

05-Feb-2020

# Cardiovascular Systems, Inc. (CSII)

Q2 2020 Earnings Call

## CORPORATE PARTICIPANTS

**Jack E. Nielsen**

*Vice President-Investor Relations & Corporate Communications,  
Cardiovascular Systems, Inc.*

**Scott R. Ward**

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

**Jeffrey S. Points**

*Chief Financial Officer, Cardiovascular Systems, Inc.*

**Rhonda J. Robb**

*Chief Operating Officer, Cardiovascular Systems, Inc.*

---

## OTHER PARTICIPANTS

**Chris Pasquale**

*Analyst, Guggenheim Securities LLC*

**Frank Takkinen**

*Analyst, Lake Street Capital Markets LLC*

**Mathew Justin Blackman**

*Analyst, Stifel, Nicolaus & Co., Inc.*

**Danielle Antalfy**

*Analyst, SVB Leerink LLC*

**Mike Matson**

*Analyst, Needham & Co. LLC*

**Jayson Bedford**

*Analyst, Raymond James & Associates, Inc.*

---

## MANAGEMENT DISCUSSION SECTION

**Operator:** Ladies and gentlemen, thank you for standing by and welcome to the Cardiovascular Systems, Inc. Fiscal Year 2020 Second Quarter Earnings Conference Call. At this time, all participants are in a listen-only mode. After the speaker presentation, there will be a question-and-answer session. [Operator Instructions]

I would now like to hand the conference over to Jack Nielsen, Vice President, Investor Relations and Corporate Communications. Thank you. Please go ahead.

---

**Jack E. Nielsen**

*Vice President-Investor Relations & Corporate Communications, Cardiovascular Systems, Inc.*

Thank you, Chris. Good afternoon and welcome to our fiscal 2020 second quarter conference call. With me today are Scott Ward, CSI Chairman, President and Chief Executive Officer; Rhonda Robb, Chief Operating Officer; Jeff Points, Chief Financial Officer; and Dr. Ryan Egeland, Chief Medical Officer.

Approximately 30 minutes ago, we issued a press release announcing our fiscal 2020 second quarter results. You may find a copy of this release on our Investor Relations section of our corporate website. Here you may also find an earnings presentation that includes additional details on our performance and outlook. In a few moments, CSI management will discuss results for our second quarter which ended on December 31, 2019. After our prepared remarks, we will entertain your questions.

During today's 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 to our investors. Today's press release contains a reconciliation table to GAAP results.

I will now turn the call over to Scott Ward.

---

## Scott R. Ward

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

Thank you, Jack. And good afternoon, everyone. Thank you for joining us today. In our second quarter, CSI delivered solid consistent growth with balanced performance across our businesses and geographic markets. Second quarter revenues of \$68.3 million represent 13.5% growth compared to last year and these results marked the seventh consecutive quarter of double-digit revenue growth for our company. Our gross profit margin remains strong at 79.9% and once again our growth was driven by the successful execution of key initiatives in our core domestic business and revenue from new products and new geographic markets.

In Q2, worldwide peripheral revenue increased 8% to \$47.6 million led by 12% unit growth in our domestic atherectomy business with continued strong performance in both the OBL and the hospital sites of service. Worldwide coronary revenue increased over 30% to \$20.8 million led by 14% unit growth in our domestic atherectomy business, increased sales of our procedure support products and continued adoption of orbital atherectomy in Japan.

Our strategy to strengthen our domestic core atherectomy franchises with product innovation and comprehensive physician education is delivering strong and consistent results. For example, new products like exchangeable and radial contributed to our success in peripheral and we are capturing greater revenue per procedure in coronary where we now offer a comprehensive set of procedure support products.

We continue to build a strong foundation for future growth with the addition of new accounts and new physicians. CSI has a reputation for delivering exceptional medical education programs and we trained approximately 200 physicians in the US and nearly 70 new customers in international markets in Q2. Overall, our company is performing very well, delivering consistent double-digit growth and strong gross profit margins while expanding our product portfolio and geographic footprint.

Rhonda will provide additional information regarding R&D and our commercial progress in just a few moments. But first, I will ask Jeff to provide you with details regarding our second quarter financial results. Jeff.

---

## Jeffrey S. Points

*Chief Financial Officer, Cardiovascular Systems, Inc.*

Thank you, Scott. And good afternoon, everyone. As Scott mentioned, second quarter revenue of \$68.3 million represented a nearly 14% increase compared to last year. In total, we sold over 22,500 atherectomy devices during the quarter, representing an 18% increase compared to last year.

Worldwide peripheral revenue increased 8% to \$47.6 million. Domestically, peripheral unit volumes increased 12%. ASP decline was again in the low single-digits similar to Q1 and consistent with expectations. Worldwide coronary revenue increased 30% to \$20.8 million. Domestic coronary revenues grew 22% from last year, driven by increased atherectomy unit volumes and increasing sales of our procedure support products.

