Cardiovascular Systems, Inc.

Q2 2017 Earnings Conference Call

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John Gillings, *JMP Securities*

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PRESENTATION

Operator:

Good afternoon. My name is Christine and I'll be your conference operator today. At this time I would like to welcome everyone to the Q2 2017 Cardiovascular Systems Inc. Earnings Conference Call. All lines have been placed on mute to prevent any background noise. After the speakers' remarks there'll be a question and answer session. If you would like to ask a question during this time, simply press star, and the number one on your telephone keypad. If you would like to withdraw your question, press the pound key. Thank you. Jack Nielsen, Senior Director of Corporate Communications and Investor Relations, you may begin your conference.

Jack Nielsen:

Thank you, Christine. Good afternoon and welcome to our Fiscal 2017 Second Quarter Conference Call. With me on today's call are Scott Ward, CSI Chairman, President and CEO, and Larry Betterley, Chief Financial Officer.

During this call we will make forward-looking statements. These forward-looking statements are covered under the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995, and include statements regarding CSI's future financial and operating results or other statements that are not historical facts. Actual results could differ materially from those stated or implied by our forward-looking

statements, due to certain risks and uncertainties, including those described in our most recent Form 10K and subsequent quarterly reports on Form 10Q. CSI disclaims any duty to update or revise our forward-looking statements as a result of new information, future events, developments or otherwise.

We will also refer to non-GAAP measures because we believe they provide useful information for our investors. Today's news release contains a reconciliation table to GAAP results.

I'll now turn the call over to Scott Ward.

Scott R. Ward:

Thank you, Jack. Good afternoon, everyone, and thank you for joining us today. For those of you that have had a chance to read today's press release, I think it's fair to say that the headline could have read, *What a Difference a Year Makes.* As our second quarter financial results illustrate, we continue to make notable progress towards our goal of delivering sustainable revenue growth, combined with improving profitability.

To quickly recap, CSI generated second quarter revenue of just over $50 million, which was 21% higher than second quarter revenue last year. CSI also achieved profitability this quarter, with net income of $1 million and Adjusted EBITDA of $4.6 million, reflecting improvements of about $16 million compared to the second quarter last year. We ended the quarter with $79 million of cash, an increase of $21 million since September 30 of 2016.

The improvements made across the organization in the past 12 months are dramatic. They reflect persistent dedication from our 600 CSI Employees working together every day to serve patients and support physicians with orbital atherectomy products that successfully treat the most challenging calcified arterial lesions.

Now I know that all that sounds great, but at CSI we aren't celebrating yet; we have a—we serve a large and growing market, characterized by significant unmet medical need, and we still have considerable work to do to increase patient access and to drive adoption of orbital atherectomy for properly selected patients.

The character of our Company is also changing. We are striving to deliver reliable financial performance based upon sustained growth and disciplined management practices.

Obviously we have made progress on our pathway to profitability. With strong performance in Q2, we have now demonstrated that our business model can be profitable. We have also entered the stage of our journey where fluctuations in the timing of expenses will influence binary profitability.

We have delivered strong growth over the past four quarters, and we continue to make progress as we optimize the alignment and focus of our sales organization. As you know, we have approximately 240 cross-trained clinically skilled sales professionals including quota-bearing reps, clinical specialists, and sales associates that provide case coverage for both our peripheral and coronary franchises.

Although we achieved strong year-over-year growth in both coronary and peripheral, our second quarter peripheral revenue was lower than the first quarter of this fiscal year. We are striving to continuously improve our ability to balance the focus of our sales organization across the two franchises, to deliver simultaneous sequential growth in both peripheral and coronary.

Demand for our Diamondback system continues to be very strong in our coronary segment, and we are making adjustments to assure that we fully capture this opportunity. Our coronary franchise is an attractive business, where we have a distinct competitive advantage, we sustain attractive margins, and

we have consistently delivered strong growth. However, supporting that customer demand can require disproportionate sales time to assure the proper adoption and use of orbital atherectomy. This demand on a finite selling resource can affect peripheral results in a quarter. As we look to the future, we are confident that enhanced case coverage and customer engagement, combined with successful implementation of therapy awareness and medical education programs, will restore sequential growth at or above the market rate for our peripheral franchise.

