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Cardiovascular Systems, Inc.

Fiscal 2017 Third Quarter Conference Call

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PRESENTATION

Operator:

Good afternoon. My name is Cheryl. I will be the conference Operator today. At this time, I would like to welcome everyone to the Q3 2017 Cardiovascular Systems Inc. Earning 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. If you would like to ask a question during this time, simply press star, then 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, Cheryl. Good afternoon, and welcome to our Fiscal 2017 Third 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 Ward:

Thank you, Jack. Good afternoon, everyone, and thank you for joining us today.

Our third quarter was characterized by strong growth, disciplined execution of our key financial objectives, and the achievement of several key milestones that position our business for long term success and strengthen our foundation for the future. Over the past 15 months we have set the business on a course for sustainable growth and profitability. I am encouraged by the consistency of our commercial execution and the steady improvement in the productivity of our sales organization.

In third quarter, CSI reported $52.1 million of revenue, a 17% increase compared to last year. We are very pleased that we achieved attractive year-over-year growth and sequential quarterly growth in both our coronary and peripheral franchises. We are the market leaders in coronary and peripheral atherectomy, and we gained additional market share in Q3. Our field sales organization is focused solely on coronary and peripheral atherectomy, and we strive to maximize total revenue while delivering predictable, sustainable growth in both franchises. Strong growth, combined with disciplined expense management and efficiency improvements across the organization, continue to propel our progress toward sustainable profitability.

Net loss for the quarter was $1.7 million, an improvement of $21 million compared to last year. Excluding one-time charges, we would have delivered our second consecutive quarter of profitability with approximately $1 million in net income in Q3. Of course, Adjusted EBITDA was positive once again in Q3 and we delivered positive cash flow from operations. So, our Company is financially stable and healthy.

In addition to strong financial performance, we also achieved several important milestones during the quarter. Our Diamondback 360 coronary micro-crown orbital atherectomy system was approved for the treatment of severely calcified coronary artery lesions by the Ministry of Health, Labor and Welfare in Japan and by the FDA in the United States. The six-month data from the Liberty 360 trial were presented at the International Symposium on Endovascular Therapy. In coronary, the first patient was enrolled in our Eclipse clinical trial by Dr. Richard Schlofmitz at Saint Francis Hospital in Roslyn, New York. We further strengthened our balance sheet with the completion of the sale and leaseback of our corporate headquarters, generating approximately $21 million.

Finally, there were two important developments in the litigation of two legal cases. First, the court granted our motion to dismiss the stockholder class action securities lawsuit. Plaintiffs can still amend their filing, but we are pleased with the progress in this case. Second, on April 25, a California jury decided against CSI in an employment case related to the termination of an employee that occurred nearly two years ago. We respectfully disagree with this decision, and we intend to vigorously challenge this outcome through all available legal means.

I will address some of these events in greater detail after Larry's comments on the financial results, but before I turn the call over to Larry I want to address our recent announcement regarding the voluntary recall of certain saline infusion pumps manufactured between April of 2015 and April of 2017.

The recall addresses approximately 50% of the pumps currently in use in cath labs around the U.S. The saline infusion pumps provide saline and lubricant infusion during orbital atherectomy procedures and electrical power to the orbital atherectomy device. We determined that electromagnetic interference, present in the hospital environment may cause the pumps to switch to standby mode during use, requiring the pump to be reset prior to continuing treatment. Restoring pump operation can result in a temporary delay in the orbital atherectomy procedure. In coronary artery procedures, this delay of therapy could present an additional risk of a temporary, medically reversible injury. However, there have been no reports of patient injury to-date, and complaints, as a percentage of procedures performed, have been less than 1%. Importantly, we have informed customers that they may continue to use the affected pumps until they receive a replacement device.

A PMA supplement addressing design changes to improve the EMI compatibility of the saline infusion pump is currently under real-time review at the FDA. We plan to replace all of the affected pumps by the end of August or sooner, subject to the timing of FDA approval and the prompt production of the replacement pumps.

