CytoSorbents Corporation (NASDAQ: CTSO)
Q2 2018 Earnings and Operating Results Conference Call
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This official company transcript has been edited for clarity and does not differ materially in content from the actual conference call except where noted. Slide numbers have been inserted to allow readers to follow along with the associated presentation.

Operator:

Good afternoon and welcome to the CytoSorbents Second 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- Moderator:

Thank you, Cassie and good afternoon. Welcome to CytoSorbents' Second 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, VP of Sales and Marketing

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 August 2, 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 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 had an outstanding second quarter. During the quarter we achieved more than 46,000 CytoSorb treatments delivered cumulatively, up from 27,000 a year ago. We also had record trailing 12-month total revenue of $19.1 million, including record 12-month product sales of $17.4 million, fueled by a mix of strong direct, distributor and partner activity. We were also very well-capitalized, with a healthy cash balance of $25.3 million at the end of the second quarter. During the end of the quarter we officially opened our new manufacturing plant, now in commercial production, that is expected to help expand blended product gross margins, which mix higher margin direct sales with lower margin distributor and partner sales, well beyond the current 74%.

During the quarter, we were also added to the Russell 2000 Small Cap and Russell 3000 indexes. CytoSorb also achieved an expansion to its label to now include the reduction of bilirubin in liver disease and myoglobin in severe trauma. As mentioned in the press release, this has the potential to significantly expand the usage of CytoSorb.

Slide 5:

In terms of a clinical trial update, we are pleased to announce that the REMOVE Endocarditis trial, which is being funded by the German government, has now enrolled 40 patients at six centers. 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.

Our U.S. REFRESH 2 pivotal trial is a 400-patient randomized controlled, multicenter, adaptive, PMA study targeting the reduction of postoperative acute kidney injury using CytoSorb during complex cardiac surgery. These include procedures such as valve replacement surgery and aortic reconstruction with hypothermic cardiac arrest. We have now expanded our active sites to a total of seven sites with three additional sites that have completed clinical trial agreements, and an additional 19 sites completing start up activities. At the recommendation of key clinical advisors, a protocol amendment was submitted to expand the inclusion criteria, improve operational aspects of the patient screening process, enhance the rate of enrollment, and ultimately increase the applicable market that CytoSorb could address if approved. Changes were back-tested to the patient screening logs, and this amendment is expected to be approved this quarter by the FDA.

Meanwhile we plan to be ready with 15 to 20 active sites recruiting when the amendment goes into effect, driving what we believe will be a step function in enrollment at roughly one patient per site per month, rather than the gradual increase in enrollment that we would have seen during the early part of this study without the amendment.

Last but not least, our HemoDefend pivotal trial is moving towards its initiation. HemoDefend is a point-of-care filter that removes non-infectious contaminants from transfused packed red blood red cells that can cause transfusion reactions, and the U.S. pivotal trial for this product is expected to start in the first quarter of 2019. Currently, we are validating our initial device builds and will be building out clinical devices later this year.

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

Kathleen Bloch - CFO:

Slide 6 & 7:

Thank you Phil and good afternoon everyone. Today, I will provide an update regarding CytoSorbents' second quarter 2018 financial results, and in addition, I will provide an update around our working capital and our cash runway. CytoSorb product sales for the second quarter of 2018 were approximately $5.2 million, which represents our best quarterly product sales ever. This is a 73% increase over product sales of approximately $3 million for the second quarter of 2017. This increase was largely driven by an increase in direct sales from both new customers and repeat orders from existing customers, along with an increase in distributor sales, as well as a stronger euro.

Based upon our second quarter 2018 results, we are currently at an annualized product sales run rate of approximately $21 million, as compared to approximately $12.2 million just one year ago.

Total revenues, which includes both product sales and grant revenue, were approximately $5.8 million for the second quarter of 2018, as compared to approximately $3.6 million for Q2 2017, an increase of approximately 61%. Second quarter 2018 gross profit grew to appropriately $4 million, an increase of approximately $1.9 million or a 90% increase, over gross profit of approximately $2.1 million for the second quarter of 2017.

