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Cardiovascular Systems, Inc. (CSII)

Q1 2022 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Hello, everyone, and welcome to the Cardiovascular Systems First Quarter Earnings Conference Call. My name is Juan and I will be coordinating your call today. [Operator Instructions]

I will now hand over to your host Jack Nielsen to begin. Jack, please go ahead.

John E. Nielsen

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

Thank you, Juan. Good morning, and welcome to our fiscal 2022 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.

This quarter, we moved our earnings call to the morning in order to avoid the multitude of medtech companies reporting quarterly results after the market close. It's our hope that this new time slot is more convenient and results in fewer scheduling conflicts for you.

Approximately three hours ago, we issued a press release announcing 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 supplement that includes additional details on our performance and outlook. In a few moments, CSI management will discuss results for the first quarter ended September 30, 2021. 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 operation, 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. Good morning, everyone, and thank you for joining us today. Today, we reported Q1 revenue of $58.4 million, a decline of 3.6% versus the prior year. Consistent with the 8-K notice that we issued in September, our procedure volumes were adversely impacted by hospital capacity constraints caused by the COVID Delta variant. The resurgence of COVID and the related staffing shortages disrupted referral patterns and had the largest impact in our procedures that are deemed to be more elective, such as the treatment of patients with lower acuity peripheral claudication.

The severity and duration of the COVID impact was greater than expected and was more pronounced due to the timing and geographic location of the Delta surge. Our procedure volumes in first quarter tend to be heavily weighted towards September. However, this year, ICU capacity was severely constrained throughout the south and the southeast region of the United States, which typically represents more than 50% of our revenue.

We do expect that some of these procedures will be recovered, and we are encouraged by improvement in recent trends, but the pace of the recovery is difficult to predict due to the dynamics of the Delta variant and the new variable introduced by the staffing shortages.

As a result, we are uncertain whether the COVID recovery will be in Q2 or later in the second half of our fiscal year. The financial guidance that we issued on August 4 did not contemplate an impact from COVID, because the waves of outbreaks experienced in fiscal 2021 caused transient sales declines, which were followed by a recovery and then a more normalized sales trends over the full 12-month period.

We anticipated that we would experience a similar trend in fiscal 2022. However, in the first quarter, the negative impact, due to the Delta variant, was larger than anticipated, and we do not expect this impact to normalize over the remainder of the fiscal year.

Although COVID remains the most important factor that is negatively impacting our business, we are also responding to an increasingly competitive environment, with new products and new players entering our markets and, following the recent issuance of the physician fee schedule, we are anticipating increased economic pressure for our customers who perform [ph] PDI (00:05:08) procedures in the office-based lab setting and, of course, this may cause a temporary disruption in the market as well.

As a result, we have reduced and widened our fiscal 2022 revenue guidance to reflect the uncertainty associated with our current revenue outlook. Despite the COVID impact, we are encouraged by the progress we are making in our commercial programs and our efforts to broaden our revenue streams.

In a few moments, Rhonda will provide an update on our commercial developments, and then Dr. Ryan Egeland will address our recent announcement regarding our first in-human experience with CVT's Coronary Everolimus Drug Coated Balloon.

But, first, Jeff will provide details regarding our financial results and guidance. Jeff?

Jeffrey S. Points

Chief Financial Officer, Cardiovascular Systems, Inc.

Thank you, Scott. Good morning, everyone. I will now provide a brief review of our Q1 financial results. Worldwide coronary revenue increased 10% to $19.4 million. In the US, coronary revenue increased 2% to $16.2 million. Outside the US, coronary revenue increased to $3.2 million as a result of continued strength in Japan, combined with the growing adoption of Coronary OAS in Europe.

Worldwide peripheral revenues decreased 9% to $39 million. In the US, peripheral revenue decreased 9%. Device revenue in hospitals decreased 16%, and device revenue in OBLs decreased about 1%. Peripheral support product revenue increased to $1.4 million.

Turning to expenses. Gross profit margin was 75.5%. This is reflective of lower volumes and a continued higher mix of ISD and international revenues. Operating expenses totaled $52.2 million. SG&A increased 4% compared

to the prior year, while R&D expenses increased $1 million. We anticipated these higher expenses given the COVID savings achieved in the prior year. Net loss was $8.6 million or $0.22 per share. We ended the quarter with $188 million in cash and marketable securities and no long-term borrowings. During Q1, we had a milestone payment associated with our strategic investment portfolio, and we'll have more of these payments in Q2, most notably related to our DCB programs.

Turning to our outlook. The COVID pandemic is not over, and uncertain market dynamics persist. Specifically, the timing of COVID recovery, staffing shortages, disrupted referral patterns, an increasingly competitive environment, and a reduction to the 2022 physician fee schedule that impacts our OBL customers are all expected to impact revenues for the remainder of fiscal 2022.

For the fiscal year ending June 30, 2022, we now forecast revenues in a range of $265 million to $285 million, representing 2% to 10% growth versus the prior year. Gross margins of approximately 75%, net loss in a range of 5% to 8% of revenues, and adjusted EBITDA in a range of 1% to 4% of revenues.