Our guidance for fourth quarter reflects the disruption that may occur as a result of the pump recall. Since cath labs can continue to use their current pumps, we do not expect a serious disruption. However, the management of the recall in the market will distract our sales reps, and we will not enroll new accounts until pump replacements are complete and supply is restored. We do anticipate that any disruption caused by the recall will be at least partially offset by increased focus on case coverage in our current accounts.

This field action underscores our commitment to ensure that we provide our customers with the highest quality products and services. Although we will endure some temporary disruption, addressing these EMI issues will improve our quality and make us stronger in the long run. We are well positioned to manage this challenge, and our organization is focused on the rapid and effective resolution of this recall.

I will provide additional thoughts regarding clinical developments and product approvals following Larry's financial commentary. Larry?

Laurence Betterley:

Thank you, Scott, and good afternoon, everyone.

Third quarter revenue of $52.1 million was 17% above last year, and above the upper end of our guidance range. We sold nearly 15,700 devices during the quarter, generating 92% of revenues.

Coronary revenue increased 28% to $13.5 million, and peripheral revenue increased 14% to $38.7 million. Below-the-knee product mix was about 60% of peripheral revenue. Our estimated below-the-knee revenue increased 15% over prior year, with above-the-knee revenue growing about 12%. Reorder revenues remained high at 98% of total revenue.

We added 37 new peripheral accounts and 35 coronary accounts during the quarter.

Gross profit margin was 78.6%, compared to 80.4% last year. This quarter's gross profit includes a $1.5 million charge related to the recall and replacement of one model of our saline infusion pump, affecting about 900 units at customer sites. The charge reduced gross margin by about 2.9 percentage points and offset reductions achieved in unit costs.

Operating expenses of $42.8 million declined $15.7 million from last year. This quarter includes a $1.3 million net charge for potential loss from an employee lawsuit disclosed last week, while the year-ago period included $12.4 million of severance and litigation costs. The remaining operating expenses

declined $4.6 million or 10%, as a result of our previous cost realignment initiatives and timing of studies and programs.

Third quarter net loss of $1.7 million or $0.05 per share improved $21 million or $0.64 per share compared to third quarter of last year. As we've discussed, this quarter's loss was affected by $2.8 million of one-time charges for the recall and employee lawsuit.

Adjusted EBITDA was positive at $1.7 million, compared to a loss of $18.6 million last year.

At quarter-end, our cash balance was $103 million, a $24 million improvement since December 31. The increase in cash was the result of two primary factors. First, in March we completed the sale-leaseback of our corporate headquarters. Proceeds from this transaction were approximately $21 million. Second, positive cash flow from operations reached $2.7 million. The sale-leaseback is accounted for as a financing transaction, where the building asset remains on our balance sheet at fair market value and we continue to recognize depreciation expense at a level similar to before the transaction. A financing obligation has been recorded for the net proceeds received. Finally, in March we entered into a $40 million senior secured revolving credit facility with Silicon Valley Bank, further strengthening our financial position. We have not drawn any funds from this facility and have no immediate plans to do so. 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. As a result of the recall, we expect to have limited pump availability to open new accounts, and a portion of sales time will be required to facilitate the recall process. In addition, some customers may reduce usage until their pumps can be replaced. Fourth quarter revenue is expected to be affected as a result. For the fourth quarter of fiscal 2017, we currently anticipate revenues in a range of $51.5 million to $52.5 million, representing year-over-year growth of 6% to 8%; gross margin of about 81%; operating expenses at a more normalized level of about $43.5 million; other expense of about $400,000, including implied interest from our sale-leaseback transaction of $417,000; and a net loss in the range of $2 million to $1.4 million. This equates to a loss per share of $0.06 to $0.04, based on approximately 32.7 million average shares outstanding.

Also, Adjusted EBITDA is expected to remain positive in the fourth quarter.

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

Scott Ward:

Thanks, Larry.

As I described earlier, the guidance that Larry has shared for the fourth quarter does reflect the temporary disruption that may occur as a result of the saline infusion pump recall. Despite this temporary disruption, our Company is healthy and stable.