Finally, our gross profit margins on product sales were approximately 74% for the second quarter of 2018, up from 65% for the second quarter of 2017, primarily as a result of the achievement of manufacturing efficiencies at our existing facility. This does not yet reflect the additional benefits that we expect to achieve from our new manufacturing facility that became operational at the very end of the second quarter 2018.

Slide 8:

Turning to our six-month financial results, product sales for the first half of 2018 were approximately $9.7 million, a 72% increase over product sales of approximately $5.6 million for the first half of 2017. Once again, increases in direct and distributor sales were the major contributors to revenue growth, and, to a lesser extent, we also benefited from a stronger euro.

Grant revenue was approximately $1 million for the 6 months ended June 30, 2018, relatively unchanged from the same period in 2017. And our total revenues, which includes product sales and grant revenues, were approximately $10.7 million for the first half of 2018, as compared to $6.7 million for the same period in 2017, an increase of approximately 60%.

Slide 9 & 10:

Next, we will look at our quarter-over-quarter product sales growth. With this quarter, Q2 2018, we have achieved our 24th consecutive quarter of year-over-year quarterly growth. As mentioned previously, our annualized run rate is now at $21 million annually. Q2 2018 sales of $5.2 million were significantly higher than Q1 2018 sales, as well, by approximately $4.4 million. This represents an 18% sequential quarter-over-quarter growth in sales.

Most importantly, management believes the underlying drivers of revenue growth have remained unchanged, and we continue to be very optimistic about continuing sales growth, particularly with regard to the second half of 2018. Next, looking at our trailing 12-month product sales, over the past three years the Company has experienced a 73% compound annual growth rate. Overall, our annual product sales growth exhibits a very strong trajectory, and we expect continuation of this trend for the future.

As we have previously stated, one of our key milestones for 2018 is the achievement of operating profitability, which excludes noncash expenses and clinical trial costs on a quarterly basis. **In Q2 2018, we have narrowed our operating loss as defined to approximately $300,000.** With that, we remain very confident that we will reach our goal of achieving operating breakeven as defined on a quarterly basis this year.

Slide 11:

Turning to working capital, as of June 30, 2018, we had approximately $25.3 million in cash and cash equivalents. This provides a very solid foundation for the Company. We believe that the existing cash runway will allow us to meet all of our operating and clinical trial needs well into 2020.

Turning to our capital structure briefly, as of June 30, 2017, we have approximately 36.3 million common shares outstanding on a fully diluted basis.

And now I'd like to turn the call back to Phil.

Phillip Chan - CEO:

Slide 12:

Thanks very much, Kathy. In terms of our guidance for the second half, we expect that second half 2018 CytoSorb sales will exceed first half 2018 CytoSorb sales. We also continue to expect solid growth and the achievement of operating profitability in 2018 on a quarterly basis, less noncash expenses and clinical trial costs. Again, we anticipate expansion in blended product gross margins, currently at 74%, as we scale up production from our new manufacturing facility.

This concludes our prepared remarks. Operator, please open up the call 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. Again, press *1, to ask a question. We will pause for a moment to allow everyone an opportunity to signal.

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

Joshua Jennings:

Hi. Good afternoon, and congratulations on another record revenue quarter. I was hoping to start off with the performance in Germany. It looked stellar, I think 75 percent year-over-year growth? Can you help us think about the drivers there? Should we be thinking that the dedicated reimbursement code has finally kicked in more thoroughly throughout Germany? Also, how would you characterize the utilization? Broad based with a lot of indications, or deep at key centers? Any incremental color you can give us on the outperformance in Germany would be great.