I will now turn the call over to Rhonda who will provide a commercial update.

Rhonda J. Robb

Chief Operating Officer, Cardiovascular Systems, Inc.

Thank you, Jeff. And good morning, everyone. Today, I will provide my thoughts regarding Q1 results, share some of the key drivers for fiscal 2022, and update you on recent reimbursement developments. Regarding Q1, we did see the momentum that we had established in Q4 decelerate in the face of another COVID surge. And as we have seen throughout much of the pandemic, the most significant weakness remains in the peripheral hospital segments of our business. While market research reveals that COVID remains a near-term headwind in select geographies, many of our customers are now anticipating backlogs of patients, and they believe it is just a matter of time before they return for treatment.

We are just now starting to see improvement in states like Florida and Texas, albeit the ramp in procedures appears to be slower than previous waves due to staffing issues and the need to normalize the full patient referral pipeline. The OBL segment of our business was less impacted than our hospital site of service where we saw a modest increase of 2% in procedures over last year. While the site of service is more resilient with patient referrals and patients showing up for their procedures, we still did experience a sequential impact from Q4 given the pandemic. Patient flow issues were less pronounced than in the hospital, however, staffing has been equally challenging. Competitive entrants have also recently targeted OBLs, and we are seeing increased and recent trialing of low-priced atherectomy device – devices for ATK claudicant patients.

Turning to coronary, US coronary revenue growth of 2% was driven by the continued adoption of our coronary support products and offset by a 2% decline in Coronary OAS procedures. We believe this decline to be primarily related to COVID with some competitive impact of introduction and trialing of a new balloon expanded into a number of our accounts. As stated previously, we largely see these cases as complementary given the increased use of imaging to discern lesion morphology, which enables proper patient selection. And that is why we continue to focus on driving adoption of orbital atherectomy in hospitals that treat complex coronary artery disease where imaging is used to distinguish calcium. We have distinct use and severely calcified lesions such as intimal calcium, nodular and eccentric calcium, lung lesions and multivessel disease, and of course, heavy stenosis where a balloon simply won't cross.

Revenue per coronary procedure continues to grow. During Q1, we sold $756 of support products for every Coronary OAS sold. The increase quarter-over-quarter shows how resilient our ISDs were even as coronary

procedures modestly declined. Our expanded contracts are also opening new doors for our representatives to sell. Recent agreements have enabled our representatives access to sell our ISD portfolio in over 50% of US health system. In total, sales of coronary support products were $2.7 million in the quarter. Our abilities for our customer with case coverage was muted in Q1 as a result of access restrictions in many facilities. Nevertheless, we continue to train new users and coronary fellows on the use of our product. And in Q1, we certified 80 new coronary users. This rate is consistent with prior quarters and is a leading indicator of our continued progress to grow OAS beyond the pandemic.

Outside the US, Q1 international revenues of $3.3 million demonstrated the strength of our business in Japan where we now have 44% market share. We are seeing increased demand for our product in Europe, where we are actually ahead of the pace of adoption that we saw in Japan. In addition, we have launched in Canada and Australia.

We continue to experience strong demand for physician training and certification in all of our international markets. We certified nearly 80 coronary interventionalists outside the United States during the quarter, exclusively using remote training and case support. Again, we see new user certifications as an important leading indicator for growth.

Shifting to Q2, we believe we are poised to resume sequential growth. This quarter, we will continue the training of new PAD accounts and new users to deepen penetration in large hospital systems in an OBL. We will also initiate the full commercial launch of the ViperCross peripheral catheter. So now, we offer a full array of peripheral balloons, guide wires, and catheters, and we continue to believe that these specialty support products will experience strong adoption going forward.

For our coronary business, we are also focused on new accounts and new users and our training pipeline has expanded significantly, and new user certifications will be a growth driver in the quarter along with ISDs and revenue per case. For both our coronary and peripheral businesses, we will leverage new contracts for OAS and ISD access and to deepen penetration.

Turning to international, we expect strong revenue growth, and we will plan to launch OAS in several countries throughout Europe in Q2 and beyond, bringing us close to 30 countries by our fiscal year-end.

Now, turning to reimbursement. Reimbursement in the US is complex with a lot of changes this year, mostly positive. Starting with coronary, both inpatient and outpatient reimbursement increased for a weighted impact of 2.2%. In peripheral, we see increases across all sites of service except the OBL. It is notable that even with the decrease, the weighted impact of all the changes across all sites of service, including the OBL, is a reduction of 1.9% for peripheral.

So let's look at the OBL changes more closely. The 2022 physician fee schedule results in a decrease of 14.5% for OBL atherectomy procedures effective January 1. While a drug reduction, this is actually better than expected as the proposed rule contemplated an approximate 23.5% reduction. This continues the trend of ongoing CMS reimbursement pressure on this site of service. We believe this could result in further consolidation of OBLs and/or impact adoption of atherectomy for underserved PAD patient population.

