report that for Q1 2018, our product gross margins grew to 74% as compared to 68% for Q1 2017. This was a result of several factors which include a reduction in the cost of devices manufactured, a favorable mix of sales between direct customers and distributors, and a benefit from a stronger Euro. Looking forward to the rest of 2018, we expect product gross margins to improve further, especially in the second half of the year after our new manufacturing facility comes online, which is expected to occur at the end of the second quarter of 2018.

#### Slide 8 & 9:

Next, we'll look at our quarter-over-quarter product sales. Q1 2018 represents another record quarter with product sales of \$4.4 million. Taking the Euro into account, it was roughly flat when compared to Q4 2017. As we mentioned in our last call, there appears to be some seasonality with a robust fourth quarter as hospitals use the remainder of their annual budget to order supplies followed by a comparable first quarter. This is an annual trend that can be observed in the graph.

We strongly believe that the underlying drivers of revenue growth continue to improve, and Management continues to see growing market awareness, interest in usage of the product which is expected to result in continuing sales growth in the coming quarters of 2018. Our direct sales are currently the dominant driver of our results, with strength in both reorders as well as new orders and new customers. Meanwhile, we have made significant investments to also expand the International Sales Team to accelerate this part of our business, and our growth continues to translate into strong year-over-year comparables. In looking at our graph of trailing 12-month product sales, we note that our compound annual growth rate, or CAGR, was 67% over the past three years, and we are continuing to observe a very positive trajectory here.

#### Slide 10:

Lastly, let us take a look at our working capital position. As of March 31, 2018, we had a record approximately \$21.1 million in cash, which provides a very solid foundation for the Company. Those shareholders who have been with us for a long time know that we have been historically very thoughtful and deliberate about financing this Company in a way that minimizes shareholder dilution with a combination of non-dilutive grants, monetization of our net operating losses, the use of debt, and of course, equity raises, while always striving to minimize shareholder dilution.

For example, in March 2018, the Company replaced its existing \$10 million term loan with \$10 million of new debt. This new debt facility is structured as a four-year term loan with monthly payments of interest-only for the first 18 months, and this has reduced our cash needs over that same period by approximately \$6 million. Another \$5 million in term loan debt is available by March 2019 to further extend our operating runway should we choose to take it.

Also, in the first quarter of 2018, we raised approximately \$6 million through our at-the-market, or ATM, equity facility with Cantor Fitzgerald at an average price of \$7.97. Using this ATM, we have been trying to strike a balance between having a strong balance sheet so that we can fund rapid growth while limiting shareholder dilution. The ATM provides an efficient and cost-effective way for us to raise funds for the Company's needs. Given our strong cash position and good working capital position, we have not utilized the ATM since mid-April 2018. We would like to remind our shareholders that we, the Company's Management, are shareholders as well, and we strive to do what is in our collective best interest. Finally, as of March 31, 2018, we had approximately 35 million common shares on a fully diluted basis.

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

# Dr. Phillip Chan

#### Slide 11:

Thank you, Kathy. In terms of guidance, we expect that Q2 2018 CytoSorb sales will exceed product sales in Q1 2018. We continue to expect solid growth and achievement of operating profitability in 2018 on a quarterly basis. That does not include non-cash expenses and clinical trial costs. We also anticipate expansion of our blended gross margins, currently at 74%, as we scale up manufacturing of our new plant that is expected to come on line in this quarter (Q2 2018).

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

# **Question-and-Answer Session**

#### Operator

Thank you. As a reminder, if you do have a question, please press \*1 on your touch-tone 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, please queue up again.

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

# Joshua Jennings

Hi. Good evening. Thanks for taking the questions and congratulations on the strong start to the year and the commencement of enrollment for REFRESH 2. I was hoping to start my questions on the REFRESH 2 trial and just get a sense how IRB approvals are tracking relative to your initial estimates and as a surrogate for enrollment. When do you think you will get the full number of sites up, and when will you be enrolling at full pace?

# Dr. Phillip Chan

Well, thanks very much Josh. Let me turn it over to Dr. Eric Mortensen, our Chief Medical Officer, to give you an update on that aspect. Eric?