When I consider the full picture, I am pleased that we are making strong progress on achieving our goal to build a strong organization capable of delivering consistent revenue growth and profitability. I'll provide additional thoughts regarding the development of our medical evidence and our progress in Japan, following Larry's financial commentary. Larry?

Laurence L. Betterley:

Thank you, Scott. Good afternoon, everyone.

Second quarter revenue of $50 million was 21% above the same period last year, and is slightly above the upper end of our guidance range.

We sold 15,000 devices during the quarter, generating 92% of revenues.

Coronary revenue increased 51% to $13 million, and peripheral revenue increased 13% to $37 million.

The below the knee product mix comprised about 58% of peripheral revenue. Our below the knee revenue increased 15% over prior year, with above the knee revenue growing at about 10%.

Reorder revenues remained high at 98% of total revenue.

We added 45 new peripheral accounts and 54 coronary accounts during the quarter.

The gross profit margin remained strong and improved to 81.7% compared to 80.5% last year, due primarily to unit cost reductions.

Operating expenses of $39.8 million declined 18% from last year, due to our previous cost alignment initiatives, cost re-alignment initiatives, and timing of expenses and projects.

Second quarter net profit of $1 million or $0.03 per share improved over $16 million or $0.50 per share from last year. Adjusted EBITDA was positive at $4.6 million, compared to a loss of $11.1 million last year.

At quarter end, our cash balance was $79.3 million, a $21.1 million improvement since September 2016. The increase in cash was the result of three factors. First, in December, we received $10 million payment from Medikit for the exclusive distribution rights for products in Japan. Second, improved cash flow from operations reached $5.9 million, excluding the Medikit payment. Finally, proceeds from employee stock plans were $5.6 million, including stock option exercises for about $4 million in proceeds. Note that CSI has not issued stock options since 2009 and has less than 200,000 option shares that remain outstanding.

In late December, we signed an agreement for sale-leaseback of our corporate headquarters, which, if completed, could provide over $20 million of additional cash. We are now well positioned financially and believe we have sufficient capital to fund our current growth strategy.

I'll now discuss our near-term financial outlook. For the third quarter of fiscal 2017, we anticipate revenues in a range of $50.5 million to $51.5 million, representing year-over-year growth of 14% to 16%; a gross margin of about 81%; operating expenses at a more normalized level of about $43 million; and net loss in the range of $1.2 million to $1.8 million. This equates to a loss per share of $0.04 to $0.06, based on approximately 32.6 million average shares outstanding. Also Adjusted EBITDA is expected to remain positive for the third quarter.

I'll now turn the call back to Scott for additional commentary. Scott?

Scott R. Ward:

Thank you, Larry.

On our second quarter conference call one year ago, I shared our vision to stabilize the Company and establish a strong foundation for sustainable profitable growth. With a determined team effort, we have delivered steady progress on that vision, and our second quarter results demonstrate that the execution of our business plan can produce impressive financial results.

Our success distinguishes CSI from other atherectomy companies. We have the best interventional solution for the treatment of calcium in the vasculature. We have a large sales force that is focused on supporting our customers with best-in-class clinical support, and we have the strongest medical evidence in the market.

In the next few months, we will set a new standard for leadership in the coronary atherectomy market with the launch of the Eclipse clinical trial. Eclipse will be the largest randomized clinical trial ever performed to assess the use of adjunctive coronary atherectomy for calcific coronary artery disease. It will be a prospective multi-center randomized clinical trial enrolling approximately 2,000 patients at up to 60 clinical sites in the United States. One half of the participants will receive orbital atherectomy prior to the placement of a drug-eluting stent, and the other half will receive conventional angioplasty, including the use of specialty balloons followed again by the placement of a stent.

This trial will be powered to demonstrate statistically and clinically significant differences in two primary endpoints, including minimum cross section stent area, measured immediately following the procedure, and target vessel failure, which will be evaluated at one year. The study will begin this spring, and we expect to complete enrollment in 18 to 24 months. We have assembled a world-class Steering Committee, which is chaired by Dr. Gregg Stone, and we are excited to have Dr. Ajay Kirtane and Philippe Généreux as co-principal investigators.