The revenue generated in the US and international markets was as follows: Total US revenue increased 13% to \$66 million consistent with our expectations. Domestic peripheral revenue increased 9% to \$47.5 million and domestic coronary revenue increased 22% to \$18.5 million. International revenue totaled \$2.4 million, which was at the upper end of the range I provided on the Q1 call.

As Rhonda will discuss in a moment, our commercialization efforts coupled with strong collaboration with our international partners has resulted in strong performance through the first six months of the year. For your models, we now anticipate full year international revenue of approximately \$11 million, which is at the high end of the range that I shared last August.

In Q2, gross profit margin remains strong at 79.9%. Operating expenses of \$58 million, increased \$9.6 million or 20% compared to last year. R&D expenses associated with investments in new product development and increase in enrollment in the ECLIPSE clinical trial increased \$3.6 million or 50%.

SG&A increased 14% due to several factors; first, increased investments in clinical specialists; second, physician training and medical education investments to support our international expansion; third, legal expenses related to intellectual property matters; and finally, amortization expense related to our recent acquisition of the WIRION embolic protection device.

Second quarter net loss was \$3.4 million. Adjusted EBITDA was a positive \$1 million. We continue to anticipate sequential increases in revenue and improving profitability in Q3 and Q4. On the balance sheet, we ended the quarter with over \$109 million in cash and marketable securities and no long-term debt. That concludes my comments on the Q2 financial results.

Now, turning to our annual guidance. Strong revenue results through the first half of the fiscal year now positioned us to deliver fiscal 2020 revenue towards the upper end of our original guidance range. As a result, we are pulling up the lower end of our fiscal 2020 guidance range to reflect our expectation of 13% to 14% revenue growth in fiscal 2020. These expectations include 10% growth in our core atherectomy business, sequential quarterly growth in procedure support product revenue and international revenues of approximately \$11 million.

Previously, I provided guidance that our net income or loss for fiscal 2020 would be approximately breakeven excluding the impact of approximately \$2 million of intangible asset amortization and direct expenses related to the WIRION acquisition. We now anticipate that fiscal 2020 investments in new product development and clinical evidence as well as legal expenses related to intellectual property matters will be higher than previously forecasted. As a result, we now anticipate a net loss for the fiscal year.

In summary, for fiscal 2020, we now anticipate revenues in the range of \$280 million to \$283 million representing annual revenue growth of 13% to 14%, gross profit margin of 79% to 80%, net loss of approximately 2% of revenues which includes approximately \$1 million of intangible asset amortization and an additional \$1 million of direct expenses related to the WIRION acquisition, and positive adjusted EBITDA.

Rhonda will now discuss our commercial developments. Rhonda?

---

**Rhonda J. Robb***Chief Operating Officer, Cardiovascular Systems, Inc.*

Thank you, Jeff. As you just heard, our second quarter revenue growth of 13.5% was driven by strong commercial execution and momentum in our three growth drivers; first, generating above market unit growth in our core domestic atherectomy businesses; next, driving growth from the sale of procedure support devices; and finally, continued international expansion. Overall, we are very pleased with strong, balanced performance across our therapy franchises, sites of service and geographies.

Starting in coronary; our worldwide revenues were 30% compared to last year and over 9% sequentially. As we have shared with you previously, the strength and stability in coronary comes from several strategies that we have been executing now for over a year. In the US, we achieved 14% unit growth. Our physicians appreciate the ease of use, anatomical flexibility and procedural outcomes from our unique mode of action that provides both bi-directional sanding as well as pulsatile forces to fracture deeper calcium.

Finally, the CSI field organization continues to provide a high level of service and commitment to the cath lab, our physicians' practices and, most importantly, their complex patients. Strong presence, ongoing education and high-touch clinical support has earned the confidence of our physicians and as a result we have the opportunity to introduce new products that improve the quality of care for their patients, while increasing our revenue per procedure.

In Q2, we sold over \$2 million of procedure support products in coronary, primarily the Sapphire angioplasty balloons and Teleport microcatheters. During the quarter, we also broadened our offering of angioplasty balloons and we now offer a full line of Sapphire balloons from 1 to 5 millimeters.

Q2 represented the sixth consecutive quarter of sequential revenue increases from our coronary support products. Now, not all of these products are used exclusively in our coronary atherectomy procedures; however, we are now selling about \$450 of support products for every coronary OAS device sold and we have significant opportunity to further increase penetration in accounts performing complex coronary procedures.

We remain excited about the recent launch of our new nitinol coronary ViperWire. Recall that we launched this wire in Japan one year ago and it has been an important contributor to our coronary success in that market. Similarly, feedback from physicians in the US has been exceptionally strong. In fact, we believe this new wire is enabling increased Diamondback OAS use.

