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<<Danielle Antalffy, Analyst SVB Leerink LLC>>

[Call Starts Abruptly] Medtech analysts here at SVB Leerink and we are very lucky to have with us the Cardiovascular Systems team. We have CEO, Scott Ward; COO, Rhonda Robb and Head of Investor Relations, Jack Nielsen.

So, I think we'll start off with a very brief presentation, sort of give an overview of the company in case you're not familiar and then we'll launch right into Q&A.

So Scott?

<<Scott Ward, Chief Executive Officer>>

Great. Thank you Danielle. And good afternoon everyone. Welcome and thanks for joining us. Before we get started, we'll get into the Q&A session in just a moment. But before we do that, I wanted to just give you just a very quick overview of the Company and our key growth initiatives.

I think as most of you know, CSI is the U.S. market leader in both peripheral and coronary atherectomy. These are both very large and growing disease states. And historically I think we have demonstrated our ability to sustain at least a 10% growth rate in our core atherectomy markets.

Last summer we announced our intention to transform CSI from a U.S. focused single product company to really becoming a multinational company that's developing a really exciting portfolio of products that are aimed at some of the most compelling unmet medical needs in interventional cardiology.

So over the next five years, we intend to invest about $250 million in research and development to bring 20 new products to market. In the first half of this fiscal year, we've already launched five new products.

This includes three products that physicians use to quickly track through a tortuous and angulated coronary anatomy to access lesions that they otherwise might not be able to get to. So really important advances, I think we're making really good progress in our product development pipeline.

Our new solid state vascular laser is right on schedule and I think many of you know that over the last two years we've been developing a mechanical circulatory support device and that device is right on schedule as well.

We're pleased with the progress that we're making with our mechanical circulatory support product. We actually have a pre-submission meeting coming up with the FDA, in the month of March, at which time we'll review our product development and our clinical programs.

So good progress there. The commercial launch of Orbital atherectomy continues to progress very well in international markets. We're really gaining strong momentum with the launch of our products now in Japan and Southeast Asia, Europe, and in the Middle East. Over the course of the first six months, really, thus far, we've trained about 50 accounts outside the United States and in the next six months, by June, we'll train another 50 accounts. So, a great progress internationally.

So taken in total, these strategies, really we think position us well to deliver a five year compounded annual growth rate of about 15% to 18% and revenue in the range of about $435 million to $500 million in 2023.

Just a quick update on – that's a little more near term. I think most of you probably saw that our second quarter revenue grew 14.4% to $60.2 million. This marked the third straight quarter of accelerating double-digit top line growth, highlights from our Q2 were 19% growth in coronary, our worldwide peripheral business grew 13%, which was powered by 19% unit growth in our core domestic atherectomy business.

And we also generated a modest profit in second quarter. So, we're driving market leading performance and gaining market share in both coronary and peripheral. That really is because we offer the best interventional solution for the treatment of calcium in the vasculature.

We have the strongest medical evidence in the market and we have a U.S. sales channel that's composed of about 200 sales representatives and about 100 clinical specialists. These individuals focus solely on supporting physicians in the treatment of calcified coronary and peripheral lesions.

So our team is really performing very well right now. We've created I think a really strong management team, one that's capable of managing a much larger company. Our organization is excited, morale is running high and these are good days for CSI. We're doing very well. We're really pleased with our progress.

So I'll stop there hand it off to you and take the questions.

<<Danielle Antalffy, Analyst SVB Leerink LLC>>

Great. So Scott, I think a good place to start would be, I'm deviating just a little bit from our questions here, because just, I think it helps to frame sort of what prompted the move from like a single product Company to saying we are total revascularization. Where did that come from and why? What are the benefits to CSI for being a revascularization company versus just an atherectomy company?

<<Scott Ward, Chief Executive Officer>>

Yes, it's such a, it's a really a good question. And to give you a kind of a really the high level answer to that, if you really think about, the core competitive advantage of a company like Cardiovascular Systems, Inc. we compete against some really big companies. We compete against Medtronic and Boston Scientific and Philips. These are the major competitors.

Our core competitive advantage is that we have 200 dedicated sales reps and 100 clinical specialists who support physicians every day in performing really complex cases. So, we collaborate, we stand shoulder to shoulder with physicians and work on these cases really to save lives.

