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# Cardiovascular Systems, Inc. (CSII)

Q4 2017 Earnings Call

# CORPORATE PARTICIPANTS

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# MANAGEMENT DISCUSSION SECTION

**Operator:** Good afternoon. My name is Ruth and I will be your conference operator today. At this time, I would like to welcome everyone to the Q4 2017 Cardiovascular Systems, Inc. Earnings Conference Call. All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question-and-answer session. [Operator Instructions]

Jack Nielsen, Senior Director of Investor Relations, you may begin your conference.

## Jack E. Nielsen

*Senior Director-Corporate Communications and Investor Relations, Cardiovascular Systems, Inc.*

Thank you, Ruth. Good afternoon and welcome to our fiscal 2017 fourth 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 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 R. Ward

*Chairman, President & Chief Executive Officer, Cardiovascular Systems, Inc.*

Thank you, Jack. Good afternoon, everyone, and thank you for joining us today. During today's call we will address our performance in the fourth quarter, reflect on fiscal year 2017 and provide our perspective on the key initiatives that will drive our growth in FY 2018. Larry will provide the details on our fourth quarter in just a moment.

But from our press release, you can see that our solid fourth quarter results are the capstone for a very successful year. By any objective measure, CSI delivered remarkable financial performance in fiscal year 2017. During the year, revenues increased 15% to $204.9 million. We not only produced attractive year-over-year growth, but our fourth quarter results of $52.9 million marked the sixth consecutive quarter of sequential revenue growth. Peripheral revenue grew 11% and coronary revenue grew 31% in fiscal 2017, and CSI sold over 60,000 orbital artherectomy devices, enabling physicians to enhance the quality of care for patients with calcific coronary and peripheral artery disease.

Strong growth combined with disciplined expense management and efficiency improvements across the organization propelled CSI towards profitability. In fact, we achieved our first ever quarterly net profit during our second quarter, and we're nearly breakeven for the year. Net loss for the fiscal year was $1.8 million, an improvement of over $54 million compared to last year. We also achieved dramatic progress in adjusted EBITDA as this measure of cash flow rebounded from a loss of $39.2 million in fiscal 2016 to a gain of $12.9 million in 2017.

Gross margin increased to just under 81%, and our operations now generate cash each quarter. In fact, we ended the year with approximately $108 million in cash and no long term debt. We are the market leaders in peripheral and coronary artherectomy. And with investments in medical education, clinical research, product development, sales and marketing, we are well positioned to further extend our competitive advantage in the future.

As we exit fourth quarter, CSI has emerged as a strong and stable company. However, we have certainly faced our share of adversity, and throughout the year we have addressed several important challenges, including the voluntary recall of about 1,100 saline infusion pumps in Q4. As we noted in May, the recall impacted approximately one half of our customers and will temporarily disrupt our sales momentum. Of course our first priority is to assure the safety of our patients and to provide a high level of communication and superior service to our customers as we replace the affected pumps.

We are pleased that there have been no reports of patient injury and we have now shipped replacement pumps to over 90% of the affected accounts. The recall negatively affected our revenue in Q4 and we expect this to continue in Q1. The lack of saline infusion pumps has disrupted our new account pipeline, caused a temporary slowdown in coronary case volumes, and diverted valuable selling time as our sales reps are focused on inventory management and paperwork associated with the return of affected pumps.

Although the sales organization continues to work with our customers to ensure that all affected pumps are properly documented and returned, we are pleased with the progress made to-date as we expect to meet or beat our target date of August 31st for completion of all recall-related activities. We have addressed this recall with the same focus and tenacity that has defined our company during the past 12 to 18 months. Although we will endure some temporary disruption in sales, addressing EMI issues will improve our quality and enhance our customer relationships in the long run.

Larry will now provide a detailed discussion of our fourth quarter financial results, and then I will return to share some thoughts on our growth plans for fiscal 2018 and beyond. Larry?