Briefly, we continue to make progress in expanding our clinical evidence in coronary. Enrollments in our 2000 patient ECLIPSE coronary trial continue to grow. We now have over 1,250 patients enrolled in the largest randomized coronary atherectomy trial ever conducted, and we continue to target completion of enrollment in fiscal 2021.

Turning now to peripheral; our worldwide business grew 8% in Q2 and 5% sequentially, driven primarily by 12% unit growth in the core domestic peripheral atherectomy business. In Q2, we continued to introduce our expanded lineup of low profile orbital atherectomy devices that leverage our core technology providing physicians with new options for treating their most challenging peripheral patients. Reception to the early launch of our exchangeable device with GlideAssist has been very positive. This device was designed to serve up to 50% of the peripheral patients that have multi-vessel disease throughout their leg. Physicians are embracing the idea of full leg revascularization using one device.

In its first full quarter, exchangeable adoption continues to grow as we educate and build value in this one of a kind system. As you recall, we sell exchangeable at a premium and the opportunity to use multiple crown sizes in one procedure can further increase revenue per procedure. We also continue to leverage 5-French low profile orbital atherectomy system to expand the use of our products that provide alternate sites of access.

Our radial devices further position CSI as a valued procedural partner in cath labs by offering physicians a minimally invasive atherectomy tool that can access the vasculature through the radial artery. In Q2, radial units sold grew 20% sequentially as physicians seek to safely treat a difficult patient population. Our radial device provides CSI with a sustainable competitive advantage. We'll drive increased adoption of our radial device with unique physician education programs and medical evidence through our REACH peripheral radial study.

We completed enrollment of this study earlier than forecasted, and as a result, we now have the opportunity to share the data this May at the New Cardiovascular Horizons or NCVH conference. As a reminder, this study will prospectively evaluate acute clinical outcomes of orbital atherectomy using radial access for the treatment of peripheral disease. We believe this study will demonstrate many of the known benefits of radial access, such as, low complication rates, high cost-effectiveness and shortened time to ambulation. The read-out of the study will dovetail nicely as we plan to introduce radial support products in fiscal 2021.

CSI again saw growth this quarter in both the hospital site of service at over 4% and the OBL at nearly 21% year-over-year. We estimate that up to 55% of peripheral procedures are now conducted in the OBLs. CSI hospital growth was driven by both exchangeable and radial programs and OBL growth was driven by continued traction and focus in large OBLs, volume-based contracting and case coverage.

Finally, in international, we continue to make great progress driving revenue growth and certifying new physicians. Our success is most notable in the second largest coronary atherectomy market, Japan. We've now been commercial there with our coronary device for over two years, and in Q2, we saw strong sequential and year-over-year growth in cases, new accounts and physicians certified. We now have nearly 200 physicians certified in that market to use Diamondback.

Overall, Q2 results represent a continuation of the successful execution of our strategy. Innovation on our core technology and adding new products are driving higher revenue per procedure domestically, efficiently targeting and training key physicians worldwide is driving strong performance internationally. Together, our efforts position us to deliver fiscal 2020 revenue growth at the upper end of our forecast.

As we begin calendar 2020, we are encouraged that US reimbursement for both peripheral and coronary atherectomy procedures remains stable. In November, CMS released their outpatient and ambulatory surgical centers final rule for 2020 payments and their Medicare physician fee schedule final rule for 2020. Consistent with the previously released final inpatient rules, the outpatient rules represent the sixth consecutive year of steady reimbursement for atherectomy. On a blended basis, the forecasted impact of the inpatient and outpatient reimbursement in 2020 is an increase of 2.5% in coronary and an increase of 0.8% in peripheral.

Looking ahead, we are aware that AMA may review the lower extremity endovascular procedure code set at a CPT Editorial Panel meeting. However, it has not yet hit the agenda including this week's panel meeting. We are monitoring this closely and we'll keep you updated in future periods if the endovascular codes are added to a future meeting agenda.

Looking forward to the back half of fiscal 2020, we will look to drive increased adoption of our coronary support devices and resulting in higher revenue per procedure and expanding the adoption of the nitinol ViperWire giving

us access to more complex patients. Internationally, we will look to train and certify increasing numbers of physicians on orbital atherectomy. In peripheral, we will drive increased adoption on our expanded OAS offering, including exchangeable, radial and the recently launched next generation peripheral OAS with GlideAssist on a 1.25 millimeter models of both Stealth and Diamondback.

Recall that the introduction of GlideAssist on our coronary Diamondback has enabled physicians to access tortuous calcified lesions in the heart. Adding GlideAssist on our 1.2 millimeter peripheral models now provides physicians an ability to better access and treat challenging vasculature below the knee.

Finally, we continue to take the learnings from the success of the commercialization of our coronary support devices and look to apply those to the launches of our peripheral support devices later this calendar year.