We are also advancing the standard in peripheral atherectomy with the Liberty 360 study. The results of this study are a call to action for primary care physicians, podiatrists and interventionalists who treat patients with peripheral vascular disease. As we stated last quarter, the 30-day results in Liberty provided evidence that intervention in Rutherford 2–3 and Rutherford 6 patients may improve outcomes. This is data that our sales organization will use to support physicians in case planning and patient management.

Next week, at the ISET Endovascular Therapy conference, Dr. William Gray will present six-month outcome data that will further build on the strong 30-day findings previously presented by Dr. George Adams. We will issue a press release summarizing the data following the presentation by Dr. Adams on February 4. Sorry, by Dr. Gray on February 6.

Before I close, I would like to provide an update on the progress we are making in Japan. As you recall, CSI submitted its application for Shonin approval of our second generation Coronary Orbital Atherectomy device last June. Japan represents an attractive first international market for CSI. This country of 127

million people, with a significant prevalence of calcified disease, represents the second largest market for coronary interventions. Physicians in Japan embrace vessel preparation and minimally invasive therapies, and are avid users of visualization tools such as IVUS and OCT to identify calcium. We recently announced an exclusive distribution agreement with Medikit Company Limited to sell our Diamondback 360 orbital atherectomy systems in Japan. We anticipate that our partnership with Medikit will boost our commercial launch and accelerate our market penetration. Medikit's sales channel includes 120 representatives selling products to over 800 hospitals that perform percutaneous coronary interventions. We continue to anticipate a Japan commercial launch of our coronary micro-crown, following receipt of regulatory and reimbursement approvals in the first half of calendar 2018.

In closing, we thank you for your continued interest in Cardiovascular Systems. We are working diligently to improve patient outcomes and to create shareholder value. Looking ahead, we will continue to invest in medical evidence to advance the use of orbital atherectomy. Concurrently, you can expect CSI to improve its clinical acumen, enabling our large sales channel to stand shoulder to shoulder with our physicians to help provide the best possible care for patients with calcific coronary and peripheral artery disease. These efforts, combined with strong financial discipline, are designed to allow CSI to deliver revenue growth, sustainable profitability, and an attractive shareholder return.

We look forward to updating you on our progress next quarter. Larry and I will now take your questions. So Christine, please provide instructions for the Q&A period now. Thank you.

Operator:

At this time, I would like to remind everyone, in order to ask a question, please press star, and the number one on your telephone keypad. We'll pause for just a moment to compile the Q&A roster.

Your first question comes from the line of Ben Andrew from William Blair. Your line is open.

Alexa Desai:

Hi, guys. This is actually Alexa in for Ben. How are you guys doing?

Scott R. Ward:

Good, thank you.

Laurence L. Betterley:

Hi, Alexa.

Alexa Desai:

So I guess to start, I mean, looking at Q3 guidance, what were the inputs to that and what kind of productivity are you assuming for the quarter? Maybe could you run through the bottlenecks to the ramp in productivity you are expecting?

Laurence L. Betterley:

Well the productivity, we're not expecting big changes on the sales organization going into the quarter, so all increases in revenue would be productivity gains by the sales force.

Alexa Desai:

Okay; and then, any color on how you got to guidance for the third quarter?

Laurence L. Betterley:

Well, we've gone through—we look at, of course, all the factors: the order rates of our customers, and the progress we're making on our sales programs, and the improved clinical acumen of the field, the tenure that they have, the relationships they're building. There's a lot of factors that that go into it, Alexa, and they all lead to continued growth in our revenue.

Alexa Desai:

Okay. That's helpful. Thank you. And then Scott, you talked about increasing market access in your prepared comments. Can you talk a little bit about the market development challenges that you see in both peripheral and coronary, and how you're working to address them?

Scott R. Ward:

Sure. So, in our peripheral business, we are pretty focused on our therapy awareness and medical education programs. But probably the most important tool available to us, to really improve patient access right now, is just assuring that our sales organization is spending time in the cath labs supporting our customers, providing that deep clinical acumen and providing support to our customers as they care for their patients.

We have had very successful programs in the marketplace. Our Limb Salvage programs are really gaining some momentum and making a difference in improving the quality of care in the market. So that—those would be the primary activities that we have underway to drive our peripheral market penetration.

