

Company Name: Cardiovascular Systems Inc (CSII)  
Event: Leerink Partners Global Healthcare Conference  
Date: February 10, 2016

<<Danielle J. Antalffy, Leerink Partners Plc>>

Good afternoon, everyone. Thank you, so much for joining us. I'm Danielle Antalffy, one of the med tech analysts here at Leerink. And I cover CSII, Cardiovascular Systems. And we are lucky to have Larry Betterley, CFO, as well as Jack Nielsen, Senior Director of Corporate Communications and IR, in the audience. This is an informal fireside chat format, if you have a question, feel free to raise your hand and ask. But why don't I start Larry?

So what is underlying growth of atherectomy market, both below and above-the-knee. And how is the market shifted over the last 12 months and then beyond that, sort of what's going on with CSII you've seen slowing growth, maybe talk about why you're growing at or below the market, if in fact that the case?

<<Laurence L. Betterley, Chief Financial Officer>>

Yes. Great, thank you Danielle and thank you all for coming. For those of you that don't know the company, we are leaders in treating artery disease and we have a unique orbital atherectomy system that's been proven to safely and effectively treat broad range of plaque types. But especially in calcium, and calcium is a very large market opportunity, very underserved market and we have been proven to safely and effectively treat calcified artery disease throughout the leg and now recently in the coronary. So that's really our business and we were uniquely positioned for that, and it's a multibillion dollar opportunity.

So overall atherectomy, Danielle, back to your question is probably growing in the single-digits from an overall standpoint. But you really have to break that down and look at the opportunity further. And in the past, below-the-knees has been growing at double-digits. And we're a large part of that, that was really, where we were focused and we are driving adoption, building that market because it was very underserved.

We do our share above-the-knee as well, little less than 60% below-the-knee, about 40% above-the-knee. Now, having said that, the below-the-knee market has slowed and we were a driver in that. And what happened is, as we got our coronary application started, and it was 70% of our customers being interventional cardiologist we made the decision to change our sales organization to focus on build the applications, coronary and peripheral, and that proved to be quite disruptive, for number of reasons.

One is, we had to train the existing reps on the coronary application, our products easy to use, as you know Danielle. But the patients are very complicated, very complex cases. So

it does take quite a bit of training. We have narrowed their territories, so that they could focus more on both applications and driving deep into those applications.

We also had to bring in new reps then to make sure we have the right coverage and then train those reps. And that created some realignment with customers when to rebuild those relationships. So it's a quite a bit disruption that happened in the marketplace. The coronary market, although our product is easy to use, again they're complicated patients and in those initial sales getting accounts going and trained and driving proper adoption takes time, it took away from some of our peripheral sales. So we did suffer in our growth and that did impact the market rate.

But going forward we think we can get back and below-the-knee back to a double-digit rate as we have now stabilized the sales force and can continue grow in the future.

<<Danielle J. Antalffy, Leerink Partners Plc>>

So just following-up on the sales force stabilization, where are you with number of reps and where are those reps in the productivity ramp? How quickly can they get to full productivity from maybe just last quarter?

<<Laurence L. Betterley, Chief Financial Officer>>

We have a full – fully staffed on the sales side, now we have a mix of about 250 sales professionals. But as we talked about on our last earnings call, we've also developed a more flexible strategy. Where we will supplement with specialists and associates where we see fits. So it's not just – the sales rep doing all the work. Now we are selectively, in some territories adding associates or specialists to supplement.

So that's about 250 strong and we feel that is about the right size for the opportunity and we're going to focus with that group. We feel it's nice, it's stabilized now and we feel we start to see improvements going forward. And we have seen for a while now, stabilization and the daily sales cadence that that group has, which as a finance person makes me feel much more comfortable. Takes a variability out of what we're seeing and we feel confident that they can continue to progress and improve.

While it'll take some time for the things we've implemented to take hold and for them to be fully productive again. We are seeing signs of improvement and expect at least by fourth quarter of this year to see, returning to some sequential revenue growth.

<<Danielle J. Antalffy, Leerink Partners Plc>>

Okay, great. Can you talk about some of the changes that you've implemented to reduce the sales force turnover?