This trend may also introduce new dynamics between treating patients in the hospital, OBL, and ASC as hospital outpatients and ASC sites of service become more economically attractive. In anticipation of these trends, CSI has developed and will be launching a new program to help our OBL customers mitigate reimbursement challenges and enable CSI to support high volume sites that will continue treating complex patients where our

technology is focused. This program will be focused in areas like volume-based contracts, inventory management, digital products and services, clinical support, claims assistant, and business consulting to help drive efficiencies and throughput.

So, in sum for our business, 75% to 80% of our business is seeing an increase of between 2% and 2.6%, showing continued stable and positive reimbursement for our coronary procedures and for our peripheral procedures with the exception of the OBL. The overall weighted impact of all of the reimbursement changes to CSI in 2022 is minus 0.9%.

Finally, as you know, the lower extremity revascularization codes were reviewed by the CPT Editorial Panel last month, and the panel recently published that the LER Code Review has once again been postponed. So, at this point, we believe the societies will continue to work with the panel to restructure the code set, and it remains uncertain when the panel will review these codes again. Our estimate is that it will be 2024 or later before these new codes are implemented.

That completes my prepared remarks, and I'll turn it over to Ryan.

Ryan D. Egeland

Chief Medical Officer, Cardiovascular Systems, Inc.

Thank you, Rhonda, and good morning. Last week, we announced the first-in-human experience with the Coronary Everolimus Drug Coated Balloon that we're developing with Chansu Vascular Technologies or CVT. We, at CSI, and our colleagues at CVT are incredibly pleased with the rapid pace of this program with this first-in-human milestone being completed almost two years earlier than we originally estimated.

Everolimus, the active drug in CVT's DCB formulation, acts as a cytostatic agent to reduce tissue hyperplasia and associated restenosis and has a long history of safety and efficacy in coronary drug-eluting stent applications.

Physicians are increasingly interested in using this agent for treating complex coronary artery disease and associated in stent restenosis, small vessel, and bifurcated lesions. As we reported last week, CVT conducted the first human use of its DCB in a case of in-stent restenosis in the left anterior descending coronary artery. The treating physician reported a successful procedure and emphasized the excellent crossability and deliverability of CVT's balloon.

Looking ahead, CVT will enroll up to 50 patients at 10 to 15 sites across Europe over the next 12 months. A six-month follow-up data from these procedures will be used to support an IDE submission for a US pivotal study, which will begin approximately two years from now.

In parallel to these exceptional coronary achievements, we're delighted to report that CVT continues to meet and exceed key peripheral DCB program milestones as well. I look forward to providing further updates on this program in the coming year.

Scott, I'll now hand it back to you for your final comments.

Scott R. Ward

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

Thank you, Ryan. Our DCB program is a great example of the progress we are making to diversify our business and broaden our revenue streams. And while the COVID headwinds are affecting our near-term financial results, they are not diminishing our drive to innovate and develop a long-term pipeline of new products.

As we have indicated previously, we plan to introduce a new line of coronary scoring balloons and a large vessel crown later this fiscal year, as well as a full line of CTO catheters in fiscal 2023. The large vessel crown will be available on all of our peripheral atherectomy platforms and is designed to treat soft and mixed plaque, providing greater luminal gain in the larger vessels above the knee.

We continue to make excellent progress on the hemodynamic support device and continue to target a first in-human experience later this fiscal year. In addition, we have initiated strategic investments for the development of other new products, specifically targeting fast-growth segments of the peripheral and coronary markets. We intend to share details of those programs with you in the coming months. Like everyone else, we are frustrated by the resurgence of the COVID headwinds, the dynamics of the Delta variant, and the growing shortage of healthcare workers introduces a higher degree of uncertainty and volatility that is now reflected in our fiscal 2022 revenue guidance.

To be clear, COVID has imposed the greatest impact on our business. And here is how I frame up our revenue guidance of $265 million to $285 million over the remainder of the fiscal year. If we see sustained improvement in COVID and staffing conditions combined with strong sales execution and continued success in our international markets, we could deliver revenue performance in the upper end of that range. The midpoint of this range reflects domestic procedure volumes at the current level, stable healthcare worker staffing, stable US market share, and modest growth in our international markets.

While new COVID surges, deteriorating healthcare staffing and decelerating US market share could reduce our performance to the lower end of the range I described. Although we don't expect a dramatic rebound in the near term, we do believe that COVID is a transient challenge and that our orbital atherectomy business will return to its historical double-digit growth trajectory.

I would like to thank our CSI employees for their perseverance, dedication, and compassion in delivering exceptional support to our customers and patients during this extraordinary time. I would also like to thank all of you for your continued interest in CSI, and we will now take your questions.

Juan, would you please repeat the instructions?

QUESTION AND ANSWER SECTION

Operator: [Operator Instructions] And our first question comes from Mathew Blackman from Stifel. Please, Mathew, go ahead.