Phillip Chan:

Thanks Josh. As we have discussed previously, our sales momentum in Germany benefits from the fact that we have been selling there the longest, and have a number of positive factors in our favor. First, we have an outstanding sales team, based out of Berlin, Germany that is about 38 people strong. Our team has been solely focused on developing the market for CytoSorb, and through this dedicated effort, CytoSorb is very well-known throughout the country amongst intensivists and many cardiac surgeons. We have the support of many major key opinion leaders in Germany and elsewhere, and are in most of the major university and public hospitals.

As you mentioned, a key piece in the puzzle was obtaining dedicated reimbursement for CytoSorb in Germany in late 2016, that was then negotiated by hospitals with the central payer during 2017, and where the dollar value of reimbursement has now been established that fully reimburses both the costs of the device and also the treatment itself, at a significantly higher level than what was available previously at our surveyed hospitals. We are beginning to see that reimbursement is having a significant impact on the order patterns for CytoSorb now that it is fully reimbursed at most of the sites that we have surveyed. We see signs that the market in Germany is changing to a "pull market" where clinicians are asking us about starting the therapy, after hearing the success from other colleagues at other institutions. We also see a lot of interest from clinicians from many different parts of the world.

But with that, let me turn it over to Christian Steiner, our Vice President of Sales and Marketing, who is based out of Germany and who has led our commercial efforts to date, for some color. Christian?

Christian Steiner:

Yes, thank you, Phil. Yes, in principal, what Phil said is the most important thing. We have been in Germany for a long time, so we have the most experience there and also we have the strongest team there. The direct sales team is 100% dedicated to this one product and focused on the introduction and development of the therapy. But I think a number of other things have to be taken into account including when departments

and people gain more experience with the therapy and begin to think about how to use it more broadly. There are so many patients with illnesses associated with systemic inflammation. Because of this, there are many other different indications where CytoSorb could be helpful. Conditions commonly seen in the ICU include septic shock and cardiac surgery patients have been our focus so far. However, there are many more including liver dysfunction, trauma, cardiac arrest, and others. Altogether, our momentum continues to be strong in our direct territories and especially in Germany.

Joshua Jennings:

Great, thanks. Then I had a follow-up for Kathy, just on the new manufacturing facility. It sounds like you are going to get a margin benefit even as soon as third quarter? Can you share any other details, including when you think you may reach 100% of CytoSorb manufacturing capacity in the new facility, and is there any risk in terms of inventory changes from the old plant and the new facility?

Kathleen Bloch:

Yes, maybe I'll leave the capacity and production levels to Vince to handle, but just to reiterate, the blended gross margins of 74% in Q2 2018 were based on efficiencies that we achieved in the old manufacturing facility. We are expecting to come out with improved margins in Q3 and Q4 2018, and into 2019. We have previously stated that we expect those blended gross margins to rise to 80% and even better given some additional time. Vince, could you comment on the capacity and how we are going to manage the scale-up?

Vincent Capponi:

Sure and thanks, Kathy. The new plant is approved for manufacturing and producing product. We are currently doing blended production out of the current facility and the new facility. We fully expect to have 100% of our production coming out of the new facility by the end of August, with Q4 2018 as the first quarter that will reflect product gross margins from only the new plant.

Inventory-wise, we plan to increase product inventory out of the new plant to ensure we have no disruptions in supply to the market. Currently we are just beginning the first of two stages of plant expansion. With a very small additional capital expenditure, we can easily double the capacity of that plant.

Phillip Chan:

Thanks Vince. The new facility at full capacity should produce roughly $80 million in product sales. We believe we can get there in the next three to five years.

Joshua Jennings:

Thanks. That's helpful. And just one last question for you, Phil. You have announced some recent distributor agreements in a handful of new countries. Just wondering how we should be thinking about the impact here in the second half of the year. Are there any stocking agreements associated there? Then also I think that you swapped out the U.K. distributor, and should we be thinking about any disruption in England and Ireland in the near term? Thanks so much for taking the questions.