And in that environment, in that instinctive care, when that patient is present, the physician is present and our sales rep is present that's when we create competitive advantage. So, our whole strategy quite simply is structured around saying, if we're going to provide that superior service, that superior support, it's pure medical evidence, superior medical education, how can we leverage that to draw more revenue and more EBITDA out of every case?

It really isn't any more complicated than that. And looking forward, what we're planning to do now is develop a line of products in peripheral that allow us to pull more revenue and EBITDA out of each case and the same in coronary.

So, if you look at the very simple approach and we think about just balloons, wires and catheters, we're taking that support revenue out of every case. Having a physician pull a CSI balloon instead of competitive balloon, and maybe over the longer term, if we think about a complex coronary case, we will be providing everything from the mechanical circulatory support for that case, the atherectomy, the CTO toolkit, the balloons, wires, catheters that would be used to serve that patient.

So that really creates, our competitive focus going forward and drives our vision.

<<Danielle Antalffy, Analyst SVB Leerink LLC>>

And can you quantify for us how much revenue you had been leaving on the table per case? I mean, is that something that you can talk about?

<<Scott Ward, Chief Executive Officer>>

Well, I think it's easier to talk about that if we just think about, the support products. I mean, we would say that that generally, if you think about a standard case, there probably is $800 to $1,000 of revenue in balloons, wires and catheters. Now it would be closer to $1,000 if you're talking about, using a higher level guide catheter.

So, if you've got a really complex case and the physician needs to change out wires, they're using a guide catheter, like our Teleport. And that environment you might be more to about $1,000 per case.

So, we could pull that, we don't expect a physician to use all of our products in every case, but we do expect to see continuous improvement in the revenue per case as a result of having these products available.

<<Danielle Antalffy, Analyst SVB Leerink LLC>>

Got it. And you keep referring to complex cases and I think that is a critical piece of the CSI story. Can you talk about, so you play in two different markets, coronary and peripheral, what percentage of these cases are what you would deem as complex where CSI has the competitive advantage in each of those markets? And I'd ask even, above the knee versus below the knee, if you could quantify that for us, if you can.

<<Scott Ward, Chief Executive Officer>>

Yes, it's a good question. And I think if you, if we think about the peripheral marketplace, the easy way to think about the complex patient population there is really the patients that have critical limb ischemia, many of which, but not all have a below the knee disease.

If we look at our revenue, roughly 60% to 70% of our revenue is from below the knee cases where you have longer calcified lesions. And generally the patients present with, wounds on their feet. So, the physicians know that this is a patient that has critical limb ischemia and they need to respond to aggressively to save that foot or to prevent a worse outcome.

And so that's where we really focus there. And so in the United States, there's probably about 2 million patients with critical limb ischemia. It really is an epidemic and we're seeing that continue to expand and grow.

Unfortunately due to diabetes, obesity, lifestyle changes, smoking and so on. So it's a very serious matter not only in the United States but around the world. And that's part of what's driving our international strategies, in the coronary marketplace. We're seeing the if you just look at PCI, PCI is generally thought to be kind of flat to down year-over-year.

And yet the complex cases are growing and probably a rate of 6% to 8%. So we are seeing this rather curious, development in coronary where the incidence of these more complex cases is rising. And there's speculation as to why that is, an increased rates of in-stent restenosis, the use of medications and so on that seems to be creating a patient population that has a more complex disease state.

So these are patients with bifurcated lesions, multi-vessel disease, calcification, low EF rates in that patient population.

<<Danielle Antalffy, Analyst SVB Leerink LLC>>

And I would just to add to that – I think, tell me if I'm wrong, just the more greater surgical turndowns too with CABG registries and such and the increased awareness around these complex interventional as can treat these complex patients in atherectomy as a facilitator of stenting that patient.

<<Scott Ward, Chief Executive Officer>>

Yes, such an important point. I mean, I think we're seeing cardiac surgeons being more selective about the patients in which they perform CABG procedures. Some of that is that they're subject to the same medicare scores as everybody else.

And so they're not taking on these difficult cases and as a result, they're turning them back. Others are very busy doing mitral valves or they're doing TAVR or they're just busy doing other things. And so there's a lot of patients now that are surgical turndowns that are coming back to cath labs. And this is driving the utilization of mechanical circulatory support devices, our devices and really other CTO products.