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

Q

Good morning, everybody. Thanks for taking my questions. Maybe to start and maybe this is for Scott or Jeff, just thinking about the cadence and thinking about the fiscal second quarter, should we expect any sequential growth or should we think more like 2Q looking like 1Q? And then I have a couple of follow-ups.

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

A

Thank you for the question, Matt. Yes, I think our second quarter will be stronger than our first quarter, and we anticipate continuing momentum as we head through the second half of this fiscal year.

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

Q

Okay. I appreciate that. And then I'm curious, you obviously called out 50% of the business in geographies that were heavily impacted by COVID. Is it possible, quantitatively or qualitatively, sort of talk about the growth you saw in that 50% of the business versus maybe the 50% of the business in the US that's outside of those regions? Just we can get a sense of the impact of COVID.

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

A

Yeah. It's difficult to segment it in that way because the other states were not necessarily unaffected by COVID, so it depends where you kind of draw the line if you anticipate, let's say, that states that had greater than 80% ICU utilization, which represented largely the south and southeast, that, in those states, we saw a larger or a disproportionately larger reduction in our sales. In states that were less impacted, our business did better, although we continue to see pressure even in that segment of our business as well.

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

Q

All right. I'll squeeze one last one in for Jeff. And I apologize if you've mentioned this in the prepared remarks. But the GM – the gross margin guide doesn't play, I think, a step down from the first quarter. And so what are you anticipating in terms of what's driving that drag if you call that out and how we should think about the pace of gross margin as we sort of work our way through fiscal 2022? Thanks so much.

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

A

Yeah. Thanks, Matt, for the question. In my guidance, I did provide 75% for the year. I think it's going to be pretty consistent and balanced at about 75% for each quarter here moving forward. And the biggest reason for that reduction from the previous guidance I provided was really the mix. We're just seeing just the higher proportion of ISD and international revenues. Of course, that's a bit of a lower margin segment. And then also just the lower

overall revenues, I think, is also pulling that down slightly. So I think you'll see a balanced 75% really throughout the rest of the year.

Operator: Thank you. The next question comes from Chris Pasquale from Guggenheim Securities. Please, Chris, go ahead.

Chris Pasquale
Analyst, Guggenheim Securities LLC

Q

Thanks. Scott, you called out competitive pressure in a way that I don't think I've heard you do previously. It sounded like it was hitting you on really two different fronts across peripheral and coronary. Can you talk a little bit more about what you're seeing and what portion of your procedure volume in those segments, you think, is really vulnerable to trialing of some of these other technologies versus something that, you think, OAS is really uniquely suited to deal with?

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

A

Yeah. Thanks for the question, Chris. As we consider our market share right now, we are seeing new players and new products enter our market in our peripheral segment, in both in-hospital and in the OBL, and we're also obviously seeing a renewed or a new competitive pressure in our coronary business.

So, let me take the peripheral segment first. In peripheral, we are seeing a number of new entrants that are coming in with lower cost and, let's say, more economically favorable alternatives, and these products are typically being trialed for the treatment of patients that have a lower acuity claudication.

We expect that this is a transient impact largely because of the unique nature of our device. You know that we have a very differentiated product. We focus on the treatment of these severely calcified lesions. We've generally sustained our market share in the in-hospital segment of peripheral in that high 30% range, and we anticipate that that will continue mainly because our technology treats a very unique pathology, and that is principally focused. As you know, 60% of our revenue comes from below the knee and is largely focused on the treatment of patients that have a critical limb ischemia. So, as we continue to focus on these higher volume accounts that are also focusing on more complex patients, we're quite confident that we will continue to sustain a strong market share in those segments.

Turning to coronary, we are seeing increased trialing of the IVL balloons. I think the reimbursement improvements have resulted -- let's say, have removed some of the economic barriers and have increased the amount of trialing that is being performed. However, we believe that our device, and in fact, atherectomy, still has a very unique indication for use in the care of patients that have complex coronary artery disease. We know, for example, that it is very important to remove calcium from the lumen. We know it's very important to change the compliance of a vessel so that you get really good position of a stent when you place that stent.

So, we are very confident that, over time, this trialing will level out and that, indeed, we'll continue to get our cases and that we expect to really sustain that low-double-digit growth that you've come to expect from us. I think we can continue to perform in our coronary business in that 10% to 13% to 15% growth range over time. Obviously, right now, we're being impacted by a number of macro environmental variables that are impacting our business and our ability to grow. But over time, and in particular, as we head into the second half of this fiscal year, we expect that these trends will begin to normalize.

Chris Pasquale
Analyst, Guggenheim Securities LLC

Q

Thanks for that. And then, I think the other piece that was obviously incremental this quarter was on the reimbursement front with OBLs. Can you talk a little bit about what you're hearing from customers now that the final rule is out and the idea that potentially this could be the first in several years, so it's not the first for peripheral but based on the changes to the codes that were made, it seems like it's going to a multiyear process of kind of rightsizing this portion of the payment structure. How does that impact the viability of that piece of the business over time? Thank you.