We continue to have strong demand for orbital atherectomy and peripheral and coronary applications. This demand and our market leadership in atherectomy is driven by three key success factors. First, we have the best interventional solution for the treatment of calcific disease in the vasculature. Second, we have a large and focused sales force that provides our customers with exceptional service and clinical support. Finally, we have the strongest medical evidence in the market.

As we have described in the past, we will continue to invest in medical evidence to support the use of orbital atherectomy and to further extend our competitive advantage. Two great examples of this strategy are the Liberty 360 trial in the peripheral and the Eclipse clinical trial in coronary.

As you all know, we are focused on amputation prevention for patients with peripheral artery disease and, specifically, critical limb ischemia. It may seem quite obvious, but the most important clinical outcome metric for these patients is amputation-free survival. The six-month data from the Liberty 360 trial was presented at the International Symposium on Endovascular Therapy in February. The results demonstrate the benefits of endovascular intervention across all Rutherford classes. But the most striking result is that the amputation-free survival rate for the Rutherford 6 patients was 73.7% at six months. Recall that the Rutherford 6 patients have critical limb ischemia and may be considered candidates for immediate amputation. So, this is an extraordinary outcome and demonstrates the importance of medical examination and the consideration of revascularization options prior to amputation for patients with CLI.

We are also gratified that the AHA and ACC issued updated guidelines in February for the management of patients with peripheral artery disease. The amended guidelines support revascularization as a reasonable treatment option for claudicants and patients with critical limb ischemia. We estimate that there are 2.6 million claudicant and CLI patients receiving treatment in the United States annually. Of these, 600,000 patients have severely calcified lesions and are candidates for orbital atherectomy. Clearly this is a large and underpenetrated market where CSI can make a real contribution to improving the quality of care.

Of course, the same is true in coronary artery disease where severely calcified lesions present a difficult challenge for interventional cardiologists. We estimate that there are approximately 180,000 patients with severely calcified coronary artery lesions receiving treatment annually in the U.S.

As I stated earlier, the Eclipse clinical trial is now actively enrolling patients. We expect that this trial will set a new standard for medical evidence in the coronary atherectomy market. Eclipse is the largest randomized controlled trial to assess the use of adjunctive coronary atherectomy for calcific coronary artery disease, and we believe the primary endpoints in this trial will demonstrate the benefits of orbital atherectomy versus conventional angioplasty treatment. Although difficult to predict in these early days, we expect to fully enroll the trial in approximately two years.

Third quarter also marked the near-simultaneous approvals of our new micro crown device in Japan and the U.S. The approval in Japan is an important first step towards our commercial launch in this market. In conjunction with Medikit, our exclusive distributor partner in Japan, we are preparing to introduce our orbital atherectomy technology for the treatment of calcified coronary artery disease. With over 280,000 procedures per year, Japan represents the second largest market for coronary interventions. Approximately 10% to 20% of these patients have severely calcified lesions. Japanese physicians embrace vessel preparation and minimally invasive therapies, and they are also avid users of visualization tools to identify calcium, such as IVUS and OCT.

This summer, we plan to submit our application for reimbursement approval in Japan, and anticipate approval by calendar year-end. We continue to plan for a controlled commercial rollout in Japan, beginning in the first half of calendar 2018. At this time, it's reasonable to anticipate meaningful revenue from our Japan operations will begin in fiscal year 2019.

So, in summary, CSI is financially stable and healthy. Strong growth and disciplined expense management has accelerated progress towards sustainable profitability. We are executing well on the key initiatives required to assure the long-term success of our business, and we are well prepared to manage our near-term challenges. Certainly, we will make every effort to minimize the disruption caused by the saline infusion pump recall and we are committed to replacing the affected pumps as quickly as possible.

As I consider the holistic state of our business, I'm encouraged that we are making strong progress in achieving our goals to build a strong, resilient organization, capable of delivering sustainable, profitable growth and an attractive Shareholder return.

Thank you for your continued interest in CSI.

Larry and I will now take your questions, so Cheryl, if you would please repeat the instructions for the Q&A period now.