# **Eric Mortensen**

Sure Phil. Thank you for the question Site initiation has been a little slow relative to what we had anticipated. We had hoped that by front-loading the study with centers involved in REFRESH I, and with the conditional FDA approval of our IDE application in December, that these sites could have started earlier. A number of our investigators were extremely eager to get going, however, these hospitals ultimately required the final FDA approved protocol which came out at the end of March, in order to begin their process [despite the FDA being very clear that sites could begin enrollment with the conditional IDE approval in December 2017]. So, because of legal and contractual aspects, we were not able to get sites onboarded until that time. We now have one site that was able to work ahead of the final protocol approval, that is now fully initiated and enrolling. We are awaiting final IRB approval for a number of sites and expect to rapidly bring additional sites onboard. We are seeing very strong interest in the protocol based upon the overseas experience with CytoSorb, as well as with our preliminary results from REFRESH 1.

# Joshua Jennings

Thanks for that and I was hoping to just follow up with what are you seeing in terms of CytoSorb utilization from an indication mix standpoint, and then has that been evolving over the last few quarters or has it been fairly consistent?

# Dr. Phillip Chan

Yes, I think that when you look at the overall 40,000 treatments to-date, the majority have been in critical care and of those, the majority have been in sepsis and septic shock. However, the uses in cardiac surgery as well as in ECMO continue to grow and are roughly about a quarter of our current usage. There is a lot of activity, broadly speaking, across many different indications and as you have seen in cardiac surgery, there have been a number of publications in endocarditis, vasoplegia after heart transplantation, and many other indications that people are using the device for. But the overall distribution is a relatively good mix with the strongest growth in critical care.

# Joshua Jennings

Great. One last question. Spectral Medical recently made some public commentary around the FDA's recognition of the challenges of conducting a randomized Phase 3 trial in sepsis and would potentially

consider options such as a single-arm study and a study that relied on Bayesian statistics. Does that change your thinking in any way on the U.S. regulatory path for sepsis and do you have bandwidth for another clinical program with REFRESH 2 and HemoDefend? Thanks for taking all the questions.

# Dr. Phillip Chan

Thanks Josh. We have a very strong desire to continue our clinical studies in sepsis. But rather than do a trial that has too much heterogeneity by including many different kinds of sepsis patients, we are using our clinical experience with CytoSorb to select subgroup populations where the therapy is working very well, reproducibly, and with a pronounced effect. Refractory shock, for example, is one of those areas that we plan to continue to study in formal clinical studies. That said, we did see that announcement by Spectral. As we have discussed, we are focused on cardiac surgery as the target for U.S. approval. However, as we look to expand the label of CytoSorb in the area of sepsis, we will look to try to take advantage of some of the guidance that the FDA is giving on those points in terms of simpler studies, single-arm studies, and other things that remain to be defined.

# Joshua Jennings

Thanks so much.

#### Dr. Phillip Chan

Sure.

# **Operator**

We'll take our next question from Jason McCarthy with Maxim Group.

## Michael Okunewitch

Hi. This is Michael Okunewitch calling in on behalf of Jason McCarthy, congratulations on the quarter. Regarding REFRESH 2, what rate of AKI is expected for cardiac surgery and is that indication specific to valve replacement versus aortic reconstruction? If so, would you stratify the study?

#### Dr. Phillip Chan

Thanks Michael. Eric, why don't you go ahead and take that.

# **Eric Mortensen**

There is definitely a demographic distribution of risk within cardiovascular surgery. The reason why we designed the study as we have, is based upon the recent experience of several other cardiac surgery trials. These studies selected patients using criteria that enriched for patients with a high risk of developing AKI, achieving AKI incidence rates in the 50-70% range. These criteria include pre-operative risk factors for AKI such as hypertension, diabetes, and decreased renal function. This gives us confidence that we will also be able to enrich the patient population to have a high rate of AKI as defined by KDIGO criteria and do so with adequate power. In doing so, we believe we are increasing our probability of technical success within

the REFRESH 2 trial, as well as improving the ability to demonstrate meaningful improvements in clinical outcomes that can support future reimbursement.

# Dr. Phillip Chan

The trial will be stratified for the two populations that we are studying - valve replacement and aortic reconstruction with hypothermic cardiac arrest.