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

A

Thanks, Chris. I think it's still early days for us to really interpret the impact of these – the physician fee schedule. Our customers are very frustrated. Customers that performed cases in office-based labs have incurred about 5% reductions on an annual basis over the course of the past few years due to the expense – the direct expense reduction that was implemented by CMS in 2019. The origin of that frustration really comes from their commitment to the treatment of their patients.

This PAD continues to be a really important epidemic in our country. The incidence and the demographics of this disease are staggering. 20 million patients have PAD in the United States, 2 million with CLI, and that's growing in a high-single-digit rate. There's – it seems unbelievable at this time that CMS would make [ph] and it would on an (00:30:53) effort to reduce patient access to care, especially in an environment where there's such important disparities in care. Black Americans are two times more likely to receive an amputation than Caucasians.

We have a situation where the office-based labs are critically important to deal with the volume of patients that need to be treated. And, yet, in that environment, policymakers have chosen to significantly reduce payment in that site of service. Quite frankly, at this point, I think I expect to see more patients return to the hospital where care is obviously more expensive. We do expect to see consolidation in the OBL segment with some of the smaller OBLs consolidating into larger OBLs, and we do expect to see these large OBLs that focus on high volume and more complex patients which, by the way, is our segment of the market. We expect them to probably be more successful over time. And as Rhonda described, we have been implementing initiatives over the course of the past several years that will improve our positioning with those high volume accounts, and will also improve their ability to continue to provide care for large volumes of patients.

So, that's where we're headed. Certainly, this reimbursement environment has been a challenge over the past few years. This latest PFS ruling now indicates that it will continue to be for the next several years. We can no longer assume that reimbursement is just going to get better. It's continuing -- it's going to continue to be a challenge in the OBL, and we now have to work with our customers to assure that they're able really to care for their patients, and that's our focus. Hope that answers your question, Chris.

Chris Pasquale
Analyst, Guggenheim Securities LLC

Q

Yeah, it does. Thank you.

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

A

Okay. Thank you.

Operator: Thank you. The next question comes from Danielle Antalffy from SVB Leerink. Please, Danielle, go ahead.

Danielle Antalffy
Analyst, SVB Leerink LLC

Q

Hey. Good morning, everyone. Thanks for taking the question. Just a follow-up on Chris's question there regarding what's going to happen with the OBLs. I mean, I guess we have to see how this all transpires. But if, in fact, a higher proportion of these cases shift back into the hospital, can you talk a little bit about your competitive differentiation in a hospital [ph] site (00:33:21) like the OBL was an area where CSI was very competitively differentiated from the service and support perspective. Is the hospital any different? How do we think about how that dynamic changes if more of these procedures go into the hospital? And I have one follow-up.

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

A

Yeah. About 20% to 25% of our overall CSI revenue is generated in the office space lab. As Rhonda had indicated, it is [Technical Difficulty] (00:33:54) to the peripheral hospital segment, we have, of course, the leading market share in that segment, which has been fairly stable in that high 30% rate. So as cases move back to the hospital, we would expect to actually probably gain more of those cases in an environment where we have more favorable pricing. And obviously, we're very well positioned with a very strong sales force. And we're in a position to support about 70% of our cases.

I think our concern about patients migrating back to the hospital is that there just simply isn't capacity in the hospital to deal with this epidemic of PAD that exists today. And so while patients may try to – while care may return to the hospital setting, the ability to handle the number of patients coming back may be quite difficult. So that is, I think, what frustrates many of the physicians in the market. There is a lot of questioning right now about just where will these patients go and how will they be cared for. Where will we see the volume open? As Rhonda pointed out, we may see that in ambulatory surgery centers. We may see ASC take on a larger role here. But all of that is to be determined, and I think we'll see that begin to shake out obviously over the course of the first half of calendar year 2022. Hope that answers your question, Danielle.

Danielle Antalffy
Analyst, SVB Leerink LLC

Q

Yeah. No, that's helpful. And then, just as a follow-up, the whole dynamic of competitive trialing, can you just remind us and sort of maybe give us a little bit of color on what's reflected from a time of trialing perspective? Is this multi quarters? Is it usually one quarter? How long does competitive trialing generally impact sales? Should we be thinking about this into fiscal 2023? Any color on sort of how to think about the timing of – or how long it will persist, the competitive trialing dynamic, both in the coronary and peripheral. Thanks so much.

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

A

I think in coronary, we'll see this trialing continue until we probably annualize to the IVL launch. And then, I think we will begin to see it slow down. So, as we head through the second half of this fiscal year, we'll begin to see that slow down. What has prolonged the trialing period here is that the reimbursement environment has continuously changed for the use of IVLs, and that has enabled sites that perhaps may not have trialed to begin trialing that product and that, as a result, has kind of extended this period.

In peripheral, I think we expect to see a less impact on CSI and maybe very little impact due to trialing. The area where we see some of the trialing impact, our businesses is also in the office space labs, largely because of the introduction of lower cost products that are perceived to be more economically favorable for customers in that environment. I expect that the trialing of those products is probably coming to a close here soon. And as we head into the second half, we'll see improvement in that area as well.