<<Danielle Antalffy, Analyst SVB Leerink LLC>>

Can we touch on the competitive landscape in the peripheral and the coronary, I mean, coronary much less crowded than the peripheral. So maybe let's start there. And where CSI's key competitive advantage lies?

<<Scott Ward, Chief Executive Officer>>

So we compete in, in coronary, principally versus Boston Scientific. And Boston has their rotor bladder device. They've had, that product, it's been in the marketplace for over 20 years. They trained and educated a lot of the market on how to perform atherectomy. Orbital atherectomy, just has a much better safety profile, a much stronger efficacy profile.

We've conducted the clinical trials that are necessary to demonstrate that our device can be used in the coronaries. So, really this device is the only device that's approved for atherectomy in the coronary artery, but it's supported by very strong medical evidence and really strong medical education.

We probably have 55% revenue share. Boston scientific is a little bit less than that. And then Philips plays in that market as well, but mainly using their laser for in-stent restenosis, which is a marketplace we don't participate in.

<<Danielle Antalffy, Analyst SVB Leerink LLC>>

And then peripheral?

<<Scott Ward, Chief Executive Officer>>

And in peripheral market, very much the same, we compete against Medtronic in that market. We probably have 40 – the low 40% market share range. Medtronic probably in the high 20s, low 30s, followed by Philips probably around 20% and then Boston Scientific with their product portfolio in the mid-teens. So those are the companies that kind of round out that peripheral marketplace.

<<Danielle Antalffy, Analyst SVB Leerink LLC>>

But I think one of the things that's interesting here, you mentioned two million critical limb ischemia patients, predominantly below the knee. And that's really CSI's bread and butter, where you have the most – that the widest competitive gap versus the Boston's and Medtronic's of the world, is that the right way to think about it?

<<Scott Ward, Chief Executive Officer>>

Well, I think, absolutely. I mean, that's why we were asked these questions about competition. And in our marketplace, if we focus solely on these patients that have these long calcified lesions, which is mainly what we're doing. There really isn't any other company that serves that patient population.

So the Medtronic device, Medtronic might be treating mixed plaque, the lasers are mainly treating softer plaque. Our device isn't really useful in the treatment of thrombosis. We just kind of spin the thrombus so we don't really even participate in that segment. So even as we think about this marketplace, we really focus on that complex calcified lesion set and CLI patients for the most part.

<<Danielle Antalffy, Analyst SVB Leerink LLC>>

Got it. Maybe let's shift gears a little bit. Let's talk about your fiscal 2019 guidance. You did just report your second fiscal quarter?

<<Scott Ward, Chief Executive Officer>>

Yes.

<<Danielle Antalffy, Analyst SVB Leerink LLC>>

And so you still have the back half of the year, comps do get tougher but your guidance does imply comp adjusted growth acceleration. Can you talk about the key drivers for this growth acceleration? I mean, you talked about a number of things on the call. You're shifting to OBL that grew 28%, I think last quarter in the peripheral business. Coronary is still a strong grower. And then you've got the layering on of international and the OEM products. So maybe help us understand what's driving the back half comp adjusted acceleration?

<<Rhonda Robb, Chief Operating Officer>>

Yeah, I'll break it down to the three areas. International is a big driver and we've been really pleased with the progress that we've made through our distributor with OrbusNeich and Medikit in Japan and increasingly throughout the rest of the world. And we just announced approval of our coronary classic device with our FlexTip wire. This is starting to roll out in Japan as we speak.

So we're really excited to bring this to the existing accounts that we've already launched into with our micro device in Japan. And then we'll be using that to expand access to additional sites as well. We're also looking forward to CE Mark for our coronary indications. This will be in Western Europe, toward the latter part of our fiscal year, expected sometime in the spring timeframe.

So continued international expansion will continue to be a driver, you mentioned some of the new product launches and we've already launched five new products this year. We have an objective to launch 20 new products over the course of the next five years. But really excited to continue the expansion of our radial launch, we have a new ViperWire Flex that is coming into our peripheral segment along with an exchange catheter.