## Laurence L. Betterley

*Chief Financial Officer, Cardiovascular Systems, Inc.*

Thank you, Scott. And good afternoon, everyone. Fourth quarter revenue of $52.9 million was 9% above last year and above our guidance range. We sold over 16,000 devices during the quarter, generating 92% of revenues. Coronary revenue increased 15% to $13.2 million, and peripheral revenue increased 7% to $39.8 million. Below-the-knee product mix comprised about 60% of peripheral revenue, growing at a double-digit rate from the fourth rate last year. Reorder revenues were over 98% of total revenue.

As we discussed on our last call, existing customers were prioritized for shipment of the new replacement pumps during the quarter. As a result, no new pumps were available for new customer evaluation. We did, however, convert 43 accounts that were already evaluating the peripheral product into new customers. In addition, 39 new coronary accounts were added, primarily through adoption of the coronary product by peripheral customers using their existing pumps. This new account revenue partially offset the decline in device usage by some existing customers as a result of the pump recall.

The conversion of evaluation units and inability to ship pumps for evaluation resulted in a decline of our new customer pipeline at the end of the quarter. This may impact the number of new customers and the related follow-on device usage in the first quarter. This has been factored into our revenue guidance.

Gross profit margin was 81.7% in the quarter compared to 79.7% last year, driven by significant unit cost reductions. Operating expenses of $42.2 million declined $1.3 million due to cost realignments implemented last year. Operating expenses were lower than guidance due to the timing of clinical study and product development expenses. Fourth quarter net income of $772,000 or $0.02 per share and adjusted EBITDA of $4.1 million both improved over $5 million compared to last year. At quarter end, our cash balance was nearly $108 million, a $47 million improvement from 12 months ago. Cash flow was positive in the quarter with $3 million generated from operations and $2 million from employee stock plans.

I'll now discuss our financial outlook. While much of the recall is behind us, available selling time will continue to be affected during the first quarter as we fully complete the process. In addition, as stated earlier, new account revenue may be limited. These effects, combined with the usual slowdown of procedures in the summer months, have been factored into our guidance.

For the first quarter of fiscal 2018, we expect revenues in a range of $52.6 million to $53.6 million, representing year-over-year growth of 6% to 8%; gross margin of about 81%; operating expenses of $45 million, reflecting a more normalized recurring level of expenses and additional costs for beginning of the year sales meetings and training; other expense of about 300,000, including implied interest from our sale leaseback transaction of $417,000; and net loss in the range of $2.2 million to $2.8 million. This equates to a loss per share of $0.07 to $0.09 based on approximately $32.9 million average shares outstanding. Also, adjusted EBITDA is expected to remain positive in the firth quarter. Revenue for the full fiscal year of 2018 is expected to be in the range of $226 million to $233 million with a growth rate over fiscal 2017 improving quarterly as the year progresses.

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

## Scott R. Ward

*Chairman, President & Chief Executive Officer, Cardiovascular Systems, Inc.*

Thank you, Larry. Well, as I am sure you've all noted, CSI is providing annual guidance for the first time. This is significant in many ways, so let me highlight two observations that I think are critically important. First, our ability to provide annual guidance reflects our growing confidence in the stability and predictability of our business model, and our performance over the past year demonstrates that we can execute a plan. Second, we are confident that as the influence of the recall subsides, we will deliver double digit growth for the full year.

We expect that revenue growth in fiscal year 2018 will be advanced by increased sales productivity, enhanced market development, product line extensions in orbital artherectomy, the launch of our coronary franchise in Japan, and continued progress in generating medical evidence to support the use of orbital artherectomy and further extend our competitive advantage.

We have achieved substantial improvements in sales productivity over the past six quarters. Today, quota bearing reps generate over $1 million per year, selling only our orbital artherectomy systems. During FY 2018, we will continue to focus on building strong customer relationships based upon superior medical education, practical clinical acumen, and increased case coverage. We intend to increase the number of clinical specialists in areas with high volume coronary and peripheral accounts. And although the vast majority of our quarter bearing sales reps will continue selling both franchises, we will also continue to support high potential accounts with specialized sales reps dedicated to either coronary or peripheral procedures.