Operator:

At this time, I would like to remind everyone, in order to ask a question, press star then the number one on your telephone keypad.

Your first question comes from Brooks O'Neil of Lake Street Capital. Your line is open.

Brooks O'Neil:

Good afternoon. Congratulations on the progress you're making in all parts of your business.

So, I have a few questions. I'm hoping you might be willing to share with us a little bit about your estimate of the effect of the recall or, said differently, how much you've reduced your guidance for Q4, related specifically to whatever assumptions you made about the impact of the recall.

Scott Ward:

Brooks, we really can't do that. I guess we don't really approach it in that context. We do more of an organic buildup of our projections. I think, as we've described on past calls, we do leverage our sales organization quite directly in developing those assumptions. So, it—we don't really arrive at a number and back off to it, instead we build up to a number.

Brooks O'Neil:

Okay. Second question, I'm curious. It looked like the number of new customers this quarter was somewhat moderated. I know you're sort of thinking that new customer growth might be slow in Q4, but can you just give us a sense for whether the new customer growth was consistent with your strategy and expectations, or whether there was anything going on there that might be worth talking about?

Laurence Betterley:

Sure, Brooks. This is Larry. We've always said somewhere around 40 accounts or so is our target in a quarter, and it's going to vary. I think in the last couple of quarters, particularly in coronary, we've had very strong new account demand, so it will go up and down. Our focus has always been to focus more on our existing accounts and drive adoption. So, there wasn't anything really unusual about the quarter other than it does tend to fluctuate.

Brooks O'Neil:

Sure. Last question, I'm just curious if you would be willing to give us your sort of sense of the competitive environment in each of your three key segments as you see it today, just help us to kind of have an overview of what's going on below-the-knee, above-the-knee and then in the coronary side.

Scott Ward:

Sure. Let's start with coronary, then. In coronary, we believe we're number one in revenue market share in coronary. Our principal competitor there is Boston Scientific with their Rotablator device. We continue to have very strong demand for orbital atherectomy, largely due to the fact that we have very strong medical evidence and a very strong safety and efficacy profile for our device. Our device is easy to use, it's easy to set up, and for patients that have very severely calcified lesions, we provide a very important form of care for what is otherwise an unmet medical need. So, we have a very strong competitive position in the coronary space.

In peripheral, peripheral is bit more of a fragmented market, there are more competitors in that space. In the broader atherectomy marketplace, we are the only company that has medical evidence to support the use of their product in the treatment of calcified lesions, and that is where we focus. So, we don't focus as much time on soft plaque or thrombus or other patients, we focus on the calcified lesions. In that area, obviously, we do extremely well because we have a very unique technology and it's only product that's available. So, in the peripheral segment, we are number one in the peripheral segment. We do compete there against some very formidable players, including Medtronic and others. We compete with these organizations really based upon our focus. We only do atherectomy for calcified lesions. This is what we do and we do it better than anybody.

So, that is really the essence of our competitive advantage. We have the best core technology in the market, we have the best sales force, and frankly, we just have the best medical evidence for physicians. So, that is a quick overview of the competitive environment, and I'll see if you have any other questions from there.

Brooks O'Neil:

No, that's great, Scott. I really appreciate that. I'm just curious how you feel you stack up next to what I think might be called a scoring balloon in terms of removing calcium in the peripheral arteries.

Scott Ward:

Well, I think in that context, as we look at the calcified lesions that we focus on, we've never—there's never been a head-to-head trial performed, but we feel very comfortable with the use of our device for that patient population. Scoring balloons have their place, and I think physicians oftentimes use them in conjunction with other treatments, but for calcified lesions in our patient population, really orbital atherectomy is the best solution.

Brooks O'Neil:

That's great. That's very helpful and thank you very much for taking my questions.

Operator:

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

Brad Mas:

Hey, guys, it's Brad in for Bob, can you hear me okay?

Scott Ward:

Hey, Brad. Yes, we can. Thanks.

Laurence Betterley:

Yes, we can.

Brad Mas:

Just one clarifying one quick, Larry or Scott, on the units, I think you said 15,700, did you give a number that were coronary?

