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Cardiovascular Systems, Inc. (CSII)

Q1 2021 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Ladies and gentlemen, thank you for standing by, and welcome to the Cardiovascular Systems, Inc. Fiscal Year 2021 First Quarter Earnings Conference Call. At this time, all participants are in a listen-only mode. After the speakers' presentation, there will be a question-and-answer session. [Operator Instructions]

I would now like to hand the conference over to Mr. Jack Nielsen. Thank you. Please go ahead, sir.

Jack E. Nielsen

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

Thank you, Kavita. Good afternoon and welcome to our fiscal 2021 first 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 first quarter results. You may find a copy of this release on the Investor Relations section of our corporate website. Here you may also find an earnings presentation that includes additional results for our performance and outlook. In a few moments, CSI management will discuss results for our first quarter, which ended on September 30th, 2020. 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. In particular, the COVID-19 pandemic has created risks and uncertainties for our business, results of operations, financial condition and prospects which we will discuss on this call. 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 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 and thank you for joining us today. I hope that you and your families are healthy and persevering through this pandemic. Today, we reported fiscal 2021 first quarter revenue of $60.5 million which represents a 6% decrease compared to Q1 of last year, but a sequential quarterly increase of 42% compared to the fourth quarter of fiscal 2020. In the US, strong sequential growth in peripheral and coronary helped drive domestic revenue of $58.8 million or 96% of domestic revenue in Q1 last year. Although our results were negatively impacted by the pandemic, we did see consistent improvement throughout the quarter with atherectomy procedure volumes recovering faster than expected. Similar to last quarter, our peripheral franchise performed better than expected reflecting a positive mix of non-elective procedures for critical limb ischemia, increased adoption at OBLs and claudicant procedures recovered faster than expected as hospitals and OBLs most likely worked through some backlog early in the quarter. Peripheral units increased 40% sequentially and nearly recovered to pre-COVID levels at 97% of last year's levels.

The recovery in coronary procedures is also better than expected with consistent improvement throughout the quarter reflecting very favorable trends in the patient referral channels and the indispensable attributes of orbital atherectomy in the treatment of patients with severely calcified coronary lesions. We are encouraged that the Q1 coronary units increased 63% sequentially and finished at 94% of Q1 last year. Despite the challenges of COVID-19, our US business is sustaining a healthy cadence of sequential organic growth. Our Q1 orbital atherectomy unit sales accurately reflect the number of procedures performed during the quarter demonstrating the robust demand for our products. International revenue of $1.7 million was negatively impacted by the pandemic and declined 42% compared to last year. Our ability to enroll new accounts and drive adoption outside the United States is hindered by international travel restrictions that began last February.

Turning to the P&L, we continue to successfully manage our business during this period, steady production volumes, favorable sales mix and continued cost reduction initiatives helped drive 79% margins during the quarter. In addition, we reduced our operating expenses 14% compared to last year. The combination of stronger revenues, improving gross margins and lower expenses resulted in over $4 million of adjusted EBITDA in Q1; an improvement of $14.9 million versus last quarter.

So, in summary, our business is strong. We experienced a robust recovery in Q1 and we're off to a great start in fiscal 2021. In a moment, Rhonda will provide highlights regarding our commercial progress, but first, Jeff will provide you with details regarding our financial results and our second quarter revenue guidance. Jeff?

Jeffrey S. Points

Chief Financial Officer, Cardiovascular Systems, Inc.

Thank you, Scott, and good afternoon, everyone. As Scott mentioned, first quarter revenue of $60.5 million represented a 6% decline compared to last year. Compared to fourth quarter last year, revenues increased 42%. In total, we sold 20,000 atherectomy devices during the quarter which also represented a 6% decrease compared to last year. Worldwide peripheral revenue decreased 6% to $42.9 million. Worldwide coronary revenue decreased 7% to $17.6 million.

The revenue generated in the United States and international markets was as follows. Total US revenue decreased 4% to $58.8 million. Domestically, peripheral revenue decreased 5%. Domestic coronary revenues declined 2%. International revenue decreased 42% to $1.7 million. We were particularly encouraged by the improvement in our gross profit margin. We've taken significant steps to ensure the safety and security of our manufacturing employees and both of our production sites have run with minimal disruption throughout the COVID pandemic. Steady production volumes, favorable sales mix and continued cost reduction measures resulted in gross margin above 79% for the first quarter of fiscal 2021.

Operating expenses of $49.6 million decreased $8.1 million or 14% compared to last year. SG&A expenses declined $6.5 million compared to last year due to actions taken to reduce variable spending. R&D expenses decreased approximately $1.7 million versus last year due primarily to lower expenses related to the temporary pause of our ECLIPSE clinical trial. First quarter net loss was $2.1 million. Adjusted EBITDA was $4.3 million. On the balance sheet, we ended the quarter with nearly $223 million in cash and marketable securities and no long term debt. That concludes my review of Q1 results.

I will now provide some commentary on what to expect in the second quarter of fiscal 2021. As we discussed our expectations for Q2, please note that we remain in a rapidly changing environment and we are monitoring several models that predict various scenarios for resurgence in the severity and duration of the COVID-19 outbreak. Although we are concerned by the recent spike in COVID cases and hospitalizations occurring across the United States, we believe that most healthcare facilities around the country are better prepared to manage a resurgence of the virus. Our customers report that they have adapted to the pandemic and are successfully performing our procedures while also caring for patients hospitalized with COVID-19. After considering all the variances introduced by the pandemic, we are expecting procedure stabilization consistent with the assumptions communicated in May and August with Q2 sales approaching 2019 levels. With that in mind, our second quarter revenue guidance of $63 million to $67 million represents sequential revenue growth of 4% to 11% compared to Q1. This range also represents approximately 92% to 98% of our Q2 revenue one year ago.

Procedure volumes were consistently strong throughout Q1, and as Scott said earlier, our worldwide revenue of $60.5 million was approximately 94% of Q1 last year. When we consider the impact of COVID-19 on our second quarter, we believe that our revenue will modestly improve and return to pre-COVID levels by the end of second quarter. Please note that the international commercial development will remain negatively impacted due to resurgence of cases in Europe, newly imposed lockdowns and travel restrictions. As a result, our international business especially operations outside of Japan are expected to be lower than Q2 last year.

So taken in total, we expect that worldwide revenue in Q2 will land at about the same range of approximately 95% of Q2 last year, and this is the basis for our revenue guidance. Gross margins are expected to remain in the 78% to 79% range. Q2 operating expenses are forecasted to be in the range of $52 million to $54 million. This represents a decline of approximately 7% to 10% from the prior year. We have resumed the enrollment of patients in our ECLIPSE trial and that will modestly increase R&D expenses in Q2. However, until procedures return to normal levels, we intend to maintain several of the business continuity plans we implemented in March which reduced operating expenses and capital expenditures across the business. On the bottom line, we anticipate a Q2 net loss of $1 million to $3 million and to generate positive adjusted EBITDA.

That concludes my prepared comments. I would be happy to answer your questions during Q&A. Rhonda will now discuss our commercial developments. Rhonda?

Rhonda J. Robb

Chief Operating Officer, Cardiovascular Systems, Inc.

Thank you, Jeff and good afternoon everyone. As you just heard from Jeff, Q1 was a strong quarter as we continue the recovery from the impact of COVID-19. The strength in domestic, organic procedure volumes improved throughout the quarter and we are pleased with our momentum. In Q1, our domestic peripheral business decreased only 5% compared to last year. As we forecasted last May, OBLs continue to lead the recovery in atherectomy. OBL revenue accounted for 29% of our peripheral revenues during the quarter and revenue at the site of service increased 4% compared to last year and 40% sequentially. Our hospital site of service also improved sequentially at 41%. However, it has not yet returned entirely to pre-COVID levels.

Strong sequential growth in our peripheral hospital segment was driven by the increased utilization of exchangeable. Purchase of an extra cartridge for multi-level disease is nearly 20% of our exchangeable unit volume. And as we anticipated, many physicians have become keen on providing full leg revascularization in one procedure, especially during this pandemic. We continued to achieve a meaningful ASP uplift to capture the value of this important innovation as well as extra revenue per case when a second cartridge is used.

Our performance in coronary was even better, increasing 63% sequentially compared to Q4. This occurred as a referral channel rebounded as patients anxiety [indiscernible] (00:13:11) and as procedure volumes increased nationwide. In addition, we continue to make great progress selling coronary support products. Our reps were granted increasing access to the cath labs throughout the quarter and we generated $543 of incremental revenue for every coronary device sold. Increased procedure volumes and higher revenue per coronary procedure resulted in US coronary revenues declining only 2% compared to last year. International revenues declined 42% to $1.7 million most of which was generated in Japan. As Scott mentioned, COVID has impacted our ability to travel and train and educate new accounts, and while our training ability slowed in Japan, we were pleased with a rebound in case volumes and increased penetration in existing sites throughout the quarter.

Looking ahead to Q2, we are forecasting stronger organic procedure volume in all types of service, increasing use of exchangeable and revenue per coronary procedure moving above $550. Of course, all of this is heavily dependent upon COVID case and ICU utilization trends, continued rep access to hospitals, and the maintenance of complex and more elective procedures. COVID has been a catalyst for change driving creative solutions for digital patient engagement, virtual medical education, remote medical education, and shift to alternative types of care like the OBL. As I highlighted last quarter, CSI pivoted with velocity in all communications and educational programming to reach our customers digitally, and this quarter was a high point in terms of our visibility at major conferences like NCVH with the REACH data release.

Additionally, we reached nearly 700 providers in the quarter through our virtual education programming and attracted over 200,000 visits to our Take A Stand website and 7,900 visits to our physician finder. We are also seeing the societies and organizations increasing their focus on the pandemic with AHA launching a Health Equity Now campaign, highlighting the disparities in care for diabetic patients including how PAD related amputations disproportionately affect people of color. SCAI launched Seconds Still Count, an initiative to address patient anxiety and the importance of seeking treatment and the cardiovascular coalition has activated a new bill that has been introduced in the house aimed at reducing amputations and emphasizing the importance of screening and imaging for patients with PAD. There is momentum in the peripheral field and these are all very positive developments for driving a standard of PAD care that starts with earlier screening and diagnosis and supports greater use of revascularization in lieu of primary amputation for CLI patients.

Transitioning to reimbursement; as many of you know, the lower endovascular revascularization or LER code set was expected to be an agenda item at the CPT panel meeting last month until it was withdrawn in late-

September. The next CPT panel meeting will be held in February and the agenda for this meeting will be issued on December 4th. If it is on the agenda in February, the very earliest and new set of LER codes would be available is calendar 2023. As we've been saying all along, this can be a complicated and long process which may not be resolved until 2024 or beyond. When these codes are reviewed, we believe that the reimbursement levels for the patients with complex lesions that we treat, many of whom are CLI patients with limited treatment alternatives, will not be materially affected and may even be improved. Moreover, as this process improves, CSI will continue to advance long term evidence reinforcing the clinical and economic value of OAS as definitive therapy as highlighted in the many recent LIBERTY applications and REACH PDI data release.

In the meantime, reimbursement for both coronary and peripheral remained positive. But the end patient final rule for calendar 2021 and the proposed outpatient reimbursement, we estimate that the weighted impact to our atherectomy business would be an increase of about 0.5% in peripheral and an increase to coronary of about 2%; so across all of our procedures, calendar 2021 looks to be another year of stable to increasing reimbursement.

Another topic of interest of the recent coronary data presented at TCT. At TCT we saw some very important real world data on OAS presented by [indiscernible] (00:17:43) from Mount Sinai in Miami; she presented data on over 500 real world patients with severely calcified cardiac disease patients; patients with lesions up to [ph] 16 millimeters (00:17:52) in length with over half falling in the category of ACC/AHA Type C grouping being the most difficult anatomy. Results showed 100% procedure success with an exceptional [indiscernible] (00:18:05) with less than 1% component and geographic complication rates. This study expands our evidence demonstrating a safe effective use of orbital atherectomy to treat real world complex patient population. With 11 studies tracking over 2200 patients today, CSI continues to extend its leadership in the development of medical evidence for the treatment of patients with severe coronary artery disease. And our technology safely works because of its unique dual mechanism of action [indiscernible] (00:18:33) and removes calcium from the lumen while uniquely protecting healthy tissue; the other TCT development with CAD 3.

Now, IVL has been positioned as safe, effective and easy to use, and the CAD 3 data shows us that IVL may not be any of these. First, there is no safety advantage. Vessel perforation and dissections, evidence of embolism with patients coding to the [indiscernible] (00:19:02) and even acute STEMI thrombolysis was observed and the data raises some meaningful concerns. IVL [indiscernible] (00:19:10) calcium in a third of the lesions and the device was difficult to use with long and highly variable procedure times. Finally, there's no 12-month data even though CAD 1 and CAD 2 were completed years ago. So overall, we do not view the positive entry of this – possible entry of this technology as a near-term threat to orbital atherectomy.

I'll close with some key events for CSI in Q2 and the back half of the year. As Jeff mentioned, we've restarted enrolment in ECLIPSE, our 2,000 randomized clinical trial in coronary. Later in our fiscal year, we plan to launch a series of peripheral products which will expand our peripheral interventional support devices considerably and add further revenue per case. These products include our WIRION embolic protection device, a full line of angioplasty balloons and additional catheters. Plus, we will introduce a new coronary specialty balloon to expand our complex coronary portfolio. We also anticipate CE Mark approval for our coronary Diamondback device this fiscal year. And finally, we continue to plan for first in-human experience for our percutaneous ventricular assist device later in fiscal 21; so several exciting developments both in Q2 and in the remainder of the year. I look forward to updating you on our progress. As always, the timing of each of these milestones represents our best estimates at this time; naturally COVID-19 and other factors could result in changes at the timing of these events.

That concludes my prepared remarks. I'll now turn the call back to Scott for his closing comments.

Scott R. Ward

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

Thank you, Rhonda. I will close today by first offering a few thoughts regarding our guidance. As Jeff noted, our guidance reflects the momentum that we have established in the market balanced by some caution emanating from the resurgence of COVID-19 cases and hospitalizations. We have provided guidance of $63 million to $67 million and here's how we think about our performance across that range. If domestic procedure volumes continue throughout the quarter at the current rate of about 95% of prior year, then we should land in the middle of the range. If the resurgence in coronavirus cases reduces ICU bed capacity in several key geographies, then Q2 revenues will be towards the lower end of the range. And finally, if the healthcare system remains resilient and procedure volumes return to pre-COVID levels later this quarter, then we could achieve the upper end of the range.

Looking ahead, the quarterly comparisons in the back half of this year may be a bit complicated due to impact of COVID-19. I think the best way to think about our back half is that we currently anticipate delivering sequential quarterly revenue growth in Q3 and Q4 with sustained momentum going into fiscal 2022. So, hopefully, you can appreciate that this remains a challenging environment for us to forecast and we will do our best to keep you updated as these circumstances dictate.

Turning to another challenging environment, I am guessing that most everybody on this call is very relieved that this election cycle is well at least nearly over. Here at CSI, we are really encouraged by recent developments in Washington related to proposed legislation that mandates more appropriate care for patients with peripheral artery disease. CSI has long advocated to accelerate patient access to appropriate care for PAD and to address disparities in PAD healthcare. The incidence and demographics of PAD related amputations in the US is staggering and can no longer be ignored. 20 patients suffer from PAD and PAD expenses represent $80 billion per year in direct healthcare costs. As you might expect, amputations are the most expensive of all PAD related hospitalizations. Most alarming is that half of those receiving amputations don't even receive an angiogram. Even though, an angiogram will reduce the odds for amputation by 90%.

Further, disparities in care by race are alarming. For example, black Americans are three times more likely to screen positive for PAD and they are two times more likely to receive an amputation than Caucasians. Clearly this has to change. So we are pleased to see the Congress is beginning to take up this fight. New Jersey Representative, Donald Payne recently introduced the Amputation Reduction and Compassion Act which would cover PAD screening for at risk patients, require diagnostic testing prior to any non-traumatic leg amputation and allocate funds for a national PAD education campaign. We are hopeful that this bill will ultimately raise PAD awareness and significantly decrease the incidence of unnecessary amputations. CSI will continue to advocate on behalf of PAD patients in a variety of ways. In fact, we recently began a collaboration with the American Diabetes Association to increase PAD education to healthcare providers who treat diabetic patients and to advocate for legislation to prevent amputations. Since one in three diabetic patients over the age of 50 is likely to have PAD, the ADA is a natural partner for CSI and we look forward to collaborating with them in the future.

In closing, I think you can tell that we are encouraged by the strong financial results and the progress we delivered in Q1. These positive results can only be achieved because of the collective strength, passion and perseverance of our 800-plus CSI employees. This is a team that really puts the patient first. Our strong financial results originate from our patient focus, and in the first quarter this team helped save the lives or improved the quality of life for over 20,000 patients and their families. Let me take this moment to thank all of our CSI employees for their steadfast dedication to our patients and their continued focus on our key growth drivers as we navigate through this pandemic. For those of you on the call, we appreciate your continued interest in the CSI and we will now take your questions.

So, if the operator, Kavita, if you would please repeat the instructions, I will take questions at this time.

QUESTION AND ANSWER SECTION

Operator: [Operator Instructions] And our first question comes from Mike Matson with Needham & Company.

Mike Matson
Analyst, Needham & Co. LLC

Q

Hi. Thanks for taking my questions. So, I guess I'll start with the guidance. So, I think you kind of laid it out in the good deal of detail there, but I just want to ask why [indiscernible] (00:26:23) more of an improvement from where you were in the first quarter in terms of your growth?

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

A

Well Mike, as I think actually we are, we're showing pretty strong sequential growth even quarter-over-quarter with this guidance. I think at this time what makes this really difficult for us to forecast is the impact that the coronavirus may have on our business. And I think it's unsettling to see this rapid resurgence in the cases and have that actually be also followed by an increase in hospitalizations. So what we're watching closely there is ICU bed capacity. And if we begin to see ICU bed capacity decline precipitously, in particular in coronary, our experience has been that that will reduce the performance of our performance of our coronary procedures. The reason is that up for these reason is that, for these severe coronary cases, we need ICU bed backup. And if we don't have that, a lot of hospitals won't perform those cases. So, they'll put them off and postpone them and that will result in the same types of issues that we saw in our Q4 and in Q1. So, that is principally the circumstance there. We're pleased with the momentum we see in the market. We're pleased with the success that we have had. There is nothing fundamental in the market that's impacting our ability to penetrate, or let's say, to gain adoption, but I think we just continue to be quite concerned about the impact of the coronavirus.

Mike Matson
Analyst, Needham & Co. LLC

Q

Thanks. And then, in the peripheral support products, WIRION, I thought that was supposed to be launched in the September quarter. Was that delay due to COVID or for some other reason?

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

A

Yeah. Thank you for the question. Yeah. I think on our last call, we said it would be launched in the fall timeframe and we are still working with regulatory authorities. We actually made an improvement to the device and we're working through that process right now and looking opportunistically at actually launching all of the peripheral support devices together in the latter part of the year, so being opportunistic on timing there as well.

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay. Thanks.

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

Thanks, Mike.

Operator: And our next question comes from Danielle Antalffy with SVB Leerink.

Danielle Antalffy
Analyst, SVB Leerink LLC
Q

Hi. Good afternoon, everyone. Thanks so much for taking the question and congrats on the strong...

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

Hi, Danielle.

Danielle Antalffy
Analyst, SVB Leerink LLC
Q

Hi. Strong quarter; just a question on the fiscal Q2 guidance, the range is a bit wider than, I think, you guys normally guide to. Can you talk about what's driving that to the low and the high end? I assume there's some component of COVID uncertainty playing into that? And then I'll ask my follow up now. When we think about the referral funnel for PAD and coronary procedures, how would you parse out new patients versus backlog work down in the quarter and what's reflected in the Q2 guidance? Is that mostly new patients? Thanks so much.

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

Danielle, I might ask you to repeat the second half of your question here in a moment, but just in terms of the guidance, I did address that in my remarks earlier, but let me just kind of repeat the way we're thinking about that. Last quarter, we said 55 to 58 which was about a $3 million spread. And this quarter we're saying 63 to 67 which is a $4 million spread and you're right. I mean that is fairly wide. I think what we're trying to do is to give you our best thinking regarding how this quarter could land while we take into consideration the potential impact of COVID-19 on our business. It is not easy and I'd unfortunately – this situation just changes every day. And we see – if you go back into September for example, we would probably arrive at the conclusion that the virus would be having very little impact on our business. And now as we are here in the early part of November, we can see this dramatic surge in cases that are occurring across the US and that is in fact translating into an increased rate of hospitalization which ultimately can impact ICU bed capacity. Those are the variables and the factors that we take into consideration as we try then to establish guidance for this coming quarter.

And as I said in my comments, if we think about that, we kind of are expecting with all of those ups and downs considered that we would remain at above that 95% of prior year level, when we think about the quarter in total. As Jeff said, by the end of the quarter we're anticipating our run rate to be back to pre-COVID levels. Now, the variance on that is, if we see a resurgence in the coronavirus and if that actually reduces ICU bed capacity in some of our key geographies, then we may see our performance trail towards that lower end of our guidance. If on the other hand, the coronavirus has really not much impact and we see that the healthcare system is able to manage the COVID-19 and perform these types of cases, then we'll probably trend more towards the higher end of our guidance. So I hope that's helpful. The guidance is really bounded nearly completely by the impact of the virus on our business. I'm sorry. I'm going to ask you to repeat the second question, Danielle, I'm sorry.

Danielle Antalffy
Analyst, SVB Leerink LLC

Q

No. No, not a problem. Just curious about where you guys think you are from a referral channel perspective. I think it's probably more relevant in peripheral than coronary, but and sort of parsing out backlog work down in the quarter versus new patients, and what you're expecting in Q2? Like will Q2 be almost entirely new patients into the system at this point?

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

A

Yes. Okay. So very good question; and let me break that up by both peripheral and coronary. In our peripheral segment, we have seen just consistent adoption of our product, and in fact continued growth in the use of orbital atherectomy for the treatment of critical limb ischemia. If you recall, in our Q4 we had reported that we were seeing a reduction or some impact in the referral channels for our claudicant patients. So the claudicant patient population we probably saw some bounce back and maybe a little bit of a snap back in our July results where we saw an increased treatment of claudicant patients. And that was probably the result of some pent up demand. That has stabilized out. And so I think at this point in time our peripheral units recovered to about 97% of prior year. And as Rhonda indicated, a lot of that growth is in the office-based labs. So our OBLs as we had indicated are leading the way and we are seeing that the coronavirus is most likely accelerating the migration of patients from the hospital setting to the OBL setting. So that is peripheral.

Now, in coronary, we had indicated earlier that we expected the coronary business recovery to look more like a Nike Swoosh. And in fact, that is what exactly what we're seeing and we were really pleased that throughout the course of the quarter, throughout the course of Q1, we just saw a consistent improvement in our coronary procedures. And we believe that is completely attributable to the recovery of the referral channel. And so to answer the second part of your question, as we look at Q2, we do think now this will be completely organic growth. We're not expecting any changes there. We don't expect that there would be any additional backlog that we would be treating. And in fact our business is really healthy right now and we're sustaining just a really good cadence of average daily sales and just a nice steady performance that is based nearly completely on organic sales. So as I commented, our sales very much reflect the procedures that are occurring in the market. We're really not seeing any return to hospitals or OBLs buying large volumes of devices. They continue to conserve their cash and are not buying in large volume. So, as a result, our results very much do reflect the procedures in the market.

Danielle Antalffy
Analyst, SVB Leerink LLC

Q

Thank you so much.

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

A

Thank you, Danielle.

Operator: And our next question comes from Mathew Blackman with Stifel.

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

Q

Good afternoon, everyone. Can you hear me okay?

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

A

Yes, Matt. Thank you.