In coronary, we will leverage our unique mechanism of action and superior medical evidence to drive adoption of orbital artherectomy for the treatment of complex calcified lesions. And in peripheral, we plan to focus on amputation prevention programs that will accelerate patient access to safe and effective care. In addition, today we announced FDA clearance for the Diamondback 360 radial access orbital artherectomy device to treat peripheral artery disease. Radial access allows physicians to reach and treat lower limb PAD lesions through the radial artery in the wrist, providing an alternative access point and more options to treat a complicated and at-risk patient population.

The radial market for percutaneous coronary interventions has developed rapidly in the United States. For patients with acute coronary syndromes, radial access has been shown to reduce mortality 27% compared to conventional femoral access. As a result, use of the radial access site for PCI procedures has grown from less than 2% of cases in 2007 to about 30% of cases today. We anticipate similar adoption in above-the-knee peripheral vascular interventions as physicians continue to drive towards reduced invasiveness, increased efficiency and better outcomes for patients.

We believe that Diamondback's low profile and unique orbital mechanism of action provides CSI with a significant competitive advantage. We plan to exploit our first-mover position and further distinguish Diamondback from our competition in the above-the-knee market segment. We plan to launch our radial device in the second half of fiscal 2018 when other products necessary to support peripheral radial access become available in the market. We also plan to launch our coronary franchise in Japan in the second half of fiscal 2018.

As you recall, we previously announced the Shonin approval for our Coronary Micro Crown Orbital Atherectomy System in Japan. With over 280,000 PCI procedures per year, Japan represents the second largest market for coronary interventions, and an attractive market for our first commercial venture outside the United States. We plan to submit our reimbursement dossier this summer and expect to receive greater insight regarding payment

and coverage later this year. We will provide more details regarding our opportunity in Japan after we receive reimbursement.

CSI is the market leader in both peripheral and coronary artherectomy because we have the best interventional solution for the treatment of calcific disease and we have the strongest medical evidence in the market. As you know, we are focused on amputation prevention for patients with peripheral artery disease, and specifically patients with critical limb ischemia. In February, we shared encouraging six-month data from the LIBERTY 360 study at the International Symposium on Endovascular Therapy.

Next Thursday at the Amputation Prevention Symposium in Chicago, Dr. Mustapha will present the one year data from LIBERTY 360, and for the first time, a sub analysis of one year outcomes for patients who received orbital artherectomy as part of their treatment regimen. We will issue a press release highlighting the one year data following the completion of Dr. Mustapha's presentation next week.

Finally, we will continue our steady march towards consistent profitability in FY 2018, and we intend to be profitable for the full year. Due to the cadence of our business, we will incur higher operating expenses in Q1 triggered by annul events like our national sales meeting. However, through disciplined expense management, focusing resource allocation on higher return initiatives, improvements in sales productivity and the execution of projects to reduce our cost of goods sold, we do expect to achieve continuous improvement in profitability throughout the year.

So in summary, our performance in FY 2017 provides compelling evidence that CSI can execute a plan and deliver consistent financial performance. We exit the year as a strong financially stable company, and we have developed very specific plans to continue our momentum driving double-digit profitable growth in fiscal 2018.

We have a robust core business, and as I have said before, our greatest asset is our people. We have the pre-eminent sales force in the market and we are well positioned to leverage the capabilities and capacity of this organization to introduce new products that will enhance our revenue per procedure and improve the quality of care for patients with coronary and peripheral artery disease. Over the past 18 months, we have built a solid foundation for growth and we look to the future with confidence and are focused on our mission to save limbs and save lives every day.