That concludes my prepared remarks. Scott.

---

## Scott R. Ward

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

Thank you, Rhonda. Well, as you've heard today, this was another outstanding quarter for CSI. Guided by our mission to save limbs and save lives every day, we're fulfilling our promise to our physician partners and patients around the world to deliver the highest quality of products, services and relationships. We are delivering on our promise to shareholders to achieve sustainable long-term growth by investing in our core business, innovating through our product pipeline and simultaneously extending our reach to patients in need around the world.

Our technologies deliver superior patient outcomes because we have the strongest medical evidence in the market and an increasing commitment to medical education. As our second quarter results illustrate, our leadership team is devoted to driving commercial execution, developing new markets and building product portfolios that improve the quality of care for patients with cardiovascular disease.

Finally, I want to thank our 800-plus strong CSI team for their tireless efforts in achieving our strategic goals. And I want to thank all of you for your continued interest in CSI. I look forward to updating you on our progress in the coming quarter.

And, we will take questions now. So, Chris, if you would please repeat the instructions, that would be great. Thank you.

## QUESTION AND ANSWER SECTION

**Operator:** Certainly. [Operator Instructions] Your first question is from Chris Pasquale with Guggenheim. Your line is open.

**Chris Pasquale**

*Analyst, Guggenheim Securities LLC*

Q

Thanks and congrats on a good quarter, guys. Scott, there's a lot of focus on the potential for the reimbursement codes to be looked at this year. And I think there's some confusion about that process and potential outcomes. So, maybe it would helpful to spend a minute making sure these on the same page in terms of the process and the variety of outcomes that you guys are preparing for as you think about what could happen there?

**Scott R. Ward**

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

A

Yeah. Thanks, Chris. Rhonda did address that through her comments. So, Rhonda, I'll let you respond to that.

**Rhonda J. Robb**

*Chief Operating Officer, Cardiovascular Systems, Inc.*

A

Yes, absolutely. Thanks, Chris. So, I think as everybody knows, the AMA and CMS routinely review and screen CPT codes and their use and typically that occurs about every five years. And last year, the code for tibial-peroneal atherectomy was identified by a high volume growth screen. And this is not really a surprise because more patients are being treated, more complex patients are being done and patients are candidly getting better care. So, that's a good thing. And so, the AMA, as a result, may update their lower extremity endovascular procedure code set. But first step in that is for the CPT Editorial Panel to convene, this is a group that meets three times a year and thus far the topic has not been scheduled on the meeting.

I think in terms of anticipating outcomes, they could go down because the efficiency of the therapy has increased so dramatically, particularly with CSI, but they could also go up because we're just treating a lot more complex patients than we were historically as well. So, as I said in the comments, it's something we're watching closely. We'll certainly be an observer in that and provide information as requested to the societies that will play a role in those meetings.

**Chris Pasquale**

*Analyst, Guggenheim Securities LLC*

Q

That's helpful. Thanks. And then, the progress on the procedural support tools within the coronary piece of the business is very encouraging. You just talked about the path to replicating that on the peripheral side, are you expecting that toolkit to be built out in the early part of FY 2021 or is it something that's going to flow through over the course of next year?

**Scott R. Ward**

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

A

Well, good point. So, we have had real good success now with increasing our revenue per procedure in coronary. And we will look to add balloons and catheters to our peripheral product line starting actually in early FY 2021. And those products will be launched throughout the year so that as we proceed through the course of next fiscal year, we would head towards having a full product offering there as well. We do certainly expect that as we add

these support products in peripheral that that will substantially enhance our revenue per case and will become an important growth driver for us as we look over the next year or two.

**Chris Pasquale**

*Analyst, Guggenheim Securities LLC*

Q

Thanks.

**Operator:** Your next question comes from Frank Takkinen with Lake Street Capital. Your line is open.

**Frank Takkinen**

*Analyst, Lake Street Capital Markets LLC*

Q

Hey. Thanks for taking my questions. First, on the OBL area, it was nice to see that reaccelerate back to 21% from 16% last quarter. I know you talked on it briefly, but if you could take a couple more minutes just to explain exactly what's going on there and the strength you're seeing and how you feel about your competitive positioning, that would be fantastic.

**Scott R. Ward**

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

A

Okay. Well, thanks, Frank. Thanks for that question. So, I think what we're seeing, as we've talked about in the past, the peripheral marketplace in the United States and perhaps around the world is really characterized today as an epidemic. You have an underlying growth rate here of a high single-digits, let's say, 7%, 8%, 9% per year, and so, these patients are continuously in need of being treated. We see in the US a move afoot to try to manage that patient population. It's difficult for all of those patients to pass through hospitals. And perhaps, it's financially not feasible to do that. As a result, more and more of these patients now are being treated in office-based labs, and we're seeing that market shift continue. That is a market trend that I think benefits us because in particular for the treatment of patients with severely calcified lesions, we are really the only device that can be used to treat that patient population.

We've made a real strong effort to collaborate and partner with OBL customers, providing them with increased support and medical education, long-term contracts to stabilize their business models and a favorable supply chain in some cases. So, we feel that we have a very strong competitive advantage in the OBLs. It's an important focus for us. And as you can see, we continue to sustain strong growth there. Over time, as that segmentation continues as we see more and more cases being performed, moving from the hospital setting to the OBL setting, I think we'll eventually see that growth rate begin to slow. But for now, we've been sustaining that 20% plus growth rate and we're happy about that. But certainly in time, we'll see that begin to come down.

**Frank Takkinen**

*Analyst, Lake Street Capital Markets LLC*

Q

Great. And then, secondly, just looking for an update on the additional coronary reps that you guys were looking to hire, I believe you were at 10 last quarter on your call of the 20 target for the year. And then, if you could just overlay that with the additional update to the guidance and the little bit wider loss and maybe if it's just because you're hiring a little bit quicker than you anticipated?

**Scott R. Ward**

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

A

Yeah, I'll let Jeff address that in just a moment. We continue to make progress on our hiring of our coronary specialists. I think, as you know, we anticipate hiring approximately 20 over the course of the fiscal year and we're doing that on a regular basis over the course of the quarter. We continue right on track with that. I think we're probably in around the mid-teens at this point. And so, that gives you a pretty good idea of where we're at. But, we continue right on schedule, and as we've talked about before, that adjustment to our sales force of just increasing the coronary focus will have impact over time and will position us to obviously take advantage of the strength we have in coronary. So, Jeff, do you want to talk just a bit about the guidance there?

---

**Jeffrey S. Points***Chief Financial Officer, Cardiovascular Systems, Inc.*

A

Yeah. Just on the guidance, Frank, just a few reasons I highlighted in my prepared remarks for the increased loss. As I mentioned, our clinical specialists have increased, we – we've seen a significant investments in our clinical specialists in the field. We've got about 125 today. Last year at this time, we had about 100, so really focused on providing that case support and increased presence in the field. The second thing is really just all the investments we're making for physician training and medical education as we support our international launch. The third item I mentioned was the legal expenses related to our intellectual property matters. And then, of course, the amortization expense related to WIRION. So, all those factors really contributed to a higher than expected net loss for the year.

---

**Frank Takkinen***Analyst, Lake Street Capital Markets LLC*

Q

Great. That's all I have. Thanks and congrats on all the progress. Thanks.

---

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

A

Thank you, Frank. Thank you very much.

---

**Operator:** Your next question is from Mathew Blackman with Stifel. Your line is open.

---

**Mathew Justin Blackman***Analyst, Stifel, Nicolaus & Co., Inc.*

Q

Thanks for taking the questions. Good afternoon, everybody. Maybe just start on the ancillary portfolio of procedure support. Before I think in our conference in November, you said you give a metric that something like 60% of your coronary accounts have adopted procedure support devices. Any updates as to how that's trending today? And then, I've got one more follow-up.

---

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

A

We continue to trend pretty strongly. We've strong adoption across our accounts. And I think, as we've talked about in the past, Matt, it does take time to get hospital contracts and to penetrate these accounts. But once we do, we're in a pretty good place. We're able to sustain and retain those accounts. So, yeah, at this point in time, we continue to have good penetration and we're very pleased with where we're at there. Did you have a follow-on question?

---

**Mathew Justin Blackman***Analyst, Stifel, Nicolaus & Co., Inc.*

Q

I did. Since we think about to the next move, you've talked about building up the peripheral support product lines over the next couple of years. If you think about sort of the magnitude of incremental revenue per case opportunity, I think in coronary, you said you're up to something like \$450 in incremental revenue per case, and with more to go, how do we think about sort of the all-in opportunity on the peripheral side when you've got a full suite of products? Is it similar in magnitude to the opportunity in coronary, is it bigger or is it smaller any way to reconcile those?

---

**Scott R. Ward**

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

A

Sure. Let's talk about coronary first just to set a baseline. You are correct and as we indicated today we're at about \$450 per case. Now, if you think about the utilization of balloons and wires in a typical coronary case, balloons and catheters and wires, we would expect that the revenue available for pull through there for us is probably on the range of \$800 to \$1,000 per case. Now, we're not going to penetrate all cases and not all of our devices will be used in every case, but that gives you kind of the total potential. And then, as Rhonda reported, we're at about that \$450 range now.

So, as we look at that in comparison to peripheral, the peripheral potential is also right around that \$800 to \$1,000 per case for balloons, catheters and wires. And then, in addition to that, we'll be adding our WIRION embolic protection device. And the average selling prices for that, for let's say EPDs, in the market today is around \$1,000. So, our overall potential in peripheral once again is probably on the range of \$1,800 to \$2,000.

---

**Mathew Justin Blackman**

*Analyst, Stifel, Nicolaus & Co., Inc.*

Q

Okay. That's really helpful. I appreciate that, Scott. That's all I had.

---

**Scott R. Ward**

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

A

Okay. Great. Thank you.

---

**Operator:** Your next question is from Danielle Antalffy with SVB Leerink. Your line is open.

---

**Danielle Antalffy**

*Analyst, SVB Leerink LLC*

Q

Hey, good afternoon, guys. Thanks so much for taking the question and congrats on another solid quarter.

---

**Scott R. Ward**

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

A

Hi, Danielle.

---

**Danielle Antalffy**

*Analyst, SVB Leerink LLC*

Q

Hi. Good to see the consistency here.

---

**Scott R. Ward**

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

A

Thank you.

**Danielle Antalfy***Analyst, SVB Leerink LLC*

Q

I had two questions for you. First of all, strong growth on the, or adoption uptake I guess I'd say, of the exchangeable platform as well as radial. Do you think or do you have a sense of whether you're growing in the market, growing share or are you cannibalizing some of your existing or what would have been your existing procedures, like how do we think about what's happening in the market there?

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

A

Yeah. Let me ask Rhonda to address that. Do you want to address that question?

**Rhonda J. Robb***Chief Operating Officer, Cardiovascular Systems, Inc.*

A

Yeah. No, I think we're growing faster than the market, Danielle. So, this is 12% unit growth and that's just really exceptional in a market that's growing in a high single-digit. So, we think it's making a real difference there and continuing to convert doctors to both devices.

**Danielle Antalfy***Analyst, SVB Leerink LLC*

Q

Got it. Okay. Thanks for that. And then, on the potential around this reimbursement dynamic, regardless of what happens here, I'd love to get your thoughts on where you – how much flexibility you have from a pricing perspective. I mean, obviously, as you shifted to OBLs, you've demonstrated the ability to come down a little bit on price and not pressure margins too much. But I would just love to get your thoughts here. Should we see reimbursement come down? How to think about the flexibility in the price while still maintaining margins? Thanks so much.

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

A

Yeah. Thanks, Danielle. Thank you for that question. Really well said and I think, first of all, let me say that it's a premature at this point to really speculate about what will happen. I think we know that there's a possibility, as Rhonda had indicated, that these codes may be open. There's no indication right now that they will be. It's not been scheduled on an agenda. There is some talk in the analyst community and elsewhere that maybe this is going to happen. We have not seen that scheduled yet. So, at this point in time, we can't say definitively that these will be reviewed. Even if they are reviewed, as Rhonda said, the relative value units for this particular procedure may go up or down depending on how the [indiscernible] (00:32:13) reviews these procedures. So, there's a lot to be said. It will happen over a period of probably a couple of years. And during that time, we'll have a lot of opportunity to keep you updated.

Now that said, if there is some pricing, some reimbursement reduction that ultimately negatively affects the use of atherectomy to treat PAD patients, we have a fair amount of room in our margins. And that's because, as you know from watching us in the OBL, we have the benefit of volume. And as we move more volume through our manufacturing operations, we can consistently reduce our cost of goods sold. So, I'm very confident that we're well positioned to manage any pricing dynamic that comes at us at this point in time. And certainly, we also believe that we have a fair amount of time to address anything that may come along here, if something were to develop. So, I hope that addresses your question and thank you for that.

**Danielle Antalffy**

*Analyst, SVB Leerink LLC*

It does. Yeah. Thank you so much.

Q

**Scott R. Ward**

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

Okay. Thanks, Danielle.

A

**Operator:** Your next question is from Mike Matson with Needham & Company. Your line is open.

**Mike Matson**

*Analyst, Needham & Co. LLC*

Hi. Thanks for taking my questions. So, the international coronary sales were obviously up a lot year-over-year, but it does look like they ticked down a little bit sequentially. So, I don't want to be nitpicky, but just curious what happened there and is that you're your normal fluctuations in the revenue in Japan or something?

Q

**Scott R. Ward**

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

Yeah. I think you need to look at that as really normal fluctuations. Our Japan business continues to perform extremely well. We are very pleased with how we are doing there. In the rest of the world, we work through OrbusNeich. OrbusNeich is our distributor for the rest of the world. And as we've said before, there will be ups and downs in their ordering because we're selling in volume to our distributor who then is moving units out for case coverage. So, there will be lumpiness to that, and I think Jeff has referred to that in the past. Jeff, do you want to add to that at all?

A

**Jeffrey S. Points**

*Chief Financial Officer, Cardiovascular Systems, Inc.*

No, I think that covers it very well. That's exactly right that, as I've stated before, Mike, there're just going to be lumpiness and timing issues that go into ordering patterns and Scott summarizes this accurately.

A

**Scott R. Ward**

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

Yeah. And you know, it is difficult because I realize we monitor this on a quarterly basis, but as we look at our international performance on an annualized basis, we are now projecting that to be around \$11 million of revenue, which is outstanding performance over the course of the full year, and that's really perhaps more how I would evaluate it.

A

**Mike Matson**

*Analyst, Needham & Co. LLC*

Okay. Thanks. And then, just wondering if you could update us if there is anything new to report on the support pump or directional atherectomy development programs.

Q

**Scott R. Ward**

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

Yeah...

A

**Rhonda J. Robb**

*Chief Operating Officer, Cardiovascular Systems, Inc.*

A

Yeah, I'll take that. We're still planning for our first-in-human in FY 2021. We've noted that in the slide, but really no new updates beyond that today. We're really focused on getting to that first-in-human and continue to have interactions with the FDA and we'll just provide additional updates in future calls when we can do so.

**Mike Matson**

*Analyst, Needham & Co. LLC*

Q

Okay. Great...

**Rhonda J. Robb**

*Chief Operating Officer, Cardiovascular Systems, Inc.*

A

And then, on direction – Yeah, I think you asked about directional too. I apologize...

**Mike Matson**

*Analyst, Needham & Co. LLC*

Q

Yeah. Yeah.

**Rhonda J. Robb**

*Chief Operating Officer, Cardiovascular Systems, Inc.*

A

We're continuing to work on the developments for that program. And I think we said first-in-human in FY 2022 for that device previously and we're staying with that. And, we'll again update as future developments occur with that program.

**Mike Matson**

*Analyst, Needham & Co. LLC*

Q

All right. Thanks a lot.

**Operator:** Your next question is from Margaret Kaczor with William Blair. Your line is open.

Q

Hi. Thanks for taking the question. This is a [ph] Brandon (00:36:02), in for Margaret. If I could first just ask a question on guidance and kind of some of the moving pieces for peripheral with the REACH study being presented in May and given kind of your unique position within the radial access side of the market. What kind of outcomes are baked into guidance for that REACH study? If there's a positive outcome is that kind of upside to peripheral expectations in the back half or is that already baked in all of that to guidance?

**Jeffrey S. Points**

*Chief Financial Officer, Cardiovascular Systems, Inc.*

A

Yeah. That would already be baked into our expectations of continuing to grow both peripheral and coronary at or at above market rates that we've talked about previously.

Q

Got it. And then...

[indiscernible] (00:36:48)

**Rhonda J. Robb**

*Chief Operating Officer, Cardiovascular Systems, Inc.*

A

...that read-out will come, just to remind you, in May which is toward the latter part of our fiscal year.

Q

Got it. Okay. And then, in terms of sales rep productivity, obviously given the good sequential increases that you're seeing within the support products, the rep productivity seems like it's increasing at a nice clip. Where do you guys think rep productivity stands today and where do you think is kind of the upper limit in terms of productivity and when you need to start kind of maybe expanding the sales force more? I guess, the question is kind of when – how much larger can the bag get for some of these reps while maintaining their focus?

**Scott R. Ward**

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

A

Yeah. Well, so, first of all, our sales rep productivity is improving. We continue to have right around 200 sales reps. And as a result, I think you're seeing a meaningful benefit there. So, we're probably at about \$1.3 million per rep right now. As I said before, we think that we can continue to improve the productivity in the sales organization. There is a limitation to that however, because part of our competitive advantage is that we do provide case support. And as a result of that, case support and having our reps present in cases, we have the potential for pull through and the pull through comes or the advantage of that comes from the sale then of these balloons, wires, catheters, embolic protection devices.

So, having those sales reps present in these cases is critically important, but the enhanced productivity can come from driving that increased revenue per procedure in every case that they're in. And really that comes back to the launch now as you've seen in coronary, the launch of our full offering and as a result, we've seen our revenue per case increased by about \$450 there. And as we've talked about earlier on this call, as we launch in peripheral, we have the potential over the course of the next year or two to continue to substantially increase our revenue per case in that segment of our business, frankly the larger part of our business.

So, I do think that there is a continued upside in our rep productivity. I will say that we continuously monitor our rep productivity and performance on a local basis. And as we need to split territories or as we need to manage our capacity, we do so on a regular basis now. And that is a continuing process of just really disciplined and careful management of our sales channel. And our sales leadership team does an excellent job at assuring that we're taking every action to continuously optimize our sales rep productivity. I hope that answers your question.

Q

Yep. Great. Thanks. That was very helpful.

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

Okay. Good. Thank you.

A

**Operator:** And our last question is from Jayson Bedford with Raymond James. Your line is open.

**Jayson Bedford***Analyst, Raymond James & Associates, Inc.*

Good afternoon and congrats on the progress. Just a couple of quick ones for me. Peripheral atherectomy volume growth was quite strong and my impression is that the drug-coated balloon market seems like it's getting a bit healthier from the summer. And so, my question is, and I go back and forth on this, but do you feel a healthier drug-coated balloon market is good or bad for the opportunity that you see or simply no impact?

Q

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

Thanks, Jayson, for your question and good to hear from you. I would say that right now it's pretty – it's become neutral. I think over the past few quarters, I've been indicating there's probably a mild tailwind for us in the sub-segment of our business. Honestly, in this quarter, I think drug-coated balloons have become somewhat neutral to us. And I think that's largely [indiscernible] (00:40:44) because we're seeing now kind of a restoration of just continuous and relatively standard use of drug-coated balloons albeit perhaps in patients that have a high risk of restenosis. But the perturbation that was caused by the Katsanos' paper in that marketplace has pretty much settled out at this point. And frankly, right now, it's probably neutral to us.

A

**Jayson Bedford***Analyst, Raymond James & Associates, Inc.*

Okay. It's helpful. And just I don't want to be greedy here, you guys give a lot of detail, but when you look at the 21% growth in the OBL channel on the peripheral side, is there any way you could kind of parse that out between same center volume growth and the benefits, which I'm sure you're getting a bit of a benefit from opening new accounts?

Q

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

No, I don't think we can parse that out to that level of detail. I think, we're seeing a less new account growth, because if you recall, a couple of years ago, we really started this focused initiative. And as a result for that – for a period of probably 12 to 18 months, we were largely benefiting from new accounts. I think a lot of our growth now is coming from same-store sales, but we don't break out that in detail.

A

**Jayson Bedford***Analyst, Raymond James & Associates, Inc.*

Okay. That's actually helpful. Thank you.

Q

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

Okay. Great. Thanks very much.

A

## Scott R. Ward

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

All right. Yes, I think that is it. So, I want to thank everybody for calling in. We look forward to giving you an additional update next quarter. Thanks, everyone.

**Operator:** Ladies and gentlemen, this concludes today's conference call. Thank you for your participation and you may now disconnect.

### Disclaimer

The information herein is based on sources we believe to be reliable but is not guaranteed by us and does not purport to be a complete or error-free statement or summary of the available data. As such, we do not warrant, endorse or guarantee the completeness, accuracy, integrity, or timeliness of the information. You must evaluate, and bear all risks associated with, the use of any information provided hereunder, including any reliance on the accuracy, completeness, safety or usefulness of such information. This information is not intended to be used as the primary basis of investment decisions. It should not be construed as advice designed to meet the particular investment needs of any investor. This report is published solely for information purposes, and is not to be construed as financial or other advice or as an offer to sell or the solicitation of an offer to buy any security in any state where such an offer or solicitation would be illegal. Any information expressed herein on this date is subject to change without notice. Any opinions or assertions contained in this information do not represent the opinions or beliefs of FactSet CallStreet, LLC. FactSet CallStreet, LLC, or one or more of its employees, including the writer of this report, may have a position in any of the securities discussed herein.

THE INFORMATION PROVIDED TO YOU HEREUNDER IS PROVIDED "AS IS," AND TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, FactSet CallStreet, LLC AND ITS LICENSORS, BUSINESS ASSOCIATES AND SUPPLIERS DISCLAIM ALL WARRANTIES WITH RESPECT TO THE SAME, EXPRESS, IMPLIED AND STATUTORY, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, ACCURACY, COMPLETENESS, AND NON-INFRINGEMENT. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, NEITHER FACTSET CALLSTREET, LLC NOR ITS OFFICERS, MEMBERS, DIRECTORS, PARTNERS, AFFILIATES, BUSINESS ASSOCIATES, LICENSORS OR SUPPLIERS WILL BE LIABLE FOR ANY INDIRECT, INCIDENTAL, SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, INCLUDING WITHOUT LIMITATION DAMAGES FOR LOST PROFITS OR REVENUES, GOODWILL, WORK STOPPAGE, SECURITY BREACHES, VIRUSES, COMPUTER FAILURE OR MALFUNCTION, USE, DATA OR OTHER INTANGIBLE LOSSES OR COMMERCIAL DAMAGES, EVEN IF ANY OF SUCH PARTIES IS ADVISED OF THE POSSIBILITY OF SUCH LOSSES, ARISING UNDER OR IN CONNECTION WITH THE INFORMATION PROVIDED HEREIN OR ANY OTHER SUBJECT MATTER HEREOF.

The contents and appearance of this report are Copyrighted FactSet CallStreet, LLC 2020 CallStreet and FactSet CallStreet, LLC are trademarks and service marks of FactSet CallStreet, LLC. All other trademarks mentioned are trademarks of their respective companies. All rights reserved.