Laurence Betterley:

Coronary units were about 3,400.

Brad Mas:

Okay, thanks; and then, so first off, Scott, just curious if you could talk a little bit about the U.S. market in both peripheral and coronary for a minute. Besides growth has kind of normalized a bit and will start to round past some easy comps in peripheral next fiscal year. So, I was just curious if you could talk a little bit about how do you view the growth over the next year or few years, and these two businesses after we lap some of these easier comps.

Scott Ward:

Well, I think our business has continued to grow quite nicely over the course of the past five quarters. As we look at the peripheral marketplace in particular, we—there is obviously some very strong underlying populations there that just continue to grow; we continue to see an increased rate of diabetes, an increased rate of obesity, the impact of smoking, all of these factors contribute to a PAD marketplace that we anticipate will continue to grow at least in the high single digits. So. we benefit from a very strong underlying growth rate in our market.

We do expect that that trend will continue, and even some might say that it may even accelerate, unfortunately, in the near term. So, we think our underlying market will continue to do well. We look at the—as I just described, the competitive environment, we think we're very uniquely positioned, that the focus of our technology on the treatment of calcium gives us a very unique place in that marketplace in order to collaborate with physicians to develop those deep relationships. As our sales reps continue to develop stronger and stronger clinical acumen across both coronary and peripheral, we think we're very well positioned to grow at or above the market rate in peripheral.

In coronary, we—as I described earlier, we have really one competitor there, there is no other competitor that's filed an IDE at this time. This is a PMA marketplace. So, we do not anticipate additional competition coming into that market. We have launched our Eclipse clinical trial. So, before any competition comes in, we will have already extended the—our competitive advantage in medical evidence, and we believe that we already have the strongest medical evidence in the market. So, over a longer period of time, I think leveraging the Eclipse clinical trial, we'll be in a very good place to continue to educate physicians, to work with interventional cardiologists to increasingly adopt our technology for vessel preparation and access, and I think we'll continue to deliver better and better outcomes for patients, and that will drive our continued growth in coronary.

Hope that answers your questions?

Brad Mas:

Yes, Scott, that was super helpful, thank you.

Just on the recall quickly. Can you just talk about the dynamic of opening accounts? I think most of these systems are placed, so currently you don't have a pump to offer, I believe. Can you just talk about the timing and requirement to getting a new pump approved, and maybe a little bit about what happened since the recall and what you're hearing from customers, if they're continuing to use the pump or not?

Scott Ward:

Sure. So, as you just pointed out, the most important observation is that we, in our notification to customers, advised them that they can continue to use the pumps that they currently have. So, customers have continued to do that. We have had very few, if any, customers come back and indicate that they would discontinue performing procedures.

It's important to note that this is an event that is related to EMI. So, there is—there are troubleshooting procedures that can be undertaken in the cath lab to manage this when it happens. It also is an event that has been occurring at a relatively low rate over time. We, in collaboration with the FDA, just decided to get out and get it fixed. That's what we're doing.

So, there isn't a sudden event or there isn't some sudden uptick or something that's occurred that's caused this to happen. It's just become time for us to solidify our base, to solidify our foundation, and to just get out and get this fixed. It does demonstrate our commitment to quality, and after we get this done we're going to be much stronger.

So, that's really how we look at it. As we think about new accounts, our—we're going to prioritize our coronary accounts and our peripheral accounts that we currently have and make sure that all of those accounts get these updated pumps that have improved EMI compatibility. We'll get—we're going to making sure they get taken care of first, and then after that's done and we have full supply, we'll begin rolling out replacement pumps—or we'll begin rolling out pumps to new accounts. Hard to estimate specifically when that will happen, but as we've said publicly, we're going to try to get it all done by the end of August or sooner.

Brad Mas:

Okay, and then, just one last one. I assume there is no effect on fiscal Q3 results or account adds, and then, the disruption that you are assuming in guidance, is that just from the lack of being able to add new accounts, or are you assuming some impact on current docs using—potentially using the Diamondback less?