In closing, we certainly appreciate your continued support and interest in CSI. Larry and I will now take your questions. So Ruth, please repeat the instructions for the Q&A period now. Thank you.

# QUESTION AND ANSWER SECTION

**Operator:** [Operator Instructions] Your first question comes from the line of Danielle Antalffy with Leerink. Please go ahead.

Danielle J. Antalffy
*Analyst, Leerink Partners LLC*

Q

Hey, guys. Good afternoon and congrats on another good quarter. Scott, first a high level question for you and then I just had a follow up on the recall more specifically. So now with the recall almost completely behind us, it seems like sales force productivity is tracking very well and you're starting to generate positive cash flow, what are your thoughts on broadening the portfolio? And as you think about potential areas where CSI could leverage existing capabilities, what are the types of potential acquisitions that a company like CSI could benefit from?

Scott R. Ward
*Chairman, President & Chief Executive Officer, Cardiovascular Systems, Inc.*

A

Well, Danielle, thanks for the points on the improvement in sales productivity. I think that that definitely is the case. And as I pointed out in my prepared remarks, we have a very robust core business now. We have really emerged coming out of our fiscal year 2017 as a very stable company. We have a strong cash position and we have obviously a very unique place in the treatment of coronary and peripheral artery disease. Our sales reps work shoulder-to-shoulder with our customers in performing procedures. And as I have said before, it's our intent to leverage those relationships and continue to bring – to, let's say, have products that will help us pull through more revenue through each of those procedures.

The other point is we have an incredibly strong organization. I mean, the competency and capacity of this team is incredible. I think we have approached this turnaround, if you will, that we've implemented over the course of the past 18 months with a great sense of tenacity and focus, and we've delivered. So I think we're in a good place now and we will start to look to the future to add new products that will enhance our revenue per procedure and where we can really make a contribution to improving the quality of care.

I can't really -- I don't want to talk about M&A and we won't comment on that, but I can tell you that, really, as we think about diversification, really, most of what we're going to be doing is organic. I mean, we're really focused on organic opportunities. We have a great R&D team here, we've got a great clinical team and that's where our focus resides.

Danielle J. Antalffy
*Analyst, Leerink Partners LLC*

Q

Okay. That's very helpful. Thank you for that. And then just a follow-up on the recall. Can you talk about any potential brand hit that you guys took during the recall, or do you feel like because you guys managed it so efficiently you've avoided any sort of potential long term issues from a brand perspective and reliability perspective? Thanks so much.

Scott R. Ward
*Chairman, President & Chief Executive Officer, Cardiovascular Systems, Inc.*

A

Yeah. Thanks, Danielle. Actually, I think we come out of this with a stronger brand. Our customers recognize that we are dedicated and committed to providing the highest quality of products, services and relationships. Our sales

reps were right on top of this. They communicated with their customers very effectively. We did have some coronary accounts that reduced their case volumes. We are seeing a return of that. Actually, we don't think we lost any customers through this experience. And as is so often the case, you come out of a recall stronger than you went in, and that is the case for CSI.

Improving the performance of our pumps, reducing that nuisance that can occur during a procedure, improving the EMI compatibility of this product substantially improves the quality of our customers' experience as they use our products. So I think we emerge from this stronger and actually not only with our brand intact, but perhaps as a stronger brand.

Danielle J. Antalffy
*Analyst, Leerink Partners LLC*

Q

That's so helpful. Thanks, Scott.

Scott R. Ward
*Chairman, President & Chief Executive Officer, Cardiovascular Systems, Inc.*

A

Yeah. Thanks, Danielle.

**Operator:** [Operator Instructions] Your next question comes from Brooks O'Neil with Lake Street Capital. Please go ahead.

Brooks O'Neil
*Analyst, Lake Street Capital Markets LLC*

Q

So good afternoon. Congratulations on the terrific finish to the year. I was hoping, Scott, you might talk a little bit, understand that number of new accounts was down in 4Q and will be down in 1Q due to the recall activities. I'm curious if you saw any benefit from increased focus on your existing accounts as I've always sensed you felt there was incremental opportunity from your higher volume accounts?