<<Laurence L. Betterley, Chief Financial Officer>>

Yes. We learned a lot, as we went through the process. Number one is that they needed some additional training. We need to enhance our training particularly in the field. And the managers need better trained. So they could be better mentors to the sales reps, so that was a big thing. We also saw, our expectations were too high on their quotas, what they were trying to do salespeople they're good, they like to run after, you give them a target, they're going to run after it very hard. But what that did with the quota is being too high, they didn't, they weren't able to spend the time they needed, in accounts to properly drive adoption and sustainable revenue growth.

So we've lowered their quotas, we're giving them more time now. Ones they weren't fully installed before we did see some falloff in those. But sales people want to win. So we needed to give them the training and the ability to reach their targets and we have gone through that and done that now.

The other we really opened up the communication, two way communication. So they know they're being heard and their concerns are being heard. And that has helped a lot too. So we feel that's been stabilized. They always going to have turnover in a med tech sales force, but we believe we're getting it to a manageable level.

<<Laurence L. Betterley, Chief Financial Officer>>

Okay, fair. How is the competitive landscape evolving, so obviously drug-coated balloon are gaining some share in the peripheral market wondering what you are seeing there from an atherectomy market perspective also, some recent acquisitions by large players, Boston Scientific all strong growth in their atherectomy business, last quarter. And then beyond that new technologies that could come to market like lithotripsy, [indiscernible] (0:06:57) therapy. So if you could opine on all of those things that would be great.

<<Laurence L. Betterley, Chief Financial Officer>>

In 60 seconds.

<<Danielle J. Antalffy, Leerink Partners Plc>>

Yes.

<<Laurence L. Betterley, Chief Financial Officer>>

Okay, thank you. Well, there is a lot of disruption in the market; a lot of noise out there. Drug-coated balloons are gaining retention they're being trialled. We have some new atherectomy products that are entering the market and old products that have changed hands. So there's new marketing efforts around them. And it is hitting us at a time when our sales force was going through disruption. So it did have an impact, there's no doubt. But the key thing is, is that those products are all challenged by calcium and that is where we shine.

We are the calcium product, we have demonstrated safe and effective in treating calcium, even the worst calcium, severe calcium, which other products tend to stay away from, in particular drug coated balloons, the data will show that they work really well, they have an advantage over regular balloons. But when calcium is present, the ability to get a good drug uptake and get a uniformed drug application is limited. And that's a good tailwind for us in the long-run.

In the near term, this trailing it's hitting us at a time like I said when our sales force is going through a transition. But we believe that is going to be a big catalyst for us, going forward, because once you remove that calcium our studies are showing that you'll get much better drug out there, more uniform and much deeper penetration, of that drug. And we believe that's the future, for those products.

<<Danielle J. Antalffy, Leerink Partners Plc>>

And what about the products potentially coming to market, the lithotripsy, is one, I think, it's not until 2017 or even...

<<Laurence L. Betterley, Chief Financial Officer>>

It's an interesting technology, we will see what the utility is, when it comes to market and it may have an application. Obviously we have wealth of data that shows we are safe and effective and we have a great track record in calcium. But the market is massive, we're just scratching the surface on the calcium market and there are going to be other products in that market. And that's not necessarily a bad thing. We've been the lone voice out there that's really been talking about calcium and driving that market development. So few other players can help develop that market, but we still feel we will be in the leadership position.

<<Danielle J. Antalffy, Leerink Partners Plc>>

Well that's a good segue into LIBERTY 360°, because I think one of the biggest pieces of market development, tell me if I'm wrong, is clinical data. So how we do – then we saw the demographic data at CRT, I think, was it yesterday or the day before? How do we think about LIBERTY 360°'s impact to market growth and how quickly can that contribute to accelerating market growth?

<<Laurence L. Betterley, Chief Financial Officer>>

Well, it's an important study, because it's including those patients that are typically excluded from others studies. So when you look at the demographics of this study, it's 1,200 patients, but over half of those are Rutherford 4, 5 and 6. So this study has three arms, claudicant arm, that's referred to 2 and 3, critical limb ischemia which is 4 and 5 and then those scheduled for amputation, which is Rutherford 6. So we're going after the worse to the worst conditions and that's one of the beauties of this.