In coronary, our coronary business is growing very rapidly, and it's mainly because we have such a strong competitive advantage right now in treating calcific coronary lesions. For patients that have severely calcified lesions, the use of orbital atherectomy has proven to be a very effective tool for physicians. So the primary—our primary goal there is not necessarily to open up a lot of new accounts but to work closely with our existing accounts and to really assure that patients that have calcified lesions are properly cared for. We do that through a number of different programs, probably the most important of which is a program we call Calcium Days, and that's where we collaborate with our customers and our larger cath labs so that they aggregate their patients that have calcified lesions into a particular day. These are usually their more complex coronary cases. Our rep can be present; we work with the physicians in managing those patients throughout the day, and it substantially improves the efficiency for our cath labs and also obviously for our sales organization, so.

Those are just some examples of what we're doing right now to increase our penetration in these markets.

Alexa Desai:

Okay, great. That's helpful. Thank you; and then just last one for me, on your decision to partner with Medikit, what were you thinking when you decided to make them your distribution partner in Japan?

Scott R. Ward:

I think it primarily goes back to the points that we made earlier, I mean, they have a very large channel in Japan, they're very experienced there, they call on 800 hospitals, and they are already targeting the key hospitals that treat patients with complex coronary lesions in the country. So we're very pleased with our collaboration with Medikit and, like I said, we do think that they'll help us as we launch in the country.

Alexa Desai:

Great. Thanks guys.

Scott R. Ward:

Okay. Thanks. Thank you.

Operator:

Your next question comes from the line of Mike Matson from Needham & Company. Your line is open.

Michael Matson:

Hi. Thanks for taking my questions. I guess I had a few more questions on Japan. So the press release mentions that they sell a coronary product, so do they have experience with peripheral products there? What's the timing? I understand the timing on coronary, but what's the timing for peripheral Shonin approval there, and would you need a trial to get that?

Scott R. Ward:

So we're pretty focused right now in coronary, and we're really driving towards getting that coronary Shonin approval, and that'll be our primary area of focus. Once we have that, we have that in hand and we have reimbursement approved for our coronary applications, we'll then turn our attention to peripheral. You can probably expect that peripheral will follow in let's say a year to a year and a half after, but I should caution you that, right now, we're very focused on coronary and we do not yet have, say, perfect clarity around our peripheral plans in Japan.

Michael Matson:

Okay, that's fine; and then, just on the balance sheet, you—close to $80 million; you got another $20 million coming in from the sale and leaseback, puts you up around $100 million. I think you've been pretty clear that you're not looking to do M&A, but I have gotten that question from a few investors, so I want to give you a chance to set the record straight here and let people know whether or not you're—what you're planning to do with that cash.

Scott R. Ward:

So, first of all, thanks for noticing that and pointing it out. I think we are proud of the fact that we have restored our balance sheet and that our cash position has come back to a level where it provides some comfort. I will say that, at the level of cash that we're at now, I think we have gotten to a point where we're properly positioned to manage risk in this Company. We are about a—we're a Company that generates about $200 million in revenue, we have a large investment in our sales organization, and to properly manage risk we should probably have cash in about the range where we are now. So I don't necessarily look at this as being an excessive cash position or one that necessarily would warrant consideration of strategic alternatives. Rather, I think right now it is very consistent with our earlier

strategies, which is to address the stability of this Company, both in terms of our operating activities and our balance sheet, and that's what's been our focus. I think we're pleased that in the course of a year we've substantially improved our cash balance, and right now we're about where we think we need to be.

Michael Matson:

Okay, and then finally, you're going to be coming up against some fairly difficult comps as you get into the latter part of calendar '17. The guidance for the upcoming quarter implies kind of mid-teens growth. I know you don't give longer-term guidance, but just do you feel comfortable that you can keep your growth solidly in the double digits as you come up against some of these more difficult comps?

Scott R. Ward:

I think, as we've talked about, our primary focus over the course of the past 12 months has been to stabilize the Company. We've, I think, done a good job at that. Now, over the course of the past couple of quarters, we've entered a new phase where we are now focused on implementing the programs that are necessary to drive growth going forward from here. As I said in my prepared remarks, we are pleased with the strong growth that we're seeing in our coronary business. We think we have identified a clear pathway to continued growth in peripheral. Some of that is just good execution through our sales organization, and some of it is the successful execution of our market development programs, which I referred to earlier. So, yes, we do feel confident in our ability to sustain growth in this Company going forward.