So really rounding out the access tools that physicians have to treat their peripheral cases both radially and otherwise; and then on the coronary side, in addition to GlideAssist, just launched a new Teleport, Microcatheter that compliments the launch of the Sapphire 1.0 balloon that occurred earlier this year really to enable physicians to get at more complex patients.

So we're seeing kind of increased utilization and pull through of these support devices in our existing cases as well as now the utilization of these new devices to get us access to new cases. And then in the next couple of months, we'll be launching a new coronary wire called FlexTip as well. So that's really kind of the second key driver.

And then I would say the third is just, continued field support and focus on new accounts, new users, the use of our medical education and evidence as well as the contracting strategy that we discussed on the call. It's been extremely effective in terms of our ability to penetrate and gain share, particularly in high volume OBLs. We'll continue that very focused strategy but we'll be expanding it more aggressively into the hospital setting as well.

<<Danielle Antalffy, Analyst SVB Leerink LLC>>

Okay. That's helpful. And just to sort of quantify, I will say, I don't know that you guys get enough credit for your product pipeline in your product iteration. So for example, the Japanese launch of the Classic Crown, I mean, how much does that open up the market versus what you were serving previously? Is it more incremental in nature? Is it something that would drive an inflection?

<<Rhonda Robb, Chief Operating Officer>>

I think its like – I think that we will see incremental patients being treated and it's really a combination of the system that's being launched. It's the coronary classic with GlideAssist. And I think that was one of the innovations that really enabled us to see growth, for example in the U.S. and the coronary market as well.

But the launch of that in particular with the FlexTip will enable physicians to have greater ease-of-use. And I think greater competence in even treating more complex patients that they're currently trading today.

<<Danielle Antalffy, Analyst SVB Leerink LLC>>

Okay. But not anything that we should be thinking of like this drives an inflection. It's again, more incremental in nature.

<<Rhonda Robb, Chief Operating Officer>>

I think it's incremental.

<<Danielle Antalffy, Analyst SVB Leerink LLC>>

Continues to widen the competitive?

<<Rhonda Robb, Chief Operating Officer>>

I think so.

<<Danielle Antalffy, Analyst SVB Leerink LLC>>

Yeah, got it, okay. All right. Maybe let's – again, shifts gears now to the long-term growth drivers of the business. You guys do have two pretty large clinical trials ongoing Liberty 360 and the peripheral, ECLIPSE and coronary. Can you talk about how those fit into the strategy, what the impact could be from these clinical trials? And then just at a high level long-term drivers? We've already touched on international. We've touched on the pipeline. Not sure if there's anything to add in the core business.

<<Scott Ward, Chief Executive Officer>>

So the Liberty 360 trial is actually, we just finished our two year follow-up. And that trial is kind of a call to action for, mainly physicians that refer patients for peripheral vascular disease. Because what that trial demonstrates is that patients that are referred and are treated have a benefit in the sense that there is a reduced rate of amputation and a reduced rate of adverse events, for that patient population.

And that's across the board. The shame in this country is that 50% of the patients that receive amputations never have an angiogram. So they present that in ER, they usually would – they usually will present with a gnarly wound on their foot, let's say. And they might at that time, have a very serious infection. And so it might be appropriate to refer them for amputation, but 50% of the time they're never even sent for an angiogram.

So what we got to do is we've got to leverage this Liberty 360 data to get out to the referring base and tell them, look, refer these patients on to at least receive an angiogram, to assess this patient population. And what Liberty 360 teaches is that if you do that 80% of the time, you can prevent an amputation. And in fact, the patient doesn't have any meaningful adverse events for almost two years, for two years. We know that now.

So great, we'll be releasing the economic data that supports Liberty 360, later this year. And then that will kind of finish out that peripheral clinical trial. But with the clinical data and the economic data, we'll have the information we need to take that information to CMS to continue to protect our reimbursement environment and hopefully even expand it over time. So really an important study not only for CSI but really for the field.

ECLIPSE is the largest randomized controlled trial underway in interventional cardiology today. This is a study comparing orbital atherectomy to plain old balloon angioplasty for severely calcified coronary lesions. The primary endpoints for this trial are a minimum stent area, which is just do you make that lumen larger when you use orbital atherectomy versus a balloon. And the second is target vessel failure, which is a clinical outcome is measured at 12 months.

The first is measured in a 500 patient study, which is 250 patients in each arm using OCT imaging to detect the size of the lumen. So that information will be available upon completion of enrollment. We have about 700 patients enrolled. So we expect to complete enrollment in this trial and probably 18 to 24 months. The TVF data will be available about 12 months after that.

That study, we believe and in fact was designed by Dr. Greg Stone and Marty Leon and others. We specifically designed that trial to fundamentally change the practice of medicine. So this is a trial that if successful should change guidelines and should make it very clear that atherectomy should be used to treating these more complex calcified lesions.

<<Danielle Antalffy, Analyst SVB Leerink LLC>>

And just to remind, success is superiority?

<<Scott Ward, Chief Executive Officer>>

Success in this is superiority, but it's versus the standard of care, which is balloon angioplasty. So it's a head to head I guess versus POBA.

<<Danielle Antalffy, Analyst SVB Leerink LLC>>

Got it. Okay. And how do we think about that? So let's say it is successful. When you say guidelines changing, I mean, does that mean overnight we go from, I don't know we're low single-digit penetrated into the PCI coronary market today. How quickly does it ramp if when guidelines change?

<<Scott Ward, Chief Executive Officer>>

Well, I mean – overnight, I don't know that anything really ever happens overnight, but thank you for your optimism, is just great.

<<Danielle Antalffy, Analyst SVB Leerink LLC>>

That's what I have in my model.

<<Scott Ward, Chief Executive Officer>>

Okay, so let's talk about that. So I think – I do think though that it would have a pretty dramatic effect. I mean, right now, most physicians, and its always a bit controversial. But probably 12% to 16% of patients that have a percutaneous coronary intervention have severely calcified lesions. Now the reason that's controversial is with the changing environment that number seems to be increasing.

<<Danielle Antalffy, Analyst SVB Leerink LLC>>

Right.

<<Scott Ward, Chief Executive Officer>>

But even if you just take 12%. Today, if you took our data and your take Boston's data and you put that together. Together we're probably only treating about 4% of all PCIs. So really there's 3x market opportunity there. Now would we move from four to 12? No, I don't think we get 100% penetration even over a longer period of time. But can we double that opportunity? I think we can.

<<Danielle Antalffy, Analyst SVB Leerink LLC>>

What's the risk if it's not successful?

<<Scott Ward, Chief Executive Officer>>

Well, I think actually we design these trials with 0.9 power. So these are really well powered trials as you can – we were doing 500 patients in the imaging study, we're doing 2,000 patients in the outcome study. These are big trials. So we powered it at 0.9. We're

looking for a one millimeter difference in the MSA. We are quite confident that we can achieve that based on past studies that we've conducted.

And if we look at the TVF trials, TVF in a severely calcified patient population, if you look at other studies is typically in the 15% to 19% range. Our ORBIT II data would suggest that we're 7% to 8%. We powered this to detect a 3% difference. So if there's a greater than a 3% difference, we would win. So that's a way to say we don't like doing studies that we don't think we'll win.

<<Danielle Antalffy, Analyst SVB Leerink LLC>>

And these are already experienced users that are in the trial?

<<Scott Ward, Chief Executive Officer>>

Yeah, we're going to – that's part of the reason why it's a difficult trial to enroll is because these physicians will see these patients that have severe calcium. And they'll say, gosh, I'm not going to home…

<<Danielle Antalffy, Analyst SVB Leerink LLC>>

They don't want to randomize them?

<<Scott Ward, Chief Executive Officer>>

I just want to treat them. I don't want to randomize them.

<<Danielle Antalffy, Analyst SVB Leerink LLC>>

Got it.

<<Scott Ward, Chief Executive Officer>>

So that's why it's been a bit slower but at 700 patients we're feeling good about it and we will finish out this study.

<<Danielle Antalffy, Analyst SVB Leerink LLC>>

Okay. We did go over time, because I had to squeeze in that – yeah, shame on you, Scott.

<<Scott Ward, Chief Executive Officer>>

I'm sorry. I thought we still had two minutes.

<<Danielle Antalffy, Analyst SVB Leerink LLC>>

No, that's the next person to come here. All right. Thank you so much, everyone.

<<Scott Ward, Chief Executive Officer>>

Okay. Thank you.