So it is a large study, 1,200 patients, out comes, so the physicians have been able to use any treatment modality that they choose. And we're not only looking at clinical outcomes, we're looking at, at a long-term, we've consented up to five years, economic benefits, quality of life. So it's going to be a robust study, a lot of data. And critical limb ischemia is such an under-treated, condition today where you have several million people in the U.S. that average only see 300,000 interventions in a year. Half of those are traumatic amputations where the life expectancy of patients is fairly short afterward. So it is really an under-study and under-treated condition. And we think this is going to shed a lot of light on what the right treatment options are.

<<Danielle J. Antalffy, Leerink Partners Plc>>

So should we be thinking about LIBERTY 360° as a potential market growth accelerator or is it more strengthening CSI's competitive positioning, or both or neither?

<<Laurence L. Betterley, Chief Financial Officer>>

I think there's a kind of the same thing right. If it strengthens our position it's going to be a more market accelerator.

<<Danielle J. Antalffy, Leerink Partners Plc>>

So given the fact that you have been one of the drivers of growth in the atherectomy market, the recent quarters where growth has decelerated a bit, have you guys still managed to grow in line with or above the market? Have you guys managed to retain share or are you losing your share, because of the sales force execution issue?

<<Laurence L. Betterley, Chief Financial Officer>>

I think above-the-knee we've lost some on the fringes. Some of that – we are effective in soft plaque, as well. So I'm sure with the sales force transition and the disruption it's caused, we have lost some share it's caused, we have lost some share, there's been trialling of balloons and new products. We feel it's recoverable. In the – below-the-knee, where we are just unmatched in our effectiveness, you will probably see in patients aren't getting treated. But we'll get back on that, now that we stabilize the sales force, and we are able to increase the productivity and we will get back to growing in that market, as well.

<<Danielle J. Antalffy, Leerink Partners Plc>>

Okay, can we talk a little bit more about coronary, you mentioned it.

<<Laurence L. Betterley, Chief Financial Officer>>

Sure.

<<Danielle J. Antalffy, Leerink Partners Plc>>

At the impact of the sales force disruption, because we're still pretty early in the coronary launch, just wondering how coronary is tracking, the underlying coronary ramp, if you do not suffer the sales force disruption that you did?

<<Laurence L. Betterley, Chief Financial Officer>>

It's a – we're very excited about the coronary market. So about 40% of the people that have interventions in a year have significant calcium and significant calcium does result, the data shows it does result in poor outcomes, higher MACE rates. So the market is very large, we look at severe calcium, which is our specific indication that we're at full force, still 10% to 15% or maybe even higher of those procedures. So it is a very attractive \$1 billion market opportunity for us. Now it is a longer sales cycle than what we had originally anticipated, when we spread our reps spend, they weren't able to drive adoption in those coronary accounts, as they needed to for sustainable growth.

So we did see some usage fall off in some of our accounts, when we started implementing this hybrid technology. So with lowering our expectations of our reps, we're going to be able to spend more time in those accounts. And they will drive that adoption for a sustainable revenue growth, even with that we have very attractive growth year-over-year in coronary. And it is a very exciting market for us.

<<Danielle J. Antalffy, Leerink Partners Plc>>

Are you seeing it as a market share gainer versus the incumbent device rotator or are you actually growing the coronary atherectomy market?

<<Laurence L. Betterley, Chief Financial Officer>>

We believe both. I mean obviously rotator spent out there and we will take our share of that business. But the opportunity is bigger than just what their usage was and we're very effective in the heaviest calcium, very easy-to-use product and we believe we will be able to continue to grow that market beyond where it was prior to our entrance.

<<Danielle J. Antalffy, Leerink Partners Plc>>

Yes, you mentioned the market opportunity, I mean, how big do you think this really is? I know you mentioned 40% of these patients have, I think, severe calcium. So can you help size the market opportunity here?

<<Laurence L. Betterley, Chief Financial Officer>>

So there's 1.3 million roughly procedures that's PCI and bypass surgery. I'd say 10% to 15%, maybe more have severe calcium, so that's our initial focus. And so you can size the market, that's pretty large right there over 0.5 billion market potential. But they did it,

I will show even if there is moderate calcium present that you will get worst outcomes, the stents don't get good deployment, you're going to have a higher MACE rate and re-treatment rate. So over the longer term there's even a bigger opportunity and that would be up to 40% of the market. That's not our initial focus, but over the long-term we expect to drive it beyond the severe calcium.