Phillip Chan:

The last press release was a little bit of a catch-up press release, because we have been working with most of these distributors in some fashion for the past several months. We do not expect there to be any major stocking orders going forward. What we hope to see is more of a recurring order pattern from these organizations. In terms of the U.K., the U.K. is a very complicated market to get in to, and our U.K. sales have been nominal to date. I think that with the new distributor, and with some dedicated efforts to work on obtaining NICE recommendation for CytoSorb, we hope to see that change. But I would not expect the U.K. to be a meaningful contributor to sales for the remainder of this year.

Joshua Jennings:

Thanks Phil.

Phillip Chan:

Thanks Josh.

Operator:

If you find your question has been answered, you may remove yourself from the queue by pressing *2. We will now take our next question from Andrew D'Silva, with B. Riley FBR.

Andrew D'Silva:

Hi. Thanks for taking my question. Congrats on the progress. I just have a couple of quick ones here. To start, just my standard question that I ask every quarter. Were any one-time bookings or any large stocking orders taken during the quarter? The reason I am asking is because on the last call, you said that Q2 would be stronger than Q1. You typically do not give that kind of quarterly granularity, and I was just curious what gave you that confidence on the last quarterly call.

Phillip Chan:

Thanks Andy. There were no major stocking orders. I think what we saw was very strong organic growth for reorders from existing accounts, which make up the vast bulk of our sales. We continue to open up new accounts as well, but those types of stocking orders are typically very small. Also, accounts in our direct sales territories typically order on an as-needed basis and are not carrying significant inventory. I think that the confidence in providing that guidance that Q2 would be stronger than Q1, and now our new guidance that the second half of 2018 will be stronger than the first half of 2018, is because of the order patterns and momentum that we are seeing in the marketplace.

To give you a little bit of color from an example. At a lot of conferences, we see very distinct changes in booth traffic and discussions. Previously, there were a lot of discussions with people who had never heard about CytoSorb, where we spent a lot of effort to educate them and get them interested enough to warrant a follow-up meeting or call. Now, in fact, we are seeing a lot of people just coming up to the booth and saying “sign me up” or “please come visit me and let's get this going at my institution.” It is that kind of momentum shift that gives us confidence that we should be able to continue strong year-over year growth. Again, we

would reiterate that although we are seeing strong growth now, we believe we are only scratching the surface of this opportunity and believe that even more rapid growth is potentially ahead of us.

Andrew D'Silva:

Okay. That is very good to hear, and that gives a really good segue into my next question, which involves what other clinical opportunities are you seeing? I know sepsis has been a big focus. We have touched base on the treatment of cytokine release syndrome (CRS) and CAR-T a couple of times. Are you seeing any opportunities to be involved or pursue your own clinical trials for either of those indications? For CAR-T, I would imagine that any U.S. trial would have to be done in conjunction with a company, but with Novartis and Gilead expected to get approval for their CAR T-cell therapies in the E.U. fairly soon, potentially this quarter, it seems like you are pretty well-positioned to treat CRS in Germany if that happens.

Phillip Chan:

Yes, I think that we are watching that very closely. Both Kymriah and Yescarta have already been recommended for approval in the E.U., and we are just waiting for the final approval. What we have been doing in the meantime is positioning ourselves to be used as a therapy to treat CRS. This is an active program that we have ongoing internally. In terms of any kind of business development efforts, we will leave that for a future discussion.

We are actively pursuing opportunities in our main markets of sepsis and cardiac surgery. However, as discussed in today's press release, we are excited about expanding new markets within liver disease and trauma. We have talked about these applications in the past because of the significant inflammatory component in these diseases. However, the expanded label of being able to reduce bilirubin, which is a toxin that accumulates in people with liver disease, as well as myoglobin that is released by damaged muscle in severe trauma, represents significant growth opportunities for the Company because now we can make a compelling argument to clinicians treating these diseases, based on the on-label reduction of cytokines, bilirubin, myoglobin, and other toxins.