## **Michael Kahanowitch**

All right, thank you and then just a quick follow-up, what kind of improvement would you expect to see to meet the criteria for approval.

# **Eric Mortensen**

It will depend upon what we actually see as the baseline rate of AKI and ongoing discussions with the FDA to make an assessment of what is clinically meaningful. However, based upon what has been considered to be a credible improvement in bundled therapy for AKI, I would say that improvements of around 9% to 12% are in the credible range.

## **Michael Kahanowitch**

All right. Thank you very much for taking my questions.

# Dr. Phillip Chan

Thanks Michael.

#### Operator

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

# Sean Lee

Hi. Thank you for taking my questions and congratulations on a strong quarter. My first question is on the REFRESH 2 study. Could you give a little bit more color on the timing you expect for patient enrollment and for study completion? Also, I noticed that the R&D expenses have dropped quite a bit this quarter compared to last quarter. Do you expect that to ramp up over the rest of the year?

## **Eric Mortensen**

Thanks. Let me just reiterate that it has been a little slower at the onset than we had initially anticipated for the reasons I have already described. We have also had some turnover at our CRO which did not help in terms of our initial site onboarding. However, I think that we are now well-poised to make progress. We have done a fantastic job of bringing on board a very experienced clinical team at CytoSorbents to be able to take in-house and directly manage and have more control over the site onboarding and management process of REFRESH 2. In the fourth quarter, there were a number of costs associated with

overall start-up, bringing on board our central laboratory, our CRO, and other trial infrastructure. First quarter clinical expenses reflect activities related to bringing sites through the IRB approval process. Once we pass this stage, we anticipate clinical costs to rise due to patient accrual.

# Sean Lee

Thank you for the color on that.

# Dr. Phillip Chan

One thing to add is from a patient enrollment standpoint, we do believe that one to two patients per site per month is possible. Again, based on our history with REFRESH 1 and work that we have done to streamline the protocol, we expect this trial to be very straightforward for sites to execute upon. The intervention with CytoSorb is just during surgery, where CytoSorb is installed into the heart lung machine in a bypass circuit. Once out of surgery, they go into the intensive care unit where all we are doing is taking urine and blood samples, and monitor patients for clinical outcomes. Then there is a 30-day follow-up period.

So, notwithstanding the enrichment criteria, which makes it a little harder to find patients for the study, we believe there are a lot of patients out there who could qualify for this study. These are patients who have risk factors for acute kidney injury such as diabetes, hypertension, hyperlipidemia, renal insufficiency, and other things. But once they are enrolled in the trial, we believe sites can execute on those patients very quickly.

We anticipated roughly a two-year enrollment period. Although there has been some delay, we believe that we are going to see a bolus of sites come on board at roughly the same time, which will help enhance the rate of enrollment overall. We will know more as we get into the trial, as we see the rate of enrollment. Eric mentioned the Thrasos study that enrolled 450 patients in a little over 2 years using very similar criteria. So we think that the two year number is credible.

#### Sean Lee

Thank you, Phil. That makes it much clearer. My second question is on HemoDefend. I know the product has been in development for over a year now, but most of focus has been on CytoSorb. Could you dive a little more into to the commercial opportunity for HemoDefend?

# Dr. Phillip Chan

Sure. HemoDefend is designed from our biocompatible porous polymer platform and is a technology that has been supported by the National Heart, Lung, and Blood Institute (NHLBI) – a division of National Institutes of Health (NIH), as well as Special Operations Command or U.S. SOCOM. HemoDefend is designed to purify packed red blood cells (pRBC), which are one of the primary transfused blood units with more than 100 million units transfused worldwide each year, while reducing non-infectious contaminants that can potentially cause life-threatening transfusion reactions. HemoDefend has demonstrated the ability to reduce a broad range of inflammatory mediators such as free hemoglobin, cytokines, bioactive lipids, antibodies, and other substances that can lead to a myriad of adverse events as mild as fever and itching, all the way to life-threatening transfusion-related acute lung injury called

TRALI that is estimated to occur in roughly one in every 5,000 blood transfusions. Those patients who get more blood transfusions have a cumulative risk of developing transfusion reactions.