Michael Matson:

All right. Thank you.

Scott R. Ward:

Yes, thanks.

Operator:

Your next question comes from the line of Danielle Antalffy from Leerink. Your line is open.

Danielle Antalffy:

Hey, good afternoon, guys. Thanks so much for taking the question. Congrats on a good quarter. It feels good to make money, doesn't it?

Scott R. Ward:

Yes, it really does.

Danielle Antalffy:

So, just, Scott, on the productivity, just following up on the productivity question; last quarter you mentioned the next target, we're sort of at this $250,000 per rep range, the next target sort of a $275,000. Without providing guidance, can you sort of talk about, in your mind, how long it takes to get there? Sort of, is it a multi-quarter process? I guess I'm just trying to get a sense of—is that an end of fiscal '18 kind of goal? When you say that's our next goal, what are the expectations you lay out for your sales force internally to get there?

Scott R. Ward:

I know that you and probably everybody else would love us to peg a date for that. We obviously can't do that at this time. But I will tell you that this is a process of continuous improvement. I think you've seen, over the course of the past four quarters that we have just continuously in a stepwise fashion continued to grow, continued to build our productivity. This is very much related to a couple of factors. One is just creating stability in our sales organization. We've done that, we've achieved that. Now we've got to continue to build clinical acumen and the business acumen of that organization, so that they can grow both our coronary and peripheral franchises simultaneously. We're working that now, and I think we're seeing good progress in that regard. It is an imperfect science, however, and it is—at a local level we provide a fair amount of flexibility so that our local regional managers can deploy resources in a manner that they think will best drive growth in their regions. That has worked very well for us. We think that that will continue to improve productivity as we go forward. We're basically driving decision-making for the best initiatives that will drive a return on our investment to the lowest level of management in our Company.

So that's where we're at. I think it will be a process of continuous improvement. I think, as we look over the course of the next period of time, we do think we will get to that 275-plus type productivity. The next question is, well, how high can their productivity go? Honestly I don't know the answer to that. We're still trying to evaluate that. We're trying to determine really, based on the—what is the amount of case coverage that's required for our product. As we learn more about that, we'll be in a better position to basically compare that to other products in the marketplace and determine really where that productivity can lie.

So, hopefully that addresses your question as best I can anyway. Any follow-on on that, Danielle?

Danielle Antalffy:

Well, I…

Laurence L. Betterley:

Danielle, I'll add a little bit to that. We've said in the past that we needed about $55 million of revenue in a quarter to be profitable, and we're still holding to that. We were profitable earlier than that, but in a more normalized operating expense level that $55 million in a quarter would be a sustainable level for profitability. Given the guidance we gave, we're not too far away from that. We aren't going to peg exactly when that's going to happen, but we'll give you an idea for that; and then as far as productivity, about a third of our reps are north of that 275 target already, so we're making good progress there.

Danielle Antalffy:

Got it. That's very helpful. Scott, you answered my follow-up question before I could it ask it, which was where that $275,000 could go. So if I could ask a question on Japan, could you help us think about how to frame the ramp in that market? Is this something—they adopt stents fairly quickly? I imagine this is going to be a slower ramp, because there has got to be education involved. Is there a competitor in Japan? I'm not sure. Thanks so much.

Scott R. Ward:

So, good questions, so let me address those kind of one at a time.

It will be a bit of a slower ramp in Japan, even though the Japanese interventional cardiology community does take a longer amount of time, really, to assure that they got good vessel prep, they're avid users, as

I said, of visualization technologies like IVUS and OCT. We are really dependent on peer-to-peer training in Japan. So, we will be pursuing a launch there where physicians will be training one another on a progressive basis. As physician training progresses, obviously we'll open more and more new accounts. So, we do expect that to be a—let's say of a more of a—almost more of a traditional ramp, really, in that segment.

There is competition there. Boston Scientific has sold the Rotablator product in Japan for some time. So we're not entering an entirely new market. There are customers that certainly are well versed in the use of atherectomy for the treatment of complex coronary lesions. We'll leverage that, but we also will assure to take the time—well it takes time to assure that our customers get the training that they need to achieve really great outcomes using our products. So we'll be pretty helpful (phon).

Danielle Antalffy:

Perfect. Thank you.

Scott R. Ward:

Okay. Thanks.

Operator:

The next question comes from the line of John Gillings from JMP Securities. Your line is open.

John Gillings:

Hey guys, can you hear me okay?

Scott R. Ward:

Yes.

John Gillings:

Okay. So, there was a question brought up about the cash balance. Obviously it's great to see you guys with that kind of a cushion. So, one of the things that came up in your prepared remarks was that there was still a little bit of pull between focus on peripheral and focus on coronary. Is there any need to hire more people, or should we expect, beyond next quarter, out over the next several quarters, the total field reps to stay at sort of that 240 kind of level?

Scott R. Ward:

Well, we will—It's a good question. Really what this is about is optimizing the deployment of resources. It's really about assuring that our management teams are paying close attention to both coronary and peripheral, that they're executing across the full spectrum of initiatives that are available. I think we will continuously adjust the size of our channel to kind of meet the needs of our—to really meet the demand that we see in the marketplace. As I've said earlier, on a local level, we do allow our managers to make local determinations about their hiring and about how they want to focus their resources. So, in some cases, local management may focus on—they may hire a coronary—a very skilled coronary rep to drive growth in coronary. In other cases they may focus on peripheral. In other cases we may hire a clinical specialist, who can help with case support, and we may form teams of peripheral, coronary and clinical specialists that go out and address a particular geographic market.

So, for right now, we feel pretty good about our channel and the size that it is in that roughly 240-person channel. Remember now that that includes some quota-bearing reps, clinical specialists, and sales associates. So that's not all quota-bearing reps, it's a combination of those three skill sets. You'll see us, I think, continuously kind of adjust our resources in order to optimize our ability to penetrate the market going forward.

John Gillings:

Okay, that makes sense. I appreciate that color. And then, maybe you could just help characterize, in terms of going out and sort of trying to get into new accounts versus driving deeper in existing accounts, I know it's probably different in different territories, but could you characterize kind of generally which one of those is the primary focus right now?

Scott R. Ward:

We really have penetrated a lot of accounts. I mean we have a large channel. We have excellent geographic coverage. We still are adding new accounts, but far and away our primary growth strategy is really to go deeper in our existing accounts. What that means is, we may have one or two or three physicians in a cath lab that have adopted our technologies, and where the great opportunity lies is broadening that adoption across other physicians in the same cath lab. That's really our focus. When we talk about clinical acumen, what we want to have is, we want our sales reps to provide strong service and support, to work shoulder to shoulder with our customers, so that a—when a physician comes across a very difficult case, they'll say, Hey, is that CSI rep still here? Send her in; I'd like to have her take a look at this. Then we know that we will have arrived, and that really is our goal. So yes, it's really more about going deeper in these existing accounts. We will still add new accounts, but it's about going deep in existing accounts.

John Gillings:

Okay; and then, maybe just looking back, I know it's been a little while, but the 30-day data from Liberty 360, one of the things that was really impressive to me was the Rutherford 6 patients that were discharged to home. Maybe you can just talk a little bit about that, give us any color you can, and help us understand what's happening with those patients today, and how this could change for them.

Scott R. Ward:

Sure. So the six-month follow-up data will be released, coming up here on February 4 at the ISET meeting, as I described. So, I'll have to kind of leave that update to that later press release. I can tell you, and I've kind of referred to our Liberty 360 trial as really a call to action. I think that that Rutherford 6 data is evidence that intervention in patients that are already potential candidates for amputation, intervention in that patient population can make a difference. We can salvage those limbs. We can save those legs, and ultimately save those lives. So I think for interventionists, for podiatrists, for family practice physicians, for the medical community that cares for patients with peripheral vascular disease, I think this is really enlightening data that shows, hey, there is an option to treat these patients. In fact, we have evidence now that you can get good clinical outcomes. So, we'll learn more about this as we get to the six-month follow-up. Obviously, this is a very sick patient population, it's a difficult patient population to treat; but we'll learn more at six months and at 12 months.

I think the other part of Liberty 360 that is really important, and our sales reps are leveraging this as they work with our customers on case planning and case management, is as we look at the earlier stage patients, we were surprised to find so many Rutherford 2–3 patients that were enrolled in that study. In fact we also saw good 30-day results. Now, that's not surprising, because it's a very very early measurement. That said, I think as we get out now to 12 months and 24-month follow-up on Liberty 360,

we're going to have some very intriguing information that very well could justify early intervention in patients that are at that Rutherford 2–3 stage.

So that's one to kind of stay tuned on. The Rutherford 6 is immediately available to us, and we're leveraging that. I think over time this Rutherford 2–3 observation has the potential to really help us as well. So. But thanks for that, and we'll give you the additional data, like I said, on February 4.

John Gillings:

All right. That's great. That's all I had for tonight. Thanks guys, and congratulations.

Scott R. Ward:

Thank you. Thanks very much.

Operator:

Your next question comes from the line of Brad Mas from Bank of America. Your line is open.

Brad Mas:

Hey guys, good afternoon. Just first on the peripheral business, going back to that being down sequentially, can you just talk a little bit more about that? I mean are you seeing any increased competition, potentially from the new HawkOne device, or potentially maybe some trialing of the Shockwave device? Are you seeing more use of balloons? Or was it really just a focus on the sales force on coronary?

Scott R. Ward:

Well, I really—we talked about the focus on drug-coated balloons, and I think the trialing of drug-coated balloons has pretty much concluded. I think, when that first—when drug-coated balloon were first launched into the marketplace, I think that there was a lot of trialing in patients that had moderate calcified lesions. For severely calcified lesions, when our reps are present in cath labs, we get those cases. Physicians know that, even if they want to use a drug-coated balloon that they really should address the calcium that's present and remove that calcium prior to using a DCB. So the key thing here to us really is the optimal deployment of our sales reps and just assuring, in a very traditional management style, that our managers are out there, reminding and encouraging their sales reps to be in the cath lab to provide their case coverage, to be present, support our customers, and to just assure that, when severely calcified cases come through, that we're getting those cases. I know, I hate to make it sound so simple, but this is about execution. We just have to improve our execution at the local level. I think we will restore that sequential growth, and I'm confident in that.

In terms of competition, we are not heavily influenced by competition. We believe that you can look at our quarter—at our year-over-year growth and see that we are growing at a rate that's about consistent with the market, maybe even a little bit above the market. But we think that we're retaining and maybe even growing share slightly. We really don't see much impact of Shockwave in the marketplace at this time in the peripheral segment. We've always been locked in a strong competition with Medtronic. So, quite honestly not much has changed, in our view, in terms of the competitive dynamic.

Brad Mas:

And then I mean just more specifically, I mean, what drove the reps to focus on coronary? I mean is it just more profitable cases for the reps, or lower fruit, or—I mean and then, kind of what's the strategy to change that?

Scott R. Ward:

So great question. I'm not sure that I want to change it. I mean look, coronary, we just have really strong demand in our coronary business right now. As I take a holistic view of the value drivers for CSI, I think we're about driving growth in coronary and peripheral, we're about generating profit, and getting to cash flow break-even. We're going to do what we need to do to get there, and that may come from coronary and it may from peripheral. Our coronary business, as I said, is a business that—where there is high demand, and we're just trying to assure that we're best positioned to fulfill that demand. We have a higher gross margin product in that segment. We've got a really strong competitive advantage. So, we're trying to manage that and take advantage of that coronary growth and at the same time keep our peripheral business going. It's a balancing act. We'll get better at it, but it sure is a nice problem to have.

Brad Mas:

Okay, thanks for that; and then, I mean, on the expense side, we've seen a pretty dramatic drop in SG&A; can you just talk a little bit about where those cuts are coming from, and then, on top of that, how to think about the cost of the Eclipse trial going forward?

Scott R. Ward:

Sure. So we made adjustments in—we announced in March of 2016 that we had taken costs out of our Company. At that time you might recall that we talked about removing basically on an annualized basis about $20 million of expense. So, we have successfully executed against that plan. We have, really across our organization, been very disciplined in managing our operating expenses. We've demonstrated that, even in light of that disciplined expense management, that we still can sustain meaningful growth and deliver really on our mission. So we feel good about that, and it really is the reduction in op ex that you're seeing now all dates back to those actions that we took in March.

In terms of the Eclipse trial, total expense on the Eclipse trial will probably be in the $10 million to $12 million range. The expenses for that will start ramping up, and so you will start seeing that flowing through our P&L over the course of the coming year. Historically, we have been a pretty heavy investor in generating medical evidence. We're somewhat in the midst—we're kind of in a tweener stage right now, in that our investments in Liberty 360 are coming down, while our investments in Eclipse are now just beginning to come up. Yes, you can expect to see that Eclipse investment flow through. It will not affect our ability to continue on our drive to profitability. We have taken that into consideration, as we're balancing our investments across our portfolio.

Laurence L. Betterley:

Now that $10 million to $12 million, of course, will happen over time. What Scott's describing is probably a continued investment in R&D in the low teens as a percentage of revenue, over time.

Brad Mas:

Okay. Thanks, and then last one for me, I'm just curious if you could talk a little bit about how the Company and specifically the sales force is dealing with the corporate integrity agreement? I mean, any effects that you've seen, either on turnover or growth or productivity or anything like that?

Scott R. Ward:

The advantage we have at CSI is we've had a pretty strong compliance culture for a long period of time. The implementation of the CIA at this Company has largely been focused on adjusting the way that we report activity, and ensuring that we're reporting activity in a manner that complies with the government's requirements. We have undertaken a lot of training and education. We have assured that our sales organization clearly understands the requirements of our corporate integrity agreement, and we've taken all the actions necessary to assure that we have a reporting structure in place that allow us to demonstrate our compliance to the government. I really don't think that that the implementation of those programs have really changed or influenced our productivity. I suppose that at a small level we have taken time out to train and educate our channel, but I think in the long run this really will improve our ability to be more competitive in the marketplace, because our customers will be assured that if they work with us they'll always be proud of our collective activities. So, yes, no, I think we're—I don't think the CIA has impacted our business a whole lot.

Brad Mas:

Thanks, Scott. Just probably the last one for me, there's no changes recently in the turnover in the sales force?

Scott R. Ward:

Oh yes, good question, sorry, I meant to follow up on that. Actually our turnover has pretty much returned to industry standards at this point and is, at least at this stage, quite stable and probably in the expected range.

Brad Mas:

Okay great. Thanks Scott.

Scott R. Ward:

Yes. Thank you.

Operator:

Your next question comes from the line of Ben Haynor from Feltl and Company. Your line is open.

Ben Haynor:

Good afternoon, gentlemen. Thanks for taking the questions. First for me, I think on the last call you mentioned that you had a bit of a slow start to this quarter, but it seems to have accelerated throughout the quarter, given the reported results. Can you talk about any trends you've seen, I know it's early, only a few weeks in here in Q3, but any trends that you've seen so far this quarter?

Scott R. Ward:

Well. I mean we really can't comment on that a whole lot, because obviously it's undergoing. But, Q3, normally you do see a slow start to Q3 because you're coming off of the holidays and that kind of thing, and that is oftentimes balanced by the fact that the cold and flu season has arrived and cath labs are generally busier. So, I would say that we're seeing a relatively normal start to what we would consider to be our third quarter, and that's about where we're at.

Ben Haynor:

Okay. That's helpful. And then kind of following up a little bit on one of Danielle's questions, specifically on the top quartile of rep productivity, I think you mentioned on last call it was I think north of $300,000. Is there any update there? Is it still kind of running at a similar level?

Scott R. Ward:

Very much so, still running at a very similar level. That does kind of give you an indication of what can be done when we optimize productivity.

Ben Haynor:

Okay. Perfect. That's all I had, gentlemen. Thank you very much.

Scott R. Ward:

Thank you.

Operator:

There are no further questions at this time. Mr. Scott Ward, I turn the call back over to you.

Scott R. Ward:

Okay, well thank you very much, Christine, and thank you to everybody on the line. Thank you for your continued interest in CSI. We do look forward to updating you on our progress next quarter, and that will conclude our conference call. Thank you.

Operator:

Thank you, ladies and gentlemen. This concludes today's conference call. You may now disconnect.