As I mentioned in the press release, the number of people with liver disease around the world is staggering. Again, it is driven by three major problems. One is the development of viral hepatitis from either food contamination or through unprotected sexual contact. The second major driver is alcoholism. The third major driver is fatty liver. You have heard of a number of companies that have done very well in addressing, for example, NASH, or non-alcoholic steatohepatitis, often called fatty liver. CytoSorb is being used to treat hospitalized patients suffering from the acute exacerbations of chronic liver disease to help stabilize them. In the future, I think we will see strong demand for our technology in liver support. Let me turn it over to Christian Steiner for some additional comments. Christian, just as background, began his career at Teraklin, which developed the MARS liver dialysis therapy, which is used widely around the world today. Christian, could you please talk a little bit about what you are seeing in the marketplace in the treatment of liver disease?

Christian Steiner:

Yes, thank you, Phil. Yes, what you said is absolutely right. Liver dysfunction is a particular problem in acute care. CytoSorb, as it is positioned on the market now as a therapy for calming down systemic inflammation, is perfectly positioned to take over the market, which is currently serviced by other liver support systems. In the past, scientists and clinicians thought that blood purification of liver toxins, like bilirubin, bile acids, and

others, were enough to save patients. But in fact, these substances are fueling inflammation, and CytoSorb is able to effectively cover all of these areas, removing the toxins and stabilizing patient inflammation. The simultaneous reduction of these factors, is what we believe is leading to clinical improvement with CytoSorb. We have seen the use of CytoSorb in liver dysfunction and liver failure already before, but now with the CE market approval and expanded label, I think we will see accelerated growth in this area.

Andrew D'Silva:

Thank you. My final question, is related to Fresenius. With everything going on with the NxStage merger, the extension of the timeline, the recent divestiture, and all the moving parts going on there, have you seen any sort of disruption with your progress there, and how do see things evolving, assuming that the merger is completed?

Phillip Chan:

I think what you have seen from Fresenius is a real focus on developing their critical care markets. Not only are they the world leader in dialysis, they are the number one or number two leader in installed base of dialysis machines in ICUs around the world. With the pending acquisition NxStage, it would put them squarely in a competitive position with Baxter in the U.S., and be very well-positioned to gain market share in the U.S. market. Several years ago, Fresenius also acquired a German company called Xenios and acquired a subsidiary called Novalung, and its novalung gas exchange technology, a form of extracorporeal membrane oxygenation (ECMO). It is very good at gas exchange, particularly carbon dioxide exchange. ECMO systems are sold by most of the major cardiac surgery players and are rapidly gaining popularity as a way to help stabilize patients who have very severe respiratory failure. With the new modality called veno-arterial ECMO, they are using it to help provide blood pressure support to hemodynamically unstable patients. But the thing about ECMO is that it is only supportive care. It does not speed patient recovery or reduce inflammation. That is one of the reasons why CytoSorb has now been estimated to have been used in more than 2,500 ECMO treatments. While ECMO is used to help with gas exchange, CytoSorb is being used to reduce the inflammatory mediators that are driving continued lung injury and other organ dysfunction.

When you look at Fresenius, I think that we fit very well into that strategy of acute care. We are the high margin razor blade disposable that works in their installed base of dialysis machines in ICUs throughout Europe and the rest of the world, in NxStage's machines that are a dominant player in the U.S. critical care market, as well as now the new machines that they have acquired from Xenios, including the novalung. We continue to have a very strong relationship with Fresenius, and we will see how that market develops and how that begins to help our sales. It is something that we are looking forward to.

Andrew D'Silva:

Okay, thank you very much for the color, and good luck going forward for the rest of this year.

Phillip Chan:

Great. Thanks, Andy.

Operator:

Once again, if you would like to ask a question, please press *1.

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

Sean Lee:

Good afternoon, guys, and congratulations on a great quarter.

Phillip Chan:

Thanks, Sean.

Sean Lee:

My first question is on the REFRESH 2 study. I know that Phil mentioned that you guys are filing a protocol amendment to help expand the patient group. What kind of patient expansion can we expect from this amendment, and could you provide some more color on that?