HemoDefend is particularly suited for patients getting a lot of blood such as surgery patients - including cardiac surgery patients, critically-ill patients - particularly trauma patients, cancer patients, and other patients who are either getting a lot of blood or are getting blood repeatedly over a long period of time. We initially believe that in the United States, HemoDefend would be focused on an initial 5% to 10% of the total addressable market, and expand from there. We plan to leverage U.S. approval to obtain approval in Europe and elsewhere where we already have a distribution channel in place. This would enable us to sell HemoDefend through our critical care or cardiac surgery sales force in our various countries all over the world. So HemoDefend is something that we could leverage but I think our primary goal for the United States is not to do this alone. It is to partner this with a major player in the blood transfusion space and we have had discussions with all of the major players in the past.

# Sean Lee

Thank you for that. That's all I have.

# Dr. Phillip Chan

Great. Thanks Sean.

## **Operator**

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

# **Brian Marckx**

Hi Guys. Congrats on the quarter. So I am trying to get a little better understanding in terms of what your expectations are now with the pace of onboarding of the REFRESH2 sites and just wondering if you are willing to give us a general forecast of what you are anticipating over say the next three to six months in terms of the number of sites that you hope to have actively enrolling?

## **Eric Mortensen**

We currently have 26 centers that have already indicated that they would like to be in the trial, and are in various stages of evaluation, qualification, and initiation. We have a block of qualified centers that have been waiting for the final protocol approval from the FDA in March, and are just now waiting for the May IRB approval, so they can get going. We have a lot of new sites that have either gone through site qualification visits or will have those completed in the next couple of weeks.

Our expectation is to bring on an initial cohort of about 20 centers to fully activate. Some of those will not perform adequately, so we are currently over-enrolling the pool of centers so that we can replace centers rapidly if needed. I think the history of my 20 years of clinical trial experience has taught me that if you are not prepared to be able to swap sites out, you are going to be underprepared.

So I cannot promise you which sites will be the optimal ones, but I think that we have a robust plan in place to make sure that all sites are performing to expectations.

# Dr. Phillip Chan

Despite the delays that Eric had mentioned, we believe the majority of REFRESH I sites will be up and running very shortly, with some poised to have their site initiation visit and begin screening for their first patients on the order of the next one to two months.

## **Brian Marckx**

Okay and then in terms of REMOVE, you have another three sites that you expect to come online. It looks like your pace of enrollment is roughly five or six patients a month to this point. Is it fair to forecast that the pace of enrollment could double with the additional three sites coming online?

# Dr. Phillip Chan

Yes, I think these sites have been selected because of the high incidence of endocarditis at their centers and because these are all major academic centers that are very used to doing clinical studies. Although this pace of four to five patients a month is actually more than we had anticipated, if they can keep that up, that would be fantastic. We will know very shortly when these additional three sites come on board, what their enrollment rates will be. But I think modeling somewhere between three to five patients a month per site based on what we have seen so far is probably realistic.

## **Brian Marckx**

Okay, great. Thank you.

# **Operator**

As a reminder, pleas press \*1 to ask a question and we will take our next question from Andrew D'Silva from B. Riley FBR.

## **Andrew D'Silva**

Hi, good afternoon, and thanks for taking my questions. I just have a couple of quick questions When comparing Q4 2017 to Q1 2018, can you refresh my memory on what the delta was in product gross margin and should we figure a similar benefit in the fourth quarter of this year or has that changed with the new expanded manufacturing capabilities?

# Dr. Phillip Chan

Kathy, did you want to take that?

## Kathleen Bloch

Yes. Andy, we have not reported the fourth quarter product gross margins, but we reported 71% blended gross margins over the year 2017. Of course now we have just reported 74% blended gross margins on product sales. What we have stated about the future is that we expect our gross margins to continue to improve in 2018, particularly in the second half of the year as we begin to realize the benefits of the

economies of scale with our bigger batch production at our new facility. The new facility is expected to be operational at the end of Q2 2018.

## Andrew D'Silva

Okay, perfect. And then with HemoDefend, is it going to be necessary for you to make any other adjustments to your manufacturing facility once you are able to actually commercialize the product or is it going to be using a lot of the same resources that you already have and equipment that you already have in place to develop CytoSorb.

# Dr. Phillip Chan

Yes, thanks Andy. Let me ask Vince Capponi, our Chief Operating Officer who oversees manufacturing to take that question.