<<Danielle J. Antalffy, Leerink Partners Plc>>

Okay that's helpful. As we think about coronary, and actually also in the periphery, what is the pushback that you get from physicians that aren't adapting the device? Is it a cost too much, is it there's not enough clinical data? Is it, I just don't want to do that?

<<Laurence L. Betterley, Chief Financial Officer>>

I think, there's a number of things. And one is properly identifying calcium, educating them on when calcium is present, the poor outcomes, the data that shows you're going to have poor outcomes, you might initially treat the symptoms, but your patient hasn't had the full procedure necessary to treat the disease, you are treating the symptoms.

So educating them on the prevalence of calcium, identifying calcium, the poor outcomes when calcium is there, if you don't treat the full disease, above and below-the-knee are some of those roadblocks. The other they've been thought many of them that treating below-the-knees is a high risk. And our device has been proven, there are very low complication rates and our device is different. Our device is proving to allow safe treatment, an effective treatment below-the-knee, which was not thought of before.

<<Danielle J. Antalffy, Leerink Partners Plc>>

And I know you guys have completed the COAST trial, I believe and have talked in the past about international expansion. Can you talk about your thoughts there now? Obviously you're focused right now on the U.S. and stabilizing the asset. Longer term maybe talk about the international markets here?

<<Laurence L. Betterley, Chief Financial Officer>>

Yes, our focus, our main focus is really Japan, coronary initially and that's the second largest coronary market for interventions. And we've done the COAST study exactly as you said. And we did in conjunction with the Ministry of Japan to allow us to use that to get approval to sell in Japan. So we are very excited about that. It also brings in our newest technology of our crown type to the coronary market. We got approval, we started the approval process a long time ago and it has one of our older crown types. So this I guess is a solid crown with some advanced sanding ability to it.

So we're very excited about that crown but also we got to believe they are used as support to enter Japan. And again it's a very large market it is the second largest market. Still takes some time to get in, we're going to file probably around this summer. It'll still

take until 2018, most likely to get commercial approval. But we think it's going to be a very lucrative market for us.

<<Danielle J. Antalffy, Leerink Partners Plc>>

Is there reimbursement in place already in Japan?

<<Laurence L. Betterley, Chief Financial Officer>>

There is, but we are working a process to get our own reimbursement, because we feel our effectiveness of our product wants a higher reimbursement than ones in place.

<<Danielle J. Antalffy, Leerink Partners Plc>>

And are you thinking at all about that is in the coronary rate. So what about the peripheral, is there any opportunity ex-U.S. in peripherals?

<<Laurence L. Betterley, Chief Financial Officer>>

Well in Japan there's an opportunity we may be able to work a somewhat parallel process. So it isn't a whole new submission after we get coronary approval. In Europe we are CE marked already, but the reimbursement, there is pretty spot. You really have to build your case and build your own reimbursement story. So we will have a pretty measured approach in Europe, so it's not on the near horizon.

<<Danielle J. Antalffy, Leerink Partners Plc>>

Okay. Now, Larry, since you are the CFO I have to ask you the operating leverage question. So now that you feel like the sales force is stabilized, you have fully enrolled Liberty 360, I believe, granted you are continuing to invest in R&D, but are we at a point where we can start to see, you generate some positive operating leverage and how do you thinking about the path to profitability from here?

<<Laurence L. Betterley, Chief Financial Officer>>

Yeah, thanks Danielle, we've really made our investments, we've invested in the business. We have a large sales force that can drive the business; it's the right size for driving the business forward. We have made and continued to make investments and studies, obviously. And we will do that, but we're not in a point where we're going to continue to increase our operating expenses. As a matter of fact, we came in 5% below our guidance for the second quarter and we continue to look at leveraging our existing spend and spending it correctly.

So that as we go over the top line we can have that drop to the bottom line and show a pathway to profitability.

<<Danielle J. Antalffy, Leerink Partners Plc>>

All right and with that, I think, we've come to the end. Thank you everyone, thank you so much Larry Bette.

<<Laurence L. Betterley, Chief Financial Officer>>

Thank you, all.