Danielle Antalffy
Analyst, SVB Leerink LLC

Q

Thank you.

Operator: Thank you. Our next question comes from Jayson Bedford from Raymond James. Please, Jayson, go ahead.

Jayson Bedford
Analyst, Raymond James & Associates, Inc.

Q

Good morning, and thanks as always for all the detail here. So, just a few questions for me. Just on the guidance, I think kind of the initial framework for the year was roughly 10% growth in your base OAS business. Can we assume that the guidance revision comes all from that base OAS business, just given the strength in OUS and support?

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

A

Yeah. I think that's a reasonable assumption, Jayson. The majority of that reduction does come from our US OAS business.

Jayson Bedford
Analyst, Raymond James & Associates, Inc.

Q

Okay. And just on the OBL hospital mix in your peripheral business, I'm getting to about 40% OBL, 60% hospital. Is that in the ballpark?

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

A

No. That would be high. We're probably more like 20% to 25% OBL and 75%, 80% hospital.

Jayson Bedford
Analyst, Raymond James & Associates, Inc.

Q

And I'm just referring to...

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

A

I'm sorry. No, no, no, wait. Yeah, that's...

Jayson Bedford
Analyst, Raymond James & Associates, Inc.

Q

[indiscernible] (00:38:56), could you correct that?

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

Yeah. Jayson, it's just above 30% in the OBL and nearly 70% or so for the hospital, if you're just looking at peripheral revenues.

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

Okay. That's helpful. You mentioned in the release and on the call here an improvement in the recent trends, I'm just wondering if you can talk about where you're seeing this improvement: coronary, peripheral, hospital or OBL, just a little bit more detail on what you're seeing kind of today in the month of October?

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

We are seeing an improvement in our coronary business, and we're seeing really much of the improvement come in the south and the southeast, where the impact of COVID was the greatest. The peripheral business – our peripheral in-hospital business continues to lag and, I think, that is largely due to the impact of staffing shortages, not only critical staffing shortages, but staffing shortages throughout our referral chain, actually beginning with primary care, and continuing straight through to the interventional healthcare workers themselves.

So, the referral chain in peripheral, in particular for the more, let's say, the lower acuity claudicant patients, we think, has been pretty damaged in the south and southeast. It will take time to rebuild that channel. We have seen this happen before in relationship to COVID. If you recall, in the period right after the COVID crisis had begun, there was a – quite a large impact to the referral channel there as well, and it took six or seven months for that to recover.

So, it – we hope that it won't take that long. We hope that it will be geographically isolated to these states that were heavily impacted. But, as I've said, right now, it's really difficult for us to predict that and it's very difficult for us to predict what that pace might be because we're dealing with just an entirely new set of variables that we hadn't seen before.

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

Okay. Thank you. And maybe just if I could squeeze one in for Rhonda. Just adapting to the reimbursement environment in the OBL setting, you mentioned the new program and kind of various factors within that program. Is there an expected change in price into the OBL when you kind of bundle this altogether?

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

We don't really expect an impact in price. What we're really trying to do is use all of the expertise that CSI brings, including a development of some new programs to really help the OBLs become more efficient and just really increase their throughput, given the new economic environment.

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

Okay. Thank you.

Operator: Thank you. Our next question comes from Margaret William (sic) [Kaczor] (00:42:11) from William Blair. Please, Margaret, go ahead.

Margaret Kaczor
Analyst, William Blair & Co. LLC

Q

Hey. Good morning, everyone. Thanks for taking the question. Yes, excuse for my dog in the background. Yes, the story of work from home. I was hoping to focus a little bit more on the OBL business again and, sorry, I'm going to be a repeat of what others are. But I guess what I'm trying to get a sense of is given the changes in reimbursement, competition, consolidation, should we still think about this as a low-double digits or mid-teens growth rate given some of that focus on more difficult cases?

And I'll kind of have a Part 1b of this question because you sort of answered it with Danielle's question, but it sounded like there is a risk around maybe in overall market volume or at least growth in that peripheral segment, driven by that consolidation. So, did I hear that right and what could that do to, I guess, market growth dynamics?

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

A

Margaret, I think you did hear that right. I think that that's a reasonable assumption for the OBL growth.

Margaret Kaczor
Analyst, William Blair & Co. LLC

Q

The low double digit to mid-teens roughly?

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

A

Yes. Yes.

Margaret Kaczor
Analyst, William Blair & Co. LLC

Q

Okay. That's helpful. And then, as we think about that consolidation as well in the OBL, if you can quantify that for us in terms of site of service or accounts, maybe what you've seen over the last few years and that -- maybe that sense of a trade potential between potential incremental volume because these guys are more efficient versus some of the consolidation and pricing concerns that they could bring as well?

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

A

Thanks for that question, Margaret. The consolidation is a little bit difficult to exactly predict. I think we see really in any economic environment when you see a significant change in pricing or value, you oftentimes do see consolidation with lower smaller players basically moving out of the segment and some of the larger players increasing their volume, in other words, becoming higher volume providers of, let's say, a lower priced service. We have seen that happening. And as you know, our strategy over time has really always been to focus on the higher volume OBLs that treat more complex patients.