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

Q

Maybe Scott, if you could just comment on the US recovery relative to sort of regional dynamics? Is that still sort of a regional specific or region specific recovery, or in the first quarter, was that more broad [indiscernible] (00:36:35) increase? And then I've got one quick follow-up after that.

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

A

Thank you. Yeah, the regional recovery actually came back pretty consistently across the market now. Now we had been seeing pretty asymmetric performance with the south and southeast and, to some degree, the western portion of the United States contributing stronger growth as the recovery in the northeast was slowed. The northeast is now very much back on track. And really we see our market across the United States performing fairly consistently. Recently in the Midwest, I would say we're monitoring pretty closely places like Wisconsin, where we are seeing a increased utilization of ICUs and we're watching that closely to see now if we begin to see an increase or an impact on sales in those states. At this time we're not seeing it, but that is largely because still up until now, hospitals are doing a pretty good job and simultaneously performing our cases while they also manage COVID-19 patients.

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

Q

Okay. That makes sense. And then just the follow-up; thinking about sort of the adoption ramp or the peripheral support portfolio, I know the magnitude of opportunity is larger, but do you think the pace or the scope of uptake we've seen with the coronary support portfolio is the right way to think about the pace of capturing this incremental revenue per procedure in peripheral or could it move faster or slower? Just help us think through that and thank you so much.

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

A

Yeah. Sure. Thank you, Matt. Our coronary business was slowed down a bit for our ISDs because we really have to struggle with hospitals to get through the contracting processes and that can take, in many cases, a year or longer. Now we've gone through that process in a lot of our major accounts and then with a lot of hospitals. So, as a result, we think that we can get our peripheral support devices on the shelves more quickly. We also have a large portion of our peripheral business within the office space lab setting where we really – if a physician decides to adopt our products, we should be able to get the products on the shelf there overnight. So, we do think that we can accelerate the adoption of our peripheral products in comparison to what happened in coronary. We did get to over $500 of revenue per procedure in coronary over a period of about two years and so that's a reasonable proxy for peripheral and we might be able to do it a little bit quicker.

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

Q

Thank you.

Operator: [Operator Instructions] Our next question comes from Mike Ott with Oppenheimer.

Mike Ott
Analyst, Oppenheimer & Co., Inc.

Q

Good afternoon and thanks for taking my questions. Just curious how a patient conversion times looking today versus pre-COVID?

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

A

Patient conversion times – can you explain that metric just for me, Mike. I'm sorry.

Mike Ott
Analyst, Oppenheimer & Co., Inc.

Q

Sure, Scott. Just from the time of my diagnosis to scheduling and completions...

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

A

I'm sorry. Okay.

Mike Ott
Analyst, Oppenheimer & Co., Inc.

Q

Sorry.

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

A

Right. Right. I think actually once again I'd segment that out into the three pieces of coronary peripheral CLI and peripheral claudicant patients. In our Q4 timeframe we saw those conversion times really elongating quite substantially because of just the issues in the referral channels with scheduling and the availability of support personnel and so on. I think throughout Q1 that consistently improved. And right now I think our conversion times are really back to normal in terms of the time that it takes for patients to move through the referral channel. And I think that's pretty consistent in all of our therapies. I really don't think that we see much of an impact in conversion times.

Mike Ott
Analyst, Oppenheimer & Co., Inc.

Q

That's great to hear. Thank you. And then also curious if you have any updated thoughts on the two camp decisions back in July and the two OBL patents specifically what it might mean for your product roadmap. Can you extend your willing to say?

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

A

Yeah, no we're not at this time disclosing our intent for our R&D programs related to the OBL. So I guess we're still holding on that.

Mike Ott
Analyst, Oppenheimer & Co., Inc.

Q

Okay, fair enough. Thanks so much, Scott.

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

A

Okay, Mike. Thank you.

Operator: And there are no further questions at this time. I'll turn the call back over to Mr. Scott Ward.

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

Okay, thank you, Kavita. So for everybody on the phone; thank you for your continued interest in CSI. We hope that you all continue to stay safe during this pandemic and as always we look forward to updating you on our progress in the future. Thanks everyone. Goodbye.

Operator: And that does conclude today's conference call. Thank you for your participation. You may now disconnect.