Phillip Chan:

Sure. Eric, would you like to take this question?

Eric Mortensen:

Sure, Phil. Let me just take one quick step back to remind you of what our overall strategy was in regard to the operational piece for the REFRESH 2 study. As we discussed at the end of last quarter, we have a simple three-step process. One, get our experienced sites who participated in REFRESH 1, quickly up and going. Two, get a better understanding as to how the protocol is working at those sites. Then, three, very rapidly, by virtue of having brought onboard a very experienced group of clinical trialists here at CytoSorbents, make sure that we then bring onboard the sites that will drive recruitment very quickly once we have finalized a revised protocol.

We are very proud of our team. They were able to get the entire cohort of REFRESH 1 study sites onboarded in the last quarter. Then in the course of about two months, they used the experience and screening logs from those sites to better understand how to optimize the enrollment and flow of the study. This is the challenge of most studies because there is always a difference between what you write down on paper and then how it actually performs in the field. We were able to work with sites that were very familiar with the REFRESH 1 protocol and quickly understand what changes were needed to optimize the study. This is why I wanted to keep my study funnel a little tight at the beginning, because if you are initially too broad and enroll patients with poor characteristics that weaken your study, there is no going back and you cannot exclude those patients. But you can always open your funnel a little bit wider. Our funnel was a little tight at the beginning, and our study coordinators really helped us with real world data to identify a few criteria that could make it a lot easier to enroll the study and not alter the desired risk of AKI.

I can give you a couple of examples of a number of changes that were made in the amendment. For example, I had included an upper age cap in the initial trial design, mostly for operational aspects, but now have determined that it was not necessary in the actual study. Also, the sites helped us simplify and streamline the description of patients, with regard to their baseline renal risk factors, making it easier to identify patients to enroll. By backchecking these changes against site screening logs, we are very confident that we are seeing

a significant multiplier. One center indicated that they would go from two eligible patients in the two months of screening to 30 patients being eligible. After reviewing those patients with our key clinical advisors, they felt that the amended criteria were very logical to use going forward. We have now discussed this with the FDA, have submitted an amendment, and are waiting shortly for approval on that amendment.

In the meantime, we are not just waiting on that amendment. Our team at CytoSorbents has taken ownership over the critical piece of the study startup, which is site identification and site initiation. With a device like CytoSorb, you really need to make sure that you have the capacity for physician-to-physician discussions with investigators, conversations with study coordinators and perfusionists that will help maintain excitement, properly educate them, properly train those sites so when we end up getting approval of the amendment, the sites can get out of the gate and get racing at high speed. With the REFRESH I sites completed, we are focusing now on bringing wave 2 sites onboard very rapidly. Coming from pharma that has a lot of money and resources to drive progress on trials, we are frankly ahead of industry baseline metrics overall. We now have 29 centers that have already gone through site evaluation and approval for continued contracting. Of these, 7 are active to enroll, 3 have completed clinical trial agreements, and 19 centers are in the active startup process. We expect to be able to meet the desired target of 15-20 centers actively enrolling by the end of Q3 2018. When we have the amended protocol, we expect to see very rapid increase in patient recruitment.

Sean Lee:

Thank you, Eric. That was very helpful. With regards to the planned HemoDefend study starting in 2019, we have not heard that much detail about the program. Could you tell us a little more about what still needs to be done on HemoDefend, and what would the pivotal study entail?

Phillip Chan:

Yes, let me hand that over to Vince. Vince?

Vincent Capponi:

Sure. Hi, Sean. We have now completed all the tooling for this project and have begun to do validation product builds. With those validation builds, we then intend to start our clinical build for the product, which will be done later this year. In the meantime, we are preparing the IDE submission based on some of the discussions we have had with FDA, targeting the end of this year. We expect to start the trial in Q1 2019. In terms of the study, it is a fairly well-defined process for these types of blood filters. We still need to negotiate and receive approval for the trial design, but based on preliminary discussions, we believe it will be two sites and roughly 20 healthy volunteers to complete the trial. Compared to some of the things that Eric is working on, this is relatively straightforward from a clinical trial standpoint and is very well-defined by the agency.