As we look to the future now, with these changes in the PFS, certainly we think that that that strategy has been correct. And we believe that we will see more consolidation, more of these patients moving to these higher volume sites. We've been implementing and we are – we're continuing to implement these strategies that will

support that segment of our market and these OBLs. I think we also anticipate over time that reimbursement will shift towards, let's say, a stratification where the more complex patients receive a higher payment rate, and it just simply makes sense that patients with critical limb ischemia, let's say, are more expensive to care for than, let's say, a lower acuity claudicant patient.

So, we believe that our strategy, focusing on these high volume accounts that also focus on more complex patients is very well-suited for our core technology. It is well-suited for the reimbursement environment, and we are really well-positioned to support customers as that change now occurs.

It's very difficult for us to predict at this time exactly how this transition from the OBL to the hospital or will patients continue to migrate from the hospital setting to the OBL? We don't know. The one thing we do know is that the value of atherectomy in the OBL setting remains intact. It still is a procedure that is reimbursed effectively and is reimbursed at a rate that enables physicians to perform these cases. So, I hope that answers your question, Margaret. I – it – we are still in early days and we will continue to give you updates on this as we proceed, probably over the course of the next year or so.

Margaret Kaczor
Analyst, William Blair & Co. LLC

Q

Okay. No, that's helpful. I know that it's a tricky question that I asked. And then, the last question for me is just talking a little bit about the support products that you guys have been able to launch. And just to get a little flavor of whether you were able to get into those accounts throughout some of these with the COVID headwinds or should we assume a little bit of a delay towards that as well given some capacity restrictions? Thanks, guys.

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

A

Yeah. The impact is less there. But we should expect some of the delay. We have seen a slowdown in the [ph] VAC committee (00:47:29) review process in some hospitals. But that said, I mean, our performance in the first quarter was consistent with our expectations. As we do have high expectations for growth from that segment of our business over time, we do think that because of the slowdown in these [ph] VAC (00:47:49) reviews in Q1, we'll see a slowdown in Q2 and beyond because of that. So we are expecting some impact in our ISD segment, although probably not as dramatic as what we're seeing in orbital atherectomy.

Margaret Kaczor
Analyst, William Blair & Co. LLC

Q

Okay. Great. Thanks, guys.

Operator: Thank you. Our next question comes from Michael Matson from Needham & Company. Please, Michael, your line is now open.

Mike Matson
Analyst, Needham & Co. LLC

Q

Yeah. Good morning. Thanks. So I want to ask another question on the competition situation. So you're using the word trialing a lot. And I understand that's kind of the first step. But how do we think about trialing as opposed to actual like market share loss? In other words, they don't just try it, but they actually start using it and sticking with that new product, the shockwave, [ph] along these other (00:48:44) things.

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

A

Thank you for that question, Mike. It's an excellent question. And what we see obviously early on is that physicians, when they receive access to a new technology will begin to trial it on a wide variety of patients to see how the product performs in their hands and their – and the procedures that they're performing. This is very common, and we've seen this in interventional cardiology over and over over the years. As they begin to gain experience with the technology and they then have the opportunity to see the ease of use to assess the utility of this new technology and the care of their patients, then they can determine both individually and at their center exactly how they want to incorporate that new technology into their traditional care patterns.

So, that is what we refer to really as trialing. It's that period of time where the physician is evaluating the performance of the product. Now, there's other evaluations that are going on as well. The Cath Lab manager will be assessing the cost. They'll be evaluating the economic impact for their hospital setting. And then, collectively, they make a decision on how they want to proceed.

What we are seeing is that after these trialing periods are concluding, and, in fact, as the trialing is going on, most oftentimes we are getting our cases. So, where we – where physicians are treating longer lesions, where they're treating heavily stenosed lesions, the requirement for atherectomy remains strong. An IVL balloon cannot remove calcium from the lumen of a vessel as effectively as an atherectomy device can. And atherectomy device also changes the compliance of the vessel and can be used in longer lesions.

So, these are cases where we will continue to get our cases, and these are also circumstances, I think, that will, and have, comprised our growth over the years. So, we will continue to gain our growth from that. As this trialing settles down, we think we will see a return to more normal or more standard practices of care. And in that environment, we think we're well-positioned to continue to grow, as I indicated, in that low-double-digit range.

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay. Thanks. And then, just on the coronary side, do you – has anything changed in your view of how much overlap there is between the kind of lesions where a shockwave is suitable and where Diamondback is suitable? And can you quantify that overlap to the best of your knowledge at this point?

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

A

Well, we have not seen really any change, Mike. I think, it – the – our assessment of where this technology is utilized remains very much the same, we think that the IVLs have and will continue to substantially expand the market. So, the vessel preparation market is growing very rapidly because of the success of the IVLs, and that is obviously also increasing awareness of calcium. And, in time, we think that that is going to create somewhat of a tailwind that that will also result in a just a good and a continuously rapidly growing market.