Scott Ward:

No, I think as I said in our remarks, there's probably three factors to consider here. A reduction in new accounts, or a significant reduction in new accounts in this quarter. We also anticipate that, due to the disruption here of just having our sales reps taking away selling time to manage the recall, to get in and educate their customers and spend time with their customers on this topic, it'll take some selling time away so there'll be some disruption there. But that's offset by the fact that our sales reps will also be now focusing on current accounts and spending a lot more time in case coverage. As you've heard us say many times before, case coverage is a critical determining factor that helps us increase utilization and increase our devices per account.

So, while the first two items I described are probably matters that will have a disruptive effect on our fourth quarter, the other item is an offset, and we'll see where this winds up. But there is a silver lining there, in the sense that our sales reps are going to be more focused on their current accounts during the course of this quarter.

What was your—I'm not sure what your first question was.

Brad Mas:

Just on any effect in Q3 on results or account adds.

Scott Ward:

Oh. Yes. Thank you. So, there was no affect in Q3.

Brad Mas:

Okay, great. Thanks for taking my question, Scott.

Scott Ward:

Yes, thank you.

Operator:

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

Danielle Antalffy:

Hey, guys. Thanks so much for taking the question. Congrats on a solid quarter there.

Scott or Larry, the above-the-knee growth at double digits, I think you said, Larry, 12%, that seems notable to me. I guess I just wanted to get a little color from you guys on how much of that is sort of making up easy comps, as it is sort of sustainable, call it, share gain? I would imagine that's pretty significantly above market growth. So, I just want to make sure I understand where that's coming from; and then I have one follow-up.

Scott Ward:

I'll let Larry address this in just a moment, Danielle, but I really don't think this is related to, as you call it, easy comps. I think we—we've been saying for a number of quarters that we're seeing kind of a restoration of a new normal in terms of the standard of care of patients. That above-the-knee segment now, there is an emerging course of care that some physicians refer to as "sand and paint", where they go in and remove the calcium using orbital atherectomy, and they respond after that with a drug-coated balloon, with the purpose being to assure that they leave nothing behind, that they can go in, they don't—they are careful not to create any dissections, there's no need to place a stent, and they can go in and basically remove the calcium, hit it with a DCB, and get out. I think, from just a therapeutic modality perspective, there's good logic for why that makes sense and why we're seeing that happen. So, that is an underlying trend that kind of buoys our performance in the marketplace, and I think that that is driving real market share gains.

Danielle Antalffy:

Okay.

Scott Ward:

Regarding the growth, Danielle, we did see sequentially, we're seeing pretty solid growth. We saw it both in peripheral and coronary, so. Yes, last year this time, our peripheral revenue was down, but we've made substantial growth and a 14% gain year-over-year, but also 4% gain sequentially, so we feel we are back on track.

Danielle Antalffy:

Okay, great, that's helpful; and then, just, my follow-up is at a higher level. Scott, we've talked in the past about sort of striking that right balance for your sales reps between focusing on the peripheral business versus the coronary, there's a bit more pool in the coronary, it's a little bit more of a rep-intensive procedure. So, I wonder if you feel—this seems like a pretty well-balanced quarter for you guys. I mean, I know one data point doesn't make a trend necessarily, but where do you feel you guys are falling out on getting—striking the right balance there between dedicating sales force efforts between peripheral and coronary? Thanks so much.

Scott Ward:

So, Danielle, thanks for that question. I think in some ways this quarter is too well balanced. We—this is not an exact science for us. We just—we can't get this perfectly nailed. I continue to say that I measure this business on our ability to generate revenue in total, and we strive to assure that we are capturing opportunities in both coronary and peripheral, but our sales organization really goes after the opportunity where it exists. We do try to balance that, we try to balance it by assuring that they are undertaking various initiatives that cause them to spend time in both coronary and peripheral; but I hesitate to say that this is a trend. I think we will continue to do the best we can to achieve a balance, but I just want to be clear, my primary goal is driving total revenue, and profitable total revenue.

Danielle Antalffy:

All right. Thank you.

Scott Ward:

Anyway. Yes. Sorry …

Danielle Antalffy:

Yes, that's helpful.

Scott Ward:

I know everyone would like to see it balance, but it just—it may not happen in nature, although it did this quarter.

Danielle Antalffy:

All right. Thanks, Scott.

Scott Ward:

Thank you.

Operator:

Your next question comes from Ethan Potasnick of Needham & Company. Your line is open.

Ethan Potasnick:

Hi, guys, thanks for taking the call. This is Ethan Potasnick filling in for Mike Matson. I was wondering if you could maybe quantify or qualify the Japanese coronary atherectomy market, and then would your pricing and margins be higher there than in the U.S.? I was also wondering if you guys have any plans to enter Europe with Diamondback, or is it just too cost-prohibitive there?

Scott Ward:

Okay, so, great questions, all on our international market opportunities.

We're really focused on Japan right now as our first international market opportunity. There—Japan is a great marketplace for us, there are about 280,000 percutaneous coronary intervention procedures per year that are performed in Japan. Japanese physicians will take longer to treat each patient. They generally are really strong users of imaging like IVUS and OCT, so they will spend the time to image a vessel, go in, perform atherectomy to properly prepare that vessel, and then drop a stent and then actually go back in and take a look at the stent again. So, they're very deliberate, very specific, and that is just the standard of care in Japan.

So, it's a marketplace where we do expect that we can get very strong adoption. There is a high rate of calcific disease in Japan, roughly 10% to 20% of the 280,000 procedures per year do involve patients that have calcified lesions, so this is a very exciting market opportunity for us.

For reimbursement and from a payment perspective, the way the process works in Japan is we get our initial approval from the MHLW and then we can apply for reimbursement, we have done that. We now anticipate that we will learn what the reimbursed rate will be for our technology, and that will occur very late this calendar year.

Following that, we then will initiate a limited commercial launch that will occur in early 2018. That will be very focused on customer training and education. We will leverage a peer-to-peer training approach in Japan where physicians will train one another. We did conduct our Coast clinical trial in the U.S. and in Japan, so we've got a number of sites in Japan that are trained and experienced in using this technology, and they will train others, and then we expect, as that additional peer-to-peer training occurs, we'll continue to see kind of exponential growth over time.

So, that's how we're anticipating this to rollout. We do—we don't think this'll be a block-wise type growth profile. We think that this will be a steady, reliable growth over time in Japan as we train and educate an increasing number of sites.

Laurence Betterley:

So, Ethan, we'll be in a better position to talk more about numbers once we understand what the reimbursement will look like, and of course we need to share that with our distribution partner in Japan. But that will be coming in the future.

Ethan Potasnick:

Okay, understood; and then could you maybe comment on the $40 million credit facility and maybe provide an update on your latest thoughts related to M&A?

Scott Ward:

You want—any comments …

Laurence Betterley:

Yes, we've entered into a—as I said, we've entered into a $40 million line of credit with Silicon Valley Bank. It's subject, of course, to levels of receivables and other working capital, but it is available at, we feel, favorable interest rates less than prime, in three-year facilities. So, that is available to us, we don't have any immediate plans for that, but I'll let Scott comment on your M&A question.

Scott Ward:

Well, that'll be easy. But just to comment on the credit facility, just considering the market environment and where credit is at right now, we just think it's really a great idea. As we look to continue to stabilize our financial position and to assure that our Company is in really the best financial condition possible, we just thought it'd be a good idea to take this at this time. We really don't have any intentions at this point to use it, but it certainly does provide us with greater financial stability and a stronger foundation going forward.

In terms of M&A, we don't really comment on M&A, so I can't really say much about that.

Ethan Potasnick:

Okay, great. Thanks, guys.

Operator:

There are no further questions at this time. I will turn the call back over to Scott for final remarks.

Scott Ward:

Thank you, Cheryl, and thanks to everybody on the call. Thank you for your continued interest in CSI. We look forward to updating you again on our progress next quarter. This concludes the conference call. Thanks, everyone.

Operator:

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