# Vincent Capponi

Sure. Thanks Andy. So basically, we will utilize many of the same processes that we currently have now. We will have to make some small equipment modifications in order to accommodate the different size device, for example, the filling setups. But it is not expected to be a significant capital expenditure, although there will be some to be able to accommodate HemoDefend. But basically, it is using a lot of the existing infrastructure, which is a real positive.

## **Andrew D'Silva**

Okay and in a previous question you mentioned that you look to partner this in the United States. Is this similar to your distribution partnership arrangements where you would take care of all the manufacturing or is this an opportunity at that price point down the road where it would make sense for you to let outside entities manufacture it?

## Dr. Phillip Chan

I think this could potentially be either a strategic distribution agreement or a license agreement, because it is a very large market. The United States is a very large consolidated market with more than 10 million pRBC transfusions administered each year. From a manufacturing standpoint, we have tried to take into account the need to be able to mass manufacturer this product in a very low-cost way. That is a technology that can either be transferred to a contract manufacturer or something that we could potentially do ourselves. I think that we will wait to see how things go but as it currently stands, our plan right now is to manufacture the initial quantities first, and we currently have the capacity to be able to do that. As we exit the current manufacturing facility for CytoSorb and move that to the new manufacturing facility, we will actually open up capacity to be able to run production for HemoDefend. So, we will see how everything goes and then at the appropriate time make the decision to either outsource or continue capital investment in our own facility. But again, because we have designed this product for automation, I think that it can potentially be manufactured in volume at a relatively low cost with relatively low capital expenditure needs.

#### Andrew D'Silva

Okay, that is good to hear. Finally, in your 10-K, you mentioned that you are going to start looking at additional indications and starting new studies. Recently, draft guidance was put out by the FDA related to breakthrough devices. So outside of opportunities like sepsis, which we have discussed in the past, are there other low hanging fruit indications that you think would be appealing to look at domestically that would directly fall into that new pathway that hopefully will emerge soon?

# Dr. Phillip Chan

Yes, absolutely. The breakthrough designation is relatively recent to the medical device space, but something that drugs and biologics have had for a while. It favors those technologies that either try to address a major unmet medical need where the risk of death is high, or where the risk of long-term disability is high. Those are exactly the kinds of markets that we serve. I believe there are a lot of opportunities to target this pathway, and you can imagine that we would be looking at many possible options.

# Andrew D'Silva

I am just trying to understand how this whole thing would work out. So let us say that you identify a critical care application, and that you are able to go down that path. With the robust data you have been able to get out of Europe, how hard would it be to go down the path of sepsis, with the strategy of expanding the use for burn injury and other indications where there are elevated levels of cytokines and inflammatory mediators?

## Dr. Phillip Chan

There are a number of focused applications in sepsis where we have seen the device work remarkably well. Because of this, we think that some of these studies could be less than a hundred patients, in a randomized controlled trial, and not have to worry about whether or not the FDA will accept data from a single arm study. That said, in terms of the breakthrough designation pathway, there are potentially easier ways through this process other than sepsis, and as I mentioned before, you can imagine that we are looking at all of those possibilities.

## Andrew D'Silva

Okay, wonderful. Thanks for the color and congratulations on the progress and good luck going forward this year.

## Dr. Phillip Chan

Thanks very much Andy.

#### Operator

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

# Dr. Phillip Chan

Thank you everyone for joining us today and thanks to all of the analysts for your questions. We certainly appreciate your interest in our progress. If you do have any other questions, and this goes out broadly to the audience, please feel free to reach out to jeremyfeffer@lifesciadvisors.com, and we will try to reply to your questions where possible. In the meantime, we hope to see you at our Annual Meeting on June 5, 2018, in New York City. This requires pre-registration. So if you did not indicate your attendance on your proxy, please contact Lea Garcia at Igarcia@cytosorbents.com to get on the invitee list. Thank you very much everyone and we look forward to talking to you again.

# **Operator**

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

Analysts
Joshua Jennings, Cowen & Company
Michael Okunewitch, Maxim Group
Sean Lee, HC Wainwright
Brian Marckx, Zacks Investment Research
Andrew D'Silva, B. Riley FBR