In terms of the segmentation, our segmentation really has not changed. We still believe that about 10% to 15% of PVI are warranted for care using orbital atherectomy, and those are patients that have multi-vessel disease, that have a long, severely calcified lesions, patients that have a high degree of stenosis where, for example, you simply can't get a balloon through the lesion, and those are the cases that really continue to be our cases and those are cases where an IVL perhaps is not indicated for use.

The same would be true in environments where imaging is used. We see a continued very strong adoption of atherectomy. And that's largely because the physician is observing the presence of a nodule or they have a much better understanding of what is really happening in the lesion and what would be the appropriate – the most appropriate way to treat it.

So, for example, in Japan where we have a very high rate of adoption of imaging, our devices is obviously continuously gaining market share there. And we continue to do extremely well in that market. There's a smaller percentage of customers that use imaging in the United States, but in those sites that are high volume sites that are focused on imaging, we also continue to sustain a very strong position.

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay. Thanks. And then my final question just on the gross margin. It was weaker than expected, I guess. But can you talk about pricing trends on Diamondback atherectomy? I mean, is it – has it been stable? Did that factor in at all to the gross margin decline?

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

A

Yeah. Mike, thanks for the question. Pricing trends were very consistent kind of in that low to mid-single digit range, really kind of what we would have expected there. So that really did not have much of an impact on gross margin. As I mentioned earlier, it was more about the mix, the lower margin revenue segments and then just overall volumes coming down a little bit from our earlier expectations.

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay. Got it. Thanks.

Operator: Thank you, Michael. And our last question is from Suraj Kalia from Oppenheimer. Please, Suraj, your line is now open.

Suraj Kalia
Analyst, Oppenheimer & Co. Inc.

Q

Morning, everyone. Scott, can you hear me all right?

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

A

Yes, Suraj. Thank you and good morning.

Suraj Kalia
Analyst, Oppenheimer & Co. Inc.

Q

So, three questions, if I may. One for Rhonda, one for you, Scott, and one for Ryan, and I'll just kind of throw all of these together. So, first for Rhonda. I heard about the 30% share in PAD, I believe 44% in CAD. Maybe you could just kind of give us how the market share is calculated if IVL included and also your embedded expectations for FY 2022 market shares.

Scott, for you, you mentioned about customers complaining about the economics part of it, just given the reimbursement changes. Maybe you could shed some light about the relative economics anecdotally that you are hearing from your customers on OAS versus IVL.

And finally, Ryan, if I could, love to get your thoughts on the substantial clinical improvement that was one of the criterias for NTAP on IVL versus others, really. Could that has spurred NTAP, and that is a domino effect? I'd love to get your clinical take on what we are missing here. Thank you for taking my questions.

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

Thanks, Suraj, for those questions. Just in terms of market share, I'll hand this off to Rhonda in one moment, but I think it's a little bit inappropriate to really be considering market share right now because until we see the IVL in the marketplace begin to annualize, it probably is not that relevant to look at market share.

And, as your question even indicates, it's very difficult to determine, let's say, atherectomy-only market share, in other words, the market share of CSI versus Boston Scientific, in contrast to what is your market share in the vessel preparation market? And that is where, I think, we begin to think about how the IVL balloons are really broadening and expanding vessel preparation because IVL balloons can be used by a larger population of physicians and is used in a broader population of patients, let's say, than just atherectomy.

I think the point we are continuously trying to make is that atherectomy retains its position within that treatment continuum while IVL expands vessel prep to a broader population. So, exactly how that plays out, the reason I say it's going to be important to annualize is that, at that time, we can really begin to talk about this vessel prep market and then discuss the atherectomy market within the vessel preparation segment.

So, with that, Rhonda, I'll try to hand it off to you and see if you can address maybe just a little bit more quantitatively.

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

Yeah – no, I think that that's entirely appropriate. And, I think, that the clear distinction for me is those two ways that we look at the market, and we do both, right? We look at all companies in, where the denominator is all about vessel prep, and then we just look at the companies that have an atherectomy indication, and then that's a different computation.

I think, vessel prep brings in a lot of other types of devices as well, you know, scoring balloons, other types of balloons, and so that's really kind of an important distinction there, Suraj. But, I think we're going to see how all of this looks after where it all settles after trialing, but we project to continue to strengthen our position in the marketplace, both in our coronary and our peripheral franchises.

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

On to your second question, Suraj, OAS versus IVL economics, as a quick reminder, the IVL is not reimbursed in the OBL setting. And, as a result, it really is not utilized there. So, that doesn't have any impact in that segment. In peripheral hospital, we expect in 2022 that IVL will be reimbursed at a rate equivalent to atherectomy for above-the-knee lesions. And with the improved economics there, we do expect to see some trialing. But, once again, we

anticipate retaining our position in that segment largely because of the unique aspects of our device for the treatment of severely calcified lesions.

In the coronary segment, the TPT, the recent improvements in reimbursement there clearly have reduced some of the economic barriers to the trialing of IVL. