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Cardiovascular Systems, Inc.

Q4 2016 Earnings Conference Call

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Danielle Antalffy, *Leerink Partners*

Bob Hopkins, *Bank of America*

Jan David Wald, *Benchmark Company*

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 Cardiovascular Systems Inc. Fiscal 2016 Fourth Quarter Earnings Conference Call. All lines have been placed on mute to prevent any background nose. After the speakers' remarks there will be a question-and-answer session. At that time, if you would like to ask a question, simply press star and then the number one on your telephone keypad. If you would like to withdraw your question, press the pound key. Thank you.

I will now turn the call over to Jack Nielsen, Senior Director of Corporate Communications and Investor Relations. Please go ahead, Sir.

Jack Nielsen:

Thank you, Christine. Good afternoon and welcome to our Fiscal 2016 Fourth Quarter Conference Call. With me on today's call are Scott Ward, CSI Chairman and Interim 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 10-K and subsequent quarterly reports on Form 10-Q. 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 Ward:

Thank you, Jack. Good afternoon, everyone. It is a pleasure to be with you on today's call. I'm excited to update you on multiple positive developments since our last quarter, as we continue to position the Company to deliver revenue growth, positive cash flow, and profitability.

First, let me summarize our stronger than expected fourth quarter results. Revenues of $48.5 million were $2 million above the high end of our guidance range, 9% higher than our third quarter of this year, and similar to fourth quarter of last year. We improved sales performance while reducing our expenses, resulting in a quarterly net loss of less than $5 million, a $10 million improvement from our December quarter just six months ago.

Our improved revenues are a direct result of our efforts to stabilize and support our field sales representatives. We have taken specific actions to improve the clinical acumen of our sales force and provide a higher level of procedural support for our physician customers, while continuing to develop the market for treating calcified lesions, a large unmet medical need that only CSI currently can address. We believe these steps are driving orbital atherectomy adoption and dramatically improving sales rep productivity.

Increased revenue, combined with efforts to right-size our cost structure, has dramatically reduced our quarterly loss and our use of cash. As a result, we are now poised to deliver positive cash flow and profitability in the near future.

During our fourth quarter, we also delivered on two important milestones: submitting our Shonin application in Japan for approval of our second generation coronary device, and reaching a settlement with the Department of Justice. We are also continuing to build on our substantial portfolio of medical evidence. Next week Dr. George Adams will present 30-day data from our Liberty 360 study in a late-breaking presentation at the Amputation Prevention Symposium.

I'll offer additional commentary regarding these and other developments after Larry provides his financial commentary. Larry?

Laurence L. Betterley:

Thanks, Scott. Good afternoon, everyone. My prepared comments today will focus on our fourth quarter results.

As Scott mentioned, fourth quarter revenue of $48.5 million was similar to a year-ago period and $2 million above the high end of our guidance range. Revenues also grew 9% in the third quarter of this year, with comparable growth rates for both coronary and peripheral. We sold 14,500 devices during the quarter, comprising 92% of revenues. Device revenue increased 3% over prior year to $44.5 million. Coronary device revenue increased 20% on 21% unit growth. Peripheral device revenue was similar to the prior year on 2% unit growth. Compared to the third quarter, peripheral units grew 12%. Peripheral product mix below the knee remained comparable to the third quarter at nearly 60%. Reorder revenues remained high at 98% of total revenue.

Other product revenue declined $1.5 million to $4 million. Last year's amount included $2 million of Asahi guide wire sales, and that agreement terminated in June of 2015. We added 48 new peripheral accounts

and 62 coronary accounts during the quarter. Gross profit margin remained strong at 79.7% compared to 77.6% last year. The improvement was driven by unit cost reductions. Operating expenses declined about 6% from last year, primarily driven by our cost realignment actions, including reduction in force of about 8% on March 31. Net loss improved over 40% to $4.9 million or $0.15 per share, compared to a loss of $8.7 million or $0.27 per share last year. Adjusted EBITDA improved over 60% to a loss of $1.4 million.

Our cash burn declined to $1.5 million in the quarter, aided by $1.5 million of cash proceeds from our employee stock purchase plan. At quarter end, our cash balance was $60.6 million. Our priority continues to be to live within our cash levels to reach positive cash flow and profitability. We believe that our cash balance is sufficient to do that. However, we are also evaluating financing options for corporate headquarters to provide additional cushion. We anticipate a facility financing could add approximately $20 million of cash.

I will now discuss our first quarter financial outlook. Please keep in mind that our fiscal first quarter includes summer months that typically produce lower procedure volumes. In addition, it's also a period of significant sales meetings and training for our sales force. These factors were taken into consideration in developing our guidance.

For the first quarter of fiscal 2017, we anticipate revenues in the range of $48 million to $49.5 million, with a mix of peripheral and coronary revenues similar to the fourth quarter of fiscal 2016. We expect gross profit as a percentage of revenues to be about 80%. Operating expenses are projected to be 4% higher than the fourth quarter, primarily driven by the timing of our sales meetings and training expenses. Net loss is expected to be in the range of $5.8 million to $6.7 million; this equates to a loss per share of $0.18 to $0.21, based on approximately 32.8 million shares outstanding.

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

Scott Ward:

Thanks, Larry.

Now I would like to take a few minutes and provide an update on our progress toward several key milestones that I described for you in January, beginning with the stabilization of our sales force. This stabilization is critical to driving revenue growth and establishing a profitable business model at CSI.

In January, I shared with you my expectation for improving sales rep productivity and the resumption of top line quarterly growth at CSI. At that time, we had just concluded a quarter where average rep productivity was about $172,000. Since then, we have dedicated time and resources to stabilize the sales force and allow our reps more time to support cases, educate their customers, and properly develop accounts. This focus is producing the desired near-term result, lower turnover and a higher productivity. A notable by-product of this sales force stability is improved rep productivity. Average revenue per representative was $245,000 in fiscal fourth quarter, a 42% improvement compared to our low point in Q2. More importantly, our dual franchise representatives generated $275,000 in average sales, which validates our strategy of developing representatives capable of providing clinical expertise in both peripheral and coronary interventions. Our field sales organization remains at about 240 professionals, including sales representatives, sales associates and clinical specialists. We continue to believe that this highly capable team is the appropriate size to address our substantial domestic market opportunity, and we are encouraged by their progress in the last two quarters.

In addition to improving rep productivity, I also noted that we would reduce our quarterly losses and demonstrate a pathway to positive cash flow and profitability. Since then, we have pursued actions throughout the organization to lower the Company's cost structure. As evidenced by our fourth quarter

results, the expense reductions we have made did not negatively impact our ability to grow revenue. In total, we reduced our annualized cost structure by nearly $20 million from our run rate in the second quarter. Fourth quarter Adjusted EBITDA loss was just over $1 million, compared to an $11 million loss in the second quarter.

Six months ago, Investors were concerned about our balance sheet, especially after burning $18.5 million of cash during the first six months of fiscal 2016. One of the key milestones that I mentioned in January was maintaining a solid cash position. Expense reductions helped reduce cash burn to less than $5 million over the last six months of our fiscal year, and only $1.5 million in our fourth quarter. As Larry indicated, we ended fiscal 2016 with $61 million in cash.

Our fourth quarter financial results demonstrate we have made substantial progress towards the milestones I identified last January, some even faster than I expected. This progress was only possible due to the dedication and passion that CSI employees bring every day for improving the quality of care for patients with calcified arterial disease.

The disruption that occurred due to the sales force realignment is largely behind us. Today we have a stable clinically-oriented sales force that is helping an increasing number of physicians treat a large under-served patient population.

Regarding our Department of Justice investigation, we were pleased to complete a settlement agreement resolving all of the Government's claims against the Company, with no admission of liability, and avoiding potentially distracting, costly, and protracted litigation. The settlement calls for a payment of $8 million, $3 million of which was paid in July, with the remainder to be paid over 11 quarters, beginning on January 1, 2017. We reserved the $8 million in our third quarter, upon reaching a settlement in principle with the Department of Justice.

As I mentioned during my preliminary remarks, another milestone we achieved during the quarter was submitting the Shonin application in Japan for approval of the Diamondback coronary OAS micro-crown to treat calcified coronary arteries. If approved, Japan would become CSI's first international market. We just submitted the application in June, but at this time we estimate commercialization in calendar 2018. We have initiated discussions with potential distribution partners and hope to announce an agreement before the end of this calendar year.

Regarding CSI's CEO opening, the Board of Directors continues to conduct a search for my permanent successor. Identifying the right candidate for this position can take time, as our standards are high. CSI is a Company with tremendous opportunity, and it is critical that the next Leader has the necessary skill set to help realize our full potential. Until that person is identified, I will remain as the interim CEO.

On the clinical front, next week at the Amputation Prevention Symposium or AMP, Dr, George Adams will present the 30-day data from the landmark Liberty 360 trial. The Liberty study is a prospective, observational, multi-center registry study evaluating the clinical and economic outcomes of endovascular interventions in patients with symptomatic peripheral artery disease, including critical limb ischemia, the most severe form of peripheral disease. The study includes all commercially available technologies, including CSI's Diamondback 360 peripheral orbital atherectomy system. We expect Liberty to illustrate how orbital atherectomy is currently being used in real-world patients. We believe this study will inform physicians on how to best use orbital atherectomy in different types of patients and what specific treatment algorithms work best with orbital atherectomy to optimize result.

This is a large study with a relevant patient population: nearly 1,200 patients were enrolled at 51 sites, including 500 Rutherford two to three patients, 589 Rutherford four to five patients, and 100 Rutherford six patients. We look forward to Dr. Adams' presentation on August 11, and we will share the results in a press release shortly thereafter.

In closing, our fourth quarter achievements demonstrate our continued focus on execution and productivity improvement throughout the Company. CSI is winning again, and we enter fiscal 2017 with a renewed sense of confidence, and here's why: CSI is the market leader in both peripheral and coronary atherectomy, with a unique powerful technology routinely used by physicians in their practices. Orbital atherectomy treats previously untreatable patients with calcified lesions. This is a growing and unmet medical need that CSI can address. CSI continues to support physicians with an expanding portfolio of medical evidence that demonstrates how orbital atherectomy provides improved patient outcomes for a very sick patient population.

Reimbursement for our atherectomy procedures remains stable and healthy. We are confident that we can maintain steady gross margins in the 80% range through continuous improvement in manufacturing and reductions in cost of goods sold. CSI sales force, now stabilized, is a significant asset, and we are just beginning to demonstrate how this clinically astute group can support our physician customers treating challenging peripheral and coronary cases. Finally, the rep productivity combined with expense control in Q4 demonstrates a strong business model, poised for future profitability.

We look forward to updating you on our progress when we report fiscal first quarter results in October. Larry and I will now take your questions. Christine, please repeat the instructions for the Q&A period. Thanks.

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 Danielle Antalffy, your line—from Leerink Partners, your line is open.

Danielle Antalffy:

Hey, good afternoon, guys. Congrats on a great quarter. It's great to see that this has started to turn around.

I was wondering if you could give some color on how much of the growth this quarter was the broader market versus you guys regaining some market share. Any color you can give there and if you can give specifics on above and below the knee that would be even more helpful.

Scott Ward:

I'll let Larry comment on above and below the knee. Thanks for your comments, Danielle.

I would say it's difficult for us to compare the performance of CSI to the market in total because, as you know, we specialize on calcium while many of our competitors focus on thrombus and stent restenosis and other indications. I think that the vast majority of our growth this quarter comes from the restoration of productivity improvements in our sales organization. I think we're just doing a much better job supporting our customers, and since we're present in cases we've got strong clinical acumen out there now amongst a large portion of our sales force, which is doing a much better job at converting the cases that have heavily calcified lesions into orbital atherectomy cases.

Larry, do you have any input on the above the knee and below the knee?

Laurence L. Betterley:

Danielle, last quarter we reported that below the knee had rebounded. We started seeing sequential growth below the knee. Overall sequentially in the fourth quarter, peripheral increased about 9%. The good news is our above the knee began growing also. So, little less below the knee than couple percent below that 9% for below the knee and above the knee was greater than 9% for the quarter sequentially.

Danielle Antalffy:

Okay, that's helpful. Thank you so much for that detail. And then on the rep productivity, I mean clearly you're gaining some traction there. I think in the past you guys have sort of talked about 250K per quarter, correct me if I'm wrong on that, per rep, from a productivity perspective. Is that still the right way to think about it, so at this point you're almost there, or do you think that rep productivity with your sales force in place today and from what you're seeing so far, would you actually think that that productivity is going to continue to move higher?

Scott Ward:

Yes, thanks. So I think we've had this conversation maybe every quarter the past few quarters, Danielle. I mean, when I refer to $250,000 per quarter, I was referring to that really as being—as somebody had asked me, at what level do we think we have a healthy channel? We look at the industry in total. That's where we had come back and said well, annualizing at $1 million or roughly $250,000 per quarter, is generally perceived as being kind of a healthy organization, at least at the margins that we have. We're ten months into this now and I am really pleased with the restoration of productivity that we're seeing. In particular, I think that the improvement in productivity over the past two quarters by our sales force is really impressive.

Our near-term goal, actually, I mean, I fully expect that we'll continue to see improvements in productivity now. I guess as I look at our near-term goal, I'd say we're now driving to get to that $275,000 per quarter level, and I think that's achievable; that's about where our Q4—where our dual reps came out in Q4. So, getting the whole group to that level is expected to deliver profitability for CSI, and that's what we're driving for.

Danielle Antalffy:

That's great to hear. Thanks so much, guys.

Operator:

Your next question comes from the line of Bob Hopkins from Bank of America. Your line is open.

Bob Hopkins:

Thanks, can you hear me okay?

Scott Ward:

Hi, Bob. Yes.

Laurence L. Betterley:

Sure can, Bob.

Bob Hopkins:

Hey great, good afternoon. So, Scott, first a question for you. Obviously you're having great success here over the last couple quarters. I was wondering, if the CEO search continues to drag on, would you consider the job?

Scott Ward:

Well, Bob. So thanks for that question. Let me just say this. I don't really think the CEO process is dragging on. It may seem like it is, because we went through a period of time where Dave Martin in particular had illness, and we were trying to manage that. But actually the CEO process has only been underway, the search process, for about three or four months. We're still well within the window of time that it should take to really—that's required to really select a strong candidate. In the meantime, this is a really strong Management Team, this is a very mature, very stable Management Team that knows how to operate this business, and I think it has really out-performed exceptionally well in supporting the Company over the course of the past six months as I've been here as the interim CEO. I will continue to serve in this role as long as is necessary, Bob, and I'm going to continue to deliver my passion and my energy to this Company, and we're going to continue to strive to get CSI to restore the greatness in this Company, and we can do that. So, I guess the answer to your question is, we're continuing to search for a new CEO.

Bob Hopkins:

Okay. Just had to ask. I think a lot of people on the phone would love to see that. Obviously you got sort of the perfect background. But I appreciate your answer. Thank you.

Scott Ward:

Small thing.

Bob Hopkins:

So the second question I have is, I was just wondering if you could go into a little bit more specifics on—you saw such a nice jump in productivity; what specifically have you done to stabilize the sales organization and re-energize the sales organization? Has it been a couple of key hires? Just wondering for some specifics. I'd love to get a better understanding of exactly what's happened there that's allowed this to happen.

Scott Ward:

Bob, what we refer to and what we talk about, what sales Leadership talks about in this Company is stabilization, focus and execution. By stabilization I think you'll recall, dating back to about a year ago and even a few quarters ago, we had been introducing many, many changes to our sales organization, changing territories, changing comp lines, changing focus, training and educating our sales reps on peripheral and coronary applications. Starting in late last calendar year, we stopped that, and we simply said, let's give our sales organization time to focus on their customers, to focus on providing excellent procedural support, being present, and to continue to get stronger at being able to support both coronary and peripheral cases. That's not a small task. Having a sales organization as capable of operating in a coronary cath lab and peripheral cath lab is tough. It requires some pretty significant clinical acumen. So we worked hard at building that in our Team. I think now we're beginning to reap the benefits of that. We're seeing the strength of this organization recover, and frankly, as I said to Danielle earlier, I do expect to continue to see improvements in productivity over time, as this Team continues to get time in territory and as we continue to stabilize.

So, yes, it's really right now it's just a maniacal focus on execution. Every day, every week, every month, every quarter. That extends throughout the whole organization, from me all the way down to our sales reps.

Bob Hopkins:

Got it. That's very helpful; and then just one really quick one. So it sort of sounds like you're absolutely convinced that the model you have today is the right model.

Scott Ward:

I am convinced that this is the right model, Bob. I really am. We are getting the productivity out of the sales force, and as we leverage that opportunity, and we maintain our cost structure. I think you've heard both Larry and I talk about the importance of balancing our cost structure against the market opportunity in front of us. So, what we really tried to do when we implemented those expense reductions in March was to take costs out of the Company in areas where we thought we could do that without negatively affecting our growth. I think, as we've seen here in fourth quarter, we achieved that. It gives me confidence that we have the right model and that we're absolutely headed in the right direction here.

Bob Hopkins:

Great. Congrats on the progress.

Operator:

Again, if you would like to ask a question, please press star and the number one on your telephone keypad. Your next question comes from the line of Jan Wald from Benchmark Company. Your line is open.

Jan David Wald:

Hello, good afternoon everyone, and congratulations on—

Scott Ward:

Oh, thanks Jan.

Jan David Wald:

I have a couple of questions left over from everybody else's. I guess one of the things I wanted to ask about was the peripheral sales that you have. I know that you're in a very specific segment of the market. But are you growing faster than what you think the procedures are in that segment, or—because I guess I was a little bit surprised that you were only back to where you were a year ago. Perhaps you're not growing it fast for some other reason besides just procedural growth in that segment.

Scott Ward:

As we look at this market we segment out the above-the-knee segment and below the knee. In below the knee, we have the vast majority of the market share there. So, as you really look at that market, I think our growth there is representative of our ability to support our customers and work with them in really reducing amputations, and just improving the quality of care in that segment. In the above-the-knee

segment, I think that our growth was consistent with the market. I think we retained our share in that segment.

Laurence L. Betterley:

No, we didn't, Jan; with the sales force transition, we did take a partial step back for a while. So we are regaining momentum on a sequential quarterly basis. It'll take a little more time to get that up to a substantial year-over-year, but we think we're well on the path there.

Jan David Wald:

Okay. My last question, I guess, is, in terms of—you've done a really nice job in bringing down costs. My experience is, once you start doing that, especially in manufacturing and other operation (inaudible) operations, you can find cost reductions that kind of surprise you and can go for—and you can do it for longer than you might have imagined. Are you still seeing an ability to cut costs? Should we expect to see op ex in some sense come down in general over the next year to two years, or what's your feelings about that?

Scott Ward:

I think we've stabilized that out nicely right now. I feel good about where our P&L is at, in that regards. As I look at operating expenses and think about our sales organization, when we've stabilized that out, I think that we're going to win with the team we have, in that regard. As we look at R&D, I think you're going to see us probably increase our spending in R&D as we continue to develop more clinical and medical evidence that demonstrates the benefits of orbital atherectomy in particular in coronary and possibly in vessel preparation in coronary as well as vessel prep in the above-the-knee segment. There also is additional clinical work that can be done and probably should be done below the knee that will help us continue to drive market penetration there.

I'll take your question in a little different direction. If you think about where this Company can go in the future and the growth potential for this Company, our coronary opportunity is still a new opportunity for us and we're still growing into that. We've achieved great growth in that segment thus far. But if we continue to generate more and more medical evidence that'll support the use of orbital atherectomy for complex coronary lesions, this business has tremendous potential to grow in the future.

So, I think R&D may—we may see more there. As we look at sustaining our gross margins, we're pleased that we're operating in a fairly stable reimbursement environment right now. We don't expect that to continue forever and we're well prepared to continue to see improvements in reducing our cost of goods sold. We have programs in place to do that. I think that those actions can help us to sustain our margins, even with some price erosion.

So, hopefully that addresses your question. Maybe I went into a little more detail than you'd like, but that's where we're at. I feel good about the P&L.

Jan David Wald:

You can never go into too much detail. Thanks a lot, and again, congratulations on the quarter.

Scott Ward:

Thank you.

Operator:

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

Scott Ward:

Okay, great. Thank you, Christine. Well thanks everyone for joining us today, and thank you for your interest in CSI. We do look forward to updating you on our progress next quarter. Good afternoon, everyone.

Operator:

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