Sean Lee:

Great. Thank you very much. My final question is on expenses. I thought there was a jump this quarter on the SG&A costs, so I was wondering whether that was a one-time thing or is that the new level we can expect going forward?

Phillip Chan:

Kathy, did you want to take that?

Kathleen Bloch:

Sure, I will take that. Sean, the biggest impact on Q2 2018 expenses was noncash stock compensation expense and also noncash restricted stock expense, which was about $2.5 million. Part of the increase in the expense is related to the rise in our stock price, which makes these stock awards more expensive. But of course, that is noncash. That was really the biggest item driving this. We will probably continue to see this in the future, due to the use of incentive milestone options by the Board of Directors that incentivize management and company employees to strive towards key milestones that are designed to create shareholder value. The value of these awards follows our stock price.

Sean Lee:

Okay, that is understandable. Thank you for the additional color on expenses.

Operator:

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

Brian Marckx:

Hi, everybody, and congrats on the quarter.

Phillip Chan:

Thanks Brian.

Brian Marckx:

Relative to the REFRESH 2 protocol amendment, does opening the enrollment criteria in any way compromise the market opportunity or the potential competitiveness in the AKI indication, assuming you get approval?

Eric Mortensen:

Although I am just speculating, I would say that the changes are intended to improve the market opportunity by widening the number of patients for whom you have study eligibility, and ultimately the end-user markets.

Brian Marckx:

I guess the other part of the question is, does the CytoSorb approach essentially bump up against something – either a product or a procedure - that is already in the market?

Eric Mortensen:

The unfortunate and sad fact is there are no approved therapies to treat or prevent AKI caused by cardiac surgery right now. Complications such as AKI, stroke, and others are a very severe unmet need right now in this area. Researchers have learned a lot in the past 20 or 30 years and have been finding improved ways to improve the cardiopulmonary bypass circuitry, or improve the way that patients are identified and managed, particularly those at risk. But despite all that, there really has not been anything with the exception of maybe a Phase 2 trial of a drug last year that showed some success. But the avoidance of severe outcomes remains a major unmet need. Broadly we have not seen significant competitive threats in the area and patient population we are targeting.

Brian Marckx:

Since the label expansion in Europe with myoglobin and bilirubin reduction, have you seen orders that you think that you may not have gotten usage or customers that you may not have gotten without the label expansion?

Phillip Chan:

One of the reasons why we sought this specific label expansion was that clinicians were telling us that they wanted it to be able to use CytoSorb on label for the removal of bilirubin and on label for the removal of myoglobin. We do not have the granular level of detail about whether or not this has made the difference between a sale or no sale yet. But looking at the broader picture and the size of the liver disease and trauma markets, we believe this will only help to accelerate sales. Christian, do you have any additional insight there?

Christian Steiner:

Yes, I think what you said is right, that the early and current users have asked for this label expansion because they have seen that the use of CytoSorb in these patients makes a lot of sense. For example, in cases of rhabdomyolysis following trauma, sepsis, drug intoxication, and extreme exercise, CytoSorb is apparently viewed by many as the most effective device to remove myoglobin. They were asking for this. Another reason is reimbursement. In some cases, cytokine reduction was not enough to get reimbursement. Now with the extension for myoglobin removal, reimbursement cannot be denied.

Brian Marckx:

Okay. There was a reimbursement aspect to it, sounds like, at least with some institutions.

Christian Steiner:

Yes, it is the same reimbursement, only the number of patients where we can use the therapy has increased. The reimbursement in Germany is the same. It is the same code. It is the same amount of money.

Brian Marckx:

All right, great. Thanks, guys.

Phillip Chan:

Thanks, Brian.

Operator:

We will take our next question from Eric Black, with DA Davidson.

Eric Black:

Hello. Congratulations on the quarter. Very impressive. You guys have a lot of celebrate but probably a lot of work ahead of you. Two really quick questions. One was on the new facility. I think I remember reading one of your recent press releases that this new facility will allow the Company to increase manufacturing production by four times. My question is if that is true, is that the maximum output of this new facility, or just the next threshold?

Vincent Capponi:

This is really the first threshold. We will be able to do $40 million with this first phase of the plant, and then with a minor investment on the order of $100,000, we will have the ability to yet double this to roughly an $80 million business.

Eric Black:

Ok, that is great. Yes, I am surprised I do not sense more enthusiasm from your voice about this capability. My next question, if possible, can you take me through your sales process, or part of your sales process, in terms of business development, given the success of the technology. Is it primarily with distributors, or is it now that you have this data behind you, is it easier to approach different institutions? I know different countries, there are different rules and things like that, but I am just trying to get a gauge of the intensity of the sales team, and what sort of resistance, if any, are you guys seeing recently with this new data that you have out on the products?

Phillip Chan:

Before I turn it over to Christian for more color, it is important to understand that critical care represents one of the largest unmet medical needs in all of medicine. Most of what exists in this market are supportive care therapies, often called life support – such as mechanical ventilation when the lungs fail and dialysis when the kidneys fail, that do not help patients get better. There are very few active therapies that help turn the tide of a life-threatening illness in the ICU. Because of this, doctors are often left between a rock and a hard place in terms of trying to manage their unstable and very sick patients. CytoSorb has been used successfully in many patients to restore hemodynamic instability, wean dangerous vasopressors, improve oxygenation, restore kidney injury, and reduce capillary leak syndrome. And the data continue to support these observations.

When we go in to meet with clinicians now, they are typically very receptive to the technology. The concept of excessive inflammation that drives organ dysfunction and organ failure, leading ultimately to death in many patients, is very well understood. So I think it is about getting them to try the technology. We have gotten to a point now where we have so much data in so many different applications, that we can go in and

show them a case report or a case series for a patient that looks very similar to the one that they are trying to manage. Oftentimes we wind up with a very positive outcome, and that positive outcome is often the light bulb that goes off in their head that the technology works. When we first started, the market awareness of CytoSorb was relatively low. Now in Germany, the market awareness of CytoSorb is very high, and the willingness to use the therapy is moving to a pull market rather than a push market.

Eric Black:

Yes, thank you but can you comment on your sales cycle?

Phillip Chan:

We have not disclosed what that sale cycle is, but with any new technology, the first sale is always the longest, and it is on the order of months. It typically takes repeat visits to be able to get that first order. But I think once the order starts, and they see how CytoSorb has benefited their patients, the reorder cycle becomes shorter and shorter. Typically, the reorders start off once a quarter. We have many places where they are ordering on a weekly or every two-week basis. Christian, any other comments there?

Christian Steiner:

No, I think you are right. It is a process that is accelerating over time because awareness in the market is increasing. When we bring a new market into the portfolio, as we have shown with this, then of course, there you have to start again from scratch. But the overall situation has improved in terms of in the medical community and also in terms of data. There are different stages in different markets. You always need to start with key opinion leaders and with the heads of departments, and then step by step you can approach different levels of doctors.

Eric Black:

That's the best approach is through the doctors now, not through the purchasers of the institutions and things like that?

Christian Steiner:

At the moment, we are focused on the prescribers. Once we have strong data that the therapy, in fact, saves money in the course of the disease - and we are very convinced that we can show this in the future - then we will target administrators of hospitals and can go from different angles into the market.

Operator:

At this time, I would like to turn it back to Management.

Phillip Chan:

Thank you all for your participation today. If you have any other questions, please feel free to reach out to Jeremy Feffer at Jeremy@LifeSciAdvisors.com, and we will try to reply to your questions where possible. We look forward to our next quarterly call. Thank you everyone very much. Good night.

Operator:

That concludes today's presentation. Thank you for your participation. You may now disconnect.

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