



**CytoSorbents Corporation (NASDAQ: CTSO)
Q2 2019 Earnings and Operating Results Conference Call
August 6, 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 Second Quarter 2019 Financial and Operating Results Conference Call. At this time, all participants are in listen-only mode. Following the formal remarks, we will open the call for your questions. Please be advised that this call will be recorded, at the Company's request.

At this time, I'd like to turn the call over to our moderator, Jeremy Feffer. Please go ahead, Mr. Feffer.

Jeremy Feffer:

Thank you, Jen and good afternoon. Welcome to CytoSorbents Second Quarter 2019 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 August 6, 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 the second quarter by Dr. Chan and Ms. Bloch. Following the 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 very much, Jeremy, and good afternoon everyone.

Slide 4:

I am pleased to report a resumption of our historical pattern of growth with more than 67,000 CytoSorbents treatments delivered, up from 46,000 a year ago. Our trailing 12-month total revenue was \$23.2 million, including product sales and grant income, versus \$19.2 million a year ago. Our second quarter 2019 product sales were \$5.9 million compared to \$5.3 million a year ago. Our results achieved the highest quarterly product sales in our history, driven by record direct sales and a rebound in distributor sales. Had the average Euro to Dollar exchange rate remained unchanged, second quarter 2019 product sales would have been \$6.2 million, and above \$6 million per quarter for the first time. We were pleased that a major distributor that did not order in the first quarter of 2019 began reordering in the second quarter of 2019. But even without these orders, product sales would still have been a quarterly record.

Fresenius Medical Care was another one of our partners that did not order in the first quarter as they exchanged several of their countries in the E.U. with Mexico, South Korea, and the Czech Republic. During the quarter, we worked closely with Fresenius Medical Care and submitted the CytoSorb registration for Mexico and South Korea and expect an update on progress by the end of the year, if not outright registration. Meanwhile, we have jointly initiated commercialization planning and pre-launch activities, including conference, marketing, and other key opinion leader events.

We had a healthy cash balance of approximately \$20 million at the end of July.

Slide 5:

Another milestone was the publishing of the U.S. REFRESH I study. This was published in *Seminars in Thoracic and Cardiovascular Surgery*, a journal of the prestigious American Association for Thoracic Surgery, or AATS, where our results were first presented at their national conference. The paper confirmed the safety of CytoSorb in complex cardiac surgery patients and reiterated the top line results that were reported previously on the statistically significant reduction of activated complement in all patients, and the significant reduction of plasma-free hemoglobin in patients undergoing valve replacement surgery on cardiopulmonary bypass for greater than three hours.

There was an associated editorial commentary by cardiac surgeons at the University of Washington in St. Louis who were not associated with the study. In that editorial commentary, they stated the following: “The Achilles' heel of complex cardiac surgery has long been the deleterious effects of prolonged cardiopulmonary bypass, characterized by the cascade of hemolysis, release of plasma-free hemoglobin, activation of inflammatory mediators and end organ dysfunction. The holy grail of research in this subject would be to find something able to mitigate or eliminate the mediators responsible for these potentially catastrophic downstream effects of prolonged cardiopulmonary bypass. Gleason, et al., have eloquently explored the use of hemadsorption technology specifically designed to reduce plasma-free hemoglobin during prolonged cardiopulmonary bypass in a multicenter randomized controlled trial.”

Slide 6:

REFRESH I led to the development of the U.S. REFRESH 2-AKI pivotal trial. Again, this trial is a 400-patient randomized controlled trial that is a pre-market approval (PMA) trial amongst many centers, targeting the reduction of postoperative acute kidney injury using CytoSorb during complex cardiac surgery. Currently, there are now 109 patients enrolled, roughly 27% of the targeted 400 patients, at 24 active trial sites, and we are currently actively adding new sites and increasing the awareness of the study to accelerate enrollment.

As the timeline below shows, we are targeting enrollment of 200 patients by the first quarter of 2020, followed by an interim analysis, and then completion of enrollment targeted by the end of 2020, provided that we are able to increase enrollment to roughly 20 patients per month, which should be feasible.

With the completion of the study, we will have multiple activities going on in parallel and plan to complete data analysis and PMA, or pre-market approval submission, that is intended to lead to U.S. approval by middle of 2021 should the study be successful.

Slide 7:

Moving on to the REMOVE endocarditis trial. This, again, is a 250-patient randomized, controlled trial funded by the German government that is evaluating the safety and efficacy of CytoSorb to improve organ dysfunction when used intraoperatively during valve replacement surgery for infective endocarditis. The trial is nearly 90% complete, with 222 patients of a targeted 250 patients enrolled at 15 active centers. Enrollment is expected to complete before the end of this

year, but as a government-sponsored multi-centered study, we cannot influence the timeline but believe that top line data by mid-2020 is feasible.

Slide 8:

Turning to HemoDefend, this is a point-of-transfusion filter that rapidly and efficiently removes non-infectious contaminants from transfused packed red blood cells that can cause transfusion reactions. This program is funded up to \$4.7 million by National Heart, Lung, and Blood Institute, a division of NIH, as well as U.S. SOCOM or Special Operations Command. The technology is technically compatible with pathogen reduction technologies that are being offered by several other companies in this space. We are targeting a total addressable market of 100 million packed red blood cell transfusions administered annually worldwide. However, initially, we intend the device for patients receiving multiple units of blood, where the risk of transfusion reaction is very high, including conditions such as trauma, gastrointestinal bleeding, high-risk surgery, cancer, and other blood disorders.

The pivotal trial design is a post-transfusion recovery and survival assay for autologous blood. The goal is to have the FDA IDE submission this year following requisite bench testing for efficacy. Meanwhile, our CRO and clinical trial sites have been selected. Following IDE approval, the clinical trial is expected to be completed within three to six months.

With that, let me turn it over to Kathy to give financial highlights for the quarter.

Kathleen Bloch - CFO:

Slide 9:

Thank you, Phil, and good afternoon, everyone.

For today's call, I'll provide an update regarding CytoSorbents' second quarter 2019 financial results, including product sales progress. In addition, I will provide an update around our working capital and cash runway.

Slide 10:

CytoSorb product sales for the second quarter of 2019 were a record \$5.9 million, which represents our best quarterly product sales ever. This is an 11.5% increase over product sales of approximately \$5.2 million for the second quarter of 2018. This brings the Company's annual product sales run rate to approximately \$23.4 million. This increase was driven by an increase in direct sales from both new customers and repeat orders from existing customers, as well as an increase in distributor sales.

The Euro to Dollar exchange rate declined from an average rate of \$1.19 in the second quarter of 2018 to an average rate of \$1.12 in the second quarter of 2019. If the Euro had remained unchanged from Q2 2018, then Q2 2019 product sales would have been approximately \$357,000 higher than product sales actually reported, or our product sales would have been approximately \$6.2 million, an increase of 18% over second quarter 2018 product sales.

Our total revenues, which includes product sales and grant revenue, were approximately \$6.2 million for the second quarter of 2019 as compared to approximately \$5.8 million for the second quarter of 2018, which is an increase of approximately 8%. Our second quarter 2019 gross profit grew to approximately \$4.4 million, which is an increase of 11% or \$428,000 over gross products of approximately \$4 million for the second quarter of 2018. Our gross profit margins on product sales were approximately 76% for Q2 of 2019. That is up from 74% for the prior year, and that is primarily as a result of the achievement of manufacturing efficiencies and we believe we are closing in on our target of 80% blended gross margins on a quarterly basis by the end of 2019.

Slide 11:

Turning to our six months financial results. Our product sales for the first half of 2019 were approximately \$10.4 million, which is an 8% increase over product sales of \$9.7 million for the first half of 2018. Once again, the Euro to Dollar exchange rate declined. In fact, if the Euro had remained unchanged from 2018, our six months 2019 product sales would have been approximately \$737,000 higher than we actually reported or approximately \$11.2 million, which would have been an increase of 15% over the prior year's product sales.

Grant revenue was basically unchanged at \$1 million for the first half of 2019 as compared to the first half of 2018. Our total revenues, which include product sales and grant revenue, were approximately \$11.4 million for the first half of 2019 as compared to \$10.7 million for the same period in 2018, an increase of approximately 7%.

Slide 12:

Next, we will look at our quarter-over-quarter product sales. We note that we have continued our trend of 27 consecutive quarters of year-over-year quarterly product sales growth. Q2 2019 sales of \$5.9 million represent a record for quarterly sales that we believe puts us back on our historical path of growth. Management remains optimistic about continued year-over-year sales growth for the remainder of this year and into the future.

Slide 13:

Next, we will look at our trailing 12 months product sales. As you can see from this chart, overall, our annual product sales growth continues to exhibit a very strong growth trajectory. Despite quarter-to-quarter variability, we expect continuation of this overall positive trend in the future, driven by:

- Expanding our sales team resources
- Organic growth in existing markets
- Increased international expansion
- Publication of new clinical data in a wide variety of clinical applications; and finally,
- Increased partner support.

Slide 14:

I want to talk about the new loan amendment with Bridge Bank. On July 31, 2019, we executed an amendment to our loan agreement with Bridge Bank. Upon execution of this amendment, we

drew down an additional \$5 million in debt, bringing our total debt from Bridge Bank to \$15 million. Importantly, this provides non-dilutive working capital, strengthening our cash position and allowing us to continue to aggressively pursue our clinical trial objectives and to rapidly grow worldwide product sales. I view this amendment as providing actually \$9 million in near-term working capital. There is the \$5 million in cash from the term loan but then in addition, we were able to extend the interest-only period on our entire debt facility another six months and potentially 12 months, provided that certain conditions are met. This will postpone principal payments until November 2020, freeing up another \$4 million in short-term working capital.

Slide 15:

With that, let us take a look at our working capital position. As of June 30, 2019, we had approximately \$16.3 million in cash, which, with the additional \$5 million in funds from the Bridge Bank term loan, puts our cash in hand at approximately \$20 million, which we believe provides a solid operating foundation for the Company. We believe the existing cash runway will allow us to meet our operating needs well into 2020.

In the second quarter of 2019, we also established an at-the-market facility of up to \$25 million with co-agents, Jefferies and B. Riley FBR. This ATM provides an efficient and cost-effective way for us to raise funds for the Company if needed. As you are aware, in the past, we have been very careful with regard to our use of the ATM. We are always trying to strike a balance between having a strong balance sheet, which provides adequate capital to meet our operating and clinical trial objectives, and also avoiding shareholder dilution.

Now turning to our capital structure. As of June 30, 2019, we have approximately 36 million common shares outstanding on a fully diluted basis.

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

Phillip Chan - CEO:

Thank you very much, Kathy.

Slide 16:

CytoSorbents has not historically given specific financial guidance on quarterly results until the quarter has been completed. However, we expect that third quarter 2019 product sales will exceed third quarter 2018 product sales, and we also expect that the second half of 2019 product sales will exceed the first half of 2019 product sales. Lastly, we also reiterate our guidance that we expect to achieve blended product gross margins of 80% on a quarterly basis this year.

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

Slide 17:

Operator:

Ladies and gentlemen, if you would like to ask a question, please press *1 on your telephone keypad. As a reminder, if you are using mute, you must turn the mute feature off for your signal to reach our system. One moment, please, while we poll for questions.

Our first question comes from the line of Josh Jennings with Cowen and Company. Please proceed with your question.

Joshua Jennings:

Hi. Good evening. Thanks for taking the questions. Congrats on the record product sales this quarter. I know you gave some details on distributor sales picking back up after some of the short-term disruption experienced in the first quarter. But can you talk about whether those issues are fully resolved?

Then how do you see the pace of distributor sales picking up over the back half of 2019 and 2020? I realize there are some countries that are pending CytoSorb registration such as Mexico and South Korea through Fresenius [that may boost sales], but are there any other tailwinds [that could help increase sales] in the distributor sales channel?

Phillip Chan:

Thanks, Josh. The distributor issue that we faced in the first quarter was that three distributors, one of which was Fresenius Medical Care, did not order related to primarily inventory issues. What we said in the first quarter is that we expect those issues would resolve amongst all three distributors by the end of the year. Again, in the second quarter, one of those distributors began reordering again, and that was very good news.

In terms of Fresenius, as we talked about, they still continue to have inventory in Europe that they are working to sell through. They are doing a very nice job on that but cannot order new devices for Mexico and South Korea until they receive registration in those countries. We expect to hear more about registration, if not receive that registration outright, before the end of the year at which point we expect that Fresenius will be ordering again.

We believe we have fairly good visibility on the third distributor that they will be also begin re-ordering before the end of the year. But to just reiterate, without those three distributors, we were still able to achieve record performance this quarter.

Joshua Jennings:

Excellent. You are still continuing to see strong growth out of Germany, and I was just wondering, it is probably hard to track each CytoSorb procedure or case where CytoSorb is being implemented. But are there any kind of trends in terms of which indications are driving growth in Germany. For example, cardiac surgery versus sepsis versus some other indication? Or is it

more broad-based across all indications, knowing that there are numerous indications for CytoSorb?

Phillip Chan:

I think it is fairly broad-based. I would say that based upon our numbers, roughly one-third of our uses are in cardiac surgery and roughly two-thirds are in the intensive care unit for critical illnesses like sepsis, trauma, burn injury and other things. But let me turn it over to Christian for more commentary.

Christian Steiner:

Yes, hello. Good evening from me here. As Phil stated already, there has been progress in the major application fields. The three major application fields we are serving at the moment is cardiac surgery, intensive care applications, especially sepsis patients, and a big new future application in liver support therapy. We have spoken about this over the last earnings call as well.

For cardiac surgery, the chance to become a standard therapy for one or more applications is potentially in the near or midterm future. There are a number of studies being conducted there. The REFRESH 2-AKI trial in the U.S. and the REMOVE endocarditis trial sponsored by the German government, are the most prominent ones. Then we have multiple investigator-initiated trials running in Europe that will be finished and published over the next few quarters.

Also, in this field, I think the number of supporting key opinion leaders and sites have been constantly increasing highlighted by a notable development in Germany. The Helios group, which is owned by Fresenius, has started to increase ordering over the last two quarters. Then in cardiac surgery, we also will publish some positive cost-effectiveness data that we will use to market CytoSorb.

Joshua Jennings:

That is great and thanks for the answer, I appreciate it. I think my last question is just a congratulations on adding new sites for REFRESH II AKI and congrats on the publication for the U.S. REFRESH I study as well. Although you touched on the timeline of REFRESH 2-AKI in your prepared remarks, could you comment on your expectations going forward there? Do you expect the enrollment pace to pick up? Are you going to have more sites? Can you remind us how many sites you plan on activating in total? Then if you could give an update on the interim analysis when you hit 200 patients, the halfway point. Thanks again for taking my questions.

Phillip Chan:

Sure. Eric would you like to provide some color on that?

Eric Mortensen:

Okay. Sure, Phil. On the current study, we are pleased that we have at least been able to maintain a steady enrollment to date, but there is more work to do. In addition to meeting our enrollment objectives this year, we are targeting full enrollment of the study in 2020. We currently have 24

active sites. Our expectation is to bring on at least an additional five sites this fall. The summertime is always a little bit slow in terms of finalizing contracts because of staff at hospitals often being on holiday, but we expect to be able to increase the rate of recruitment with the addition of additional sites in the fall.

The final number of sites is being determined based upon our desired rate of recruitment. Our goal is to try to maintain maximum study quality by having enough resources to monitor data very aggressively. For example, we need to make sure we are collecting the appropriate data for our primary endpoints, and also recording adverse events. We are working to maximize the enrollment output from our existing centers and do not intend to add additional study sites beyond what is required to meet our objectives.

With regard to your question about the interim analysis, we expect to achieve this target from a timing standpoint as Phil described. However, the study will remain blinded to maintain study integrity and we will not be reporting any efficacy data. However, the study analysis plan that was filed with the FDA will have stopping rules for overwhelming efficacy or futility, and will allow for adjustment in patient numbers depending on what the Data Safety Monitoring Board (DSMB), who will be doing the analysis, sees.

Joshua Jennings:

Thanks, I appreciate it.

Operator:

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

Andrew D'Silva:

Good afternoon. Thanks for taking my questions. In terms of the three distributors who did not order in Q1, and not including the distributor who began re-ordering in Q2, do you expect any of the others to contribute to Q3 revenue? Or would you expect that to be more of a Q4 event?

Phillip Chan:

We expect that both will be coming in by Q4, but whether or not they will contribute to Q3 remains a question. That said, the first distributor has worked through their inventory and is back to a traditional ordering pattern.

Andrew D'Silva:

Okay, great. Given your concentration of revenue in Europe, and given that E.U. business slows in summer months due to vacations, do you have any sense of how Q3 will turn out? Is there any kind of normalized trend that you are seeing? Or should we expect sales to be more weighted towards Q4?

Phillip Chan:

Last year was the first year we saw seasonality in the third quarter. As you say, given that the majority of our revenue are coming from the European Union, and July and August are particularly busy months for holidays, things slow down quite a bit. Elective surgery slows down, a lot of hospital shut down operating suites, and last year was particularly a slow year for infections and sepsis. That said, although it is still too early to say how Q3 2019 will turn out, to date we have been tracking better than we did last year, giving us confidence in our guidance that Q3 2019 will be stronger than Q3 last year.

Andrew D'Silva:

Okay. Thank you. Good color. I just was skimming through your 10-Q and noticed just rest of world direct sales went up about 14%, 15% year-over-year, which was about in line with what was seen out of Germany. When do you think you will be recognizing revenue from the new regions?

Phillip Chan:

We added five additional direct territories, including Poland, which began sales in April 2019, and the Netherlands, Denmark, Norway, and Sweden in January. It takes time for them to get up and running. Poland is the biggest country of the five, and has been making some great progress in terms of establishing our infrastructure, market awareness of the technology, and key opinion leader support. For all five countries, we expect they will accelerate in terms of sales, less likely for Q3, more likely for Q4.

Andrew D'Silva:

Great. That is all I have right now. Thank you very much.

Phillip Chan:

Thanks, Andy.

Operator:

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

Jason McCarthy:

Hey, guys. Thanks for taking the question. Congratulations on the quarter. As we approach the IDE for HemoDefend and the trial in the next 6 months or so, can you describe what you will need to do to get approval? Does that mean that HemoDefend could make it to the U.S. market before CytoSorb? How much are you expecting the HemoDefend trial to run? Would it be substantially covered by the \$4.7 million from the U.S. government?

Phillip Chan:

For HemoDefend, there will be quite a bit of work to try to drive approval. It will come in two parts. The first part is bench studies, which are designed to establish the efficacy of the filter in terms of being able to remove the substances that we are looking to remove. Then there is a human post transfusion recovery and survival assay, where approximately 25 healthy volunteers will donate their blood. This blood is aged and radiolabeled, and then filtered through our HemoDefend filter and a portion transfused back into the same patient. After 24 hours, samples are taken and expect to see roughly 75% recovery. This is meant to measure the survivability of those red blood cells once they are transfused back into the patient and make sure that our HemoDefend filter is not doing anything untoward to that blood to cause it to have a decreased longevity. This is a very standard and well-accepted assay in the blood transfusion industry, very well accepted endpoints across the board.

The study itself is expected to go quickly. We plan to complete the requisite bench testing prior to our IDE submission. Following IDE approval, we will need to execute clinical trial agreements, ethics committee approvals, and site initiations. But once we get those done, the trial itself is expected to be relatively quick. Should everything go well, HemoDefend is expected to be on the market here in the United States prior to CytoSorb.

Jason McCarthy:

All right. Thank you. Then just the second part on the cost of the trial, if you think that \$4.7 million is going to cover a big chunk of the total cost.

Phillip Chan:

In addition to the \$1.7 million in Phase I and Phase II SBIR funding we have already received, we have a \$3 million grant from National Heart, Lung and Blood Institute that is a Phase IIb bridge. This is a one-to-one matching grant where NHLBI will provide up to \$3 million in matching funds towards the development, which includes clinical studies, leading to potential U.S. approval. Our goal is to match that one-to-one. At the very least, it represents a 50% discount off the trial and from a total cost perspective, the grant, with our matching funds should be more than sufficient to pay for the study.

Jason McCarthy:

All right. Thank you very much.

Phillip Chan:

Sure. Thanks Jason.

Operator:

Thank you. Our next question comes from the line of Jason Kolbert with Dawson James. Please proceed with your question.

Jason Kolbert:

Thank you. Congratulations, fantastic quarter. Can you just go through the timelines with me on the U.S. trial, again, in detail?

Phillip Chan:

Thanks Jason, I assume you are talking about the REFRESH 2-AKI trial, not HemoDefend?

Jason Kolbert:

I was, but if you could touch on both, that would be helpful.

Phillip Chan:

Sure. In terms of REFRESH 2- AKI, based upon the current pace of enrollment that we are on right now, we expect to achieve 200 patients enrolled by the end of the first quarter, at which point an interim analysis is scheduled. As Eric mentioned previously, his team is working very hard to accelerate the rate of enrollment by increasing the number of active trial sites and making sure that we are actively involved and visiting sites and doing all the kinds of things that we need to do to be able to accelerate enrollment. Our goal is to get somewhere on the order of one patient per site per month, which we believe is very doable. But obviously, when you are dealing with many sites, it becomes more challenging.

That being said, provided that we can get to that 20 patients per month per site, we believe that we should be able to complete enrollment by the end of 2020, followed by data monitoring and review, database lock, data and statistical analysis, and then PMA preparation and submission. Our goal is to try to submit our PMA, probably sometime mid-year to the third quarter.

Jason Kolbert:

That is very helpful. Could you please touch on the HemoDefend timelines as well?

Phillip Chan:

For HemoDefend, our goal is to file that IDE submission by the end of this year. Vince, would you like to comment on the timeline?

Vincent Capponi:

Sure. We have continued to make progress on the HemoDefend program and are at the stage now where we are filling devices for the bench testing Phil spoke of previously, which we need to complete in order to do the IDE submission. We plan submit the IDE application sometime in the fourth quarter, with the expectation of starting the study during the first quarter of 2020. The trial will likely take three to six months. The advantage of these types of blood filtration products is that the trials are relatively small and fast. By mid-2020, we expect to complete the trial. Should

everything go smoothly, we think we could have this in the FDA for potential approval by the end of 2020.

Jason Kolbert:

Terrific. Thank you, guys. Congratulations on all the progress.

Phillip Chan:

Thanks, Jason.

Operator:

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

Brian Marckx:

Hi, Phil. Congrats on the quarter. In terms of the registration process and timeline for Mexico and South Korea, do you have a sense of how long that may take?

Phillip Chan:

Yes. Vince has been leading that effort. Vince, would you care to comment?

Vincent Capponi:

We have made all the submissions both for Korea and Mexico. It is now somewhat out of our control, because you never know with these various regulatory bodies exactly what their scheduled timeline is going to be. Based on our discussions with FMC in Korea and Mexico, we may get approval at the end of this year, but it would more than likely be into the beginning of next year.

Brian Marckx:

Okay. How significant do you think those two territories are in terms of revenue? Then is there a reimbursement component after regulatory approval?

Phillip Chan:

I will turn that over to Chris, who has been working very closely with FMC as well.

Christopher Cramer:

Brian, thanks for the question. We have been working with the senior sales leadership in both countries, and have a lot of support at the highest levels. That is important because when you have that, they tend to prioritize your product. We also see a good responsiveness from these teams. Both of these markets are big. I do not have the exact population in front of me, but they

are quite large. I think we have them in the original press release that we put out, and there is a significant unmet need in both of these markets.

The biggest difference between the two is that Mexico has more of a self-pay component. It will set up a little bit more like our business in India, where there is also a self-pay component. But in both cases, we will look to go through and take advantage of existing reimbursement codes that we can use. Then longer term, we look to establish a dedicated code like we have in Germany. Meanwhile, we have been putting a lot of investment into our health economics team to give tools to our direct salespeople and distributors to make the economic case. That will be something we actively will do in both of these countries.

Just to piggy back onto what Vince was saying, we are working on pre-marketing activities in both countries ahead of registration expected later this year, or early next year. We are already talking to key opinion leaders and will be out there at several major conferences to get the market launch started as soon as we can. I think both will be good markets for us.

Brian Marckx:

Okay, great. Phil, you talked about a potential timeline for the PMA for REFRESH 2-AKI trial. Do we just need the trial data, or are there other things the FDA will want to see?

Phillip Chan:

Vince or Eric, would you like to take that?

Eric Mortensen:

The FDA is always interested in safety data, and we have been working hard to make sure we leverage the extensive experience, particularly the large number of utilizations in cardiac surgery, that has been developed in Europe. Vince?

Vincent Capponi:

Thanks. This is a pivotal trial, so in theory, we should have all the information we need to submit a PMA for the device. I don't believe anything else will be required, but to Eric's point, you never know. But again, the study has been powered to show the endpoint, and providing that we are successful there, then I do not expect that there should be any additional information requested.

Brian Marckx:

Okay. Great. Thank you.

Operator:

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

Sean Lee:

Hi, guys. Thanks for taking my question. Just a quick update on the REMOVE study. I know that it is being run by the German government but with the enrollment at 90%, we should expect to see data as early as the end of this year or early next year. I was just wondering, is endocarditis a major indication for you guys right now in Germany? If the results are positive, what kind of impact would you expect to see on your commercial efforts there?

Phillip Chan:

What is quite interesting is the pace of enrollment that they have been able to achieve in that trial. They began in January 2018 with only a handful of sites. Now at 15 sites, they are enrolling very rapidly. What I think it speaks to is the growing population of people at risk for endocarditis, both from the traditional path of mouth bacteria seeding the bloodstream from dental procedures in elderly people, but also from the growing problem of the opiate crisis and the use of dirty needles for IV drug abuse. Certainly, in the United States, the opiate crisis is a massive problem and we have a lot of interest to bring CytoSorb here to the United States for valve replacement surgery caused by IV drug abuse associated endocarditis.

Valve replacement is a ten-fold greater-sized market than endocarditis. On the other hand, endocarditis patients are in desperate need of help because they are very sick from a combination of sepsis from dangerous Staphylococcus aureus...you have heard of Staph aureus from MRSA, or methicillin-resistant Staph aureus – the most common hospital acquired infection – and heart failure from a destroyed heart valve. Endocarditis patients are very difficult to operate on because of this instability, and have a very high incidence of peri-operative adverse event rates, including complications such as shock, organ failure, and death. The value of CytoSorb has been seen in many, many centers around Europe because it helps to stabilize those patients intra-operatively as well as post-operatively. As Christian mentioned before, we believe this is one of those indications where, should we have success in these studies, we could potentially become standard of care in that application.

Sean Lee:

Great. Thank you for the additional info. My last question is on the direct sales operations. Are there plans to expand that in the second half of this year?

Phillip Chan:

There are two answers to your question. First, we are expanding our direct sales force in our direct territories, with an ongoing expansion of the sales support teams in those countries, particularly in Germany, but also in other countries where we have momentum. But there are still a lot of countries that are not claimed by distributors or partners. In certain of those countries, we would look to potentially go direct as the economics of going direct are often highly favorable in terms of product gross margins, and that our salespeople are typically the most efficient sellers of our product, given that we are so closely tied to the product and that is all we sell. So both internal expansion within our current direct territories, as well as an expansion of additional territories are in the plan.

Sean Lee:

I see. Thanks for answering my questions and congratulations on a great quarter.

Phillip Chan:

Thanks very much, Sean.

Operator:

Ladies and gentlemen, at this time, I would like to turn the call back over to management for any additional closing remarks.

Phillip Chan:

Thank you everyone for your participation today. If you do have any other questions, please feel free to reach out to Jeremy Feffer at jeremy@lifesciadvisors.com, and we will reply to your questions where possible. Thank you very much, everyone, and have a good night.

Operator:

Thank you. Ladies and gentlemen, this concludes today's teleconference. You may disconnect your lines at this time.

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*

Jason Kolbert, *Dawson James Securities*