Scott R. Ward
*Chairman, President & Chief Executive Officer, Cardiovascular Systems, Inc.*

A

Yeah. Hi. First, thanks for the note on the strong finish to Q4. We appreciate that Brooks. I do think that we saw some improvement in same-store sales in our peripheral business. I think you can see that we grew 3% quarter-over-quarter. That does obviously reflect, really, above market growth. So we do see some improvement or we certainly experienced some improvement in the performance of our peripheral business, and then that was largely due to increased case coverage and the presence of our sales reps in the cath labs.

Brooks O'Neil
*Analyst, Lake Street Capital Markets LLC*

Q

Secondly, I recall, I don't know, a year or two ago when drug-coated balloons were first introduced to the marketplace. There was some disruption out there as doctors experimented with their use. I'm curious with recent product approvals, do you see continued disruption or is the market settled down somewhat? Do you expect to see any impact from recently approved new products, either DCBs or stents that might have an impact on your business?

Scott R. Ward
*Chairman, President & Chief Executive Officer, Cardiovascular Systems, Inc.*

A

No, we don't see any negative effects, Brooks. I think the introduction of drug-coated balloons a few years ago had an effect on our business because it was introduction of an entirely new technology, and we saw some physicians begin changing their practice, trialing the use of these devices in a wider variety of patients. Now we have seen the standard of care kind of return to a more normal process. And if anything, the increased attention that drug coated balloons now bring to the market increases patient referrals, it moves more patients into cath labs.

As that happens, naturally, we get our percentage of those patients that have these severally calcified lesions. And quite honestly, the more awareness, the more patients that are referred for treatment, the better for our business, and truly the better for everybody involved. We can significantly reduce amputations when given the opportunity to intervene at the right time for these patients. So the introduction of drug coated balloons increased competition in that market space I think will only drive more patients to intervention and be a benefit to us.

Brooks O'Neil
*Analyst, Lake Street Capital Markets LLC*

Q

Yes, great. And then the last question I had was I appreciate your comments about radial access. I'm excited to see how you do there. Curious if you expect incremental use of your products because doctors are using radial, or do you think it's going to be more a switch from femoral access to radial access by individual physicians?

Scott R. Ward
*Chairman, President & Chief Executive Officer, Cardiovascular Systems, Inc.*

A

Since we're the first mover here, we're the first ones to offer a radial access artherectomy device, we will see some cannibalization of our business. We'll see some of our femoral business switch over to radial. The interesting thing about radial that we have seen in coronary PCI is when a cath lab commits to the radial access procedure, they commit fully because their business practice changes, their clinical practice changes, their patient management work flow changes quite substantially, and as a result, they become a radial cath lab.

So where we have the opportunity to expand our business is to go to those coronary radial cath labs and access the physicians in those sites of service who are right now providing, let's say, coronary interventions via the radial access point. So we have the opportunity to really expand our business in that segment. I think initially we'll see – mostly we'll see transference of thermal accounts to radial accounts, but over time having the opportunity to support these radial accounts will really create sticky market share.

Brooks O'Neil
*Analyst, Lake Street Capital Markets LLC*

Q

Great. Thank you very much. And again, congratulations.

Scott R. Ward
*Chairman, President & Chief Executive Officer, Cardiovascular Systems, Inc.*

A

Okay. Thanks.

**Operator**: As there are no further questions at this time, I turn the call over to Scott Ward.

Scott R. Ward
*Chairman, President & Chief Executive Officer, Cardiovascular Systems, Inc.*

Okay, great. Thanks Ruth. Well, thank you, everyone. Thank you for your interest in CSI. And actually, we look forward to updating you on our progress in October. So this concludes our conference call. Have a great evening.

**Operator**: This concludes today's conference call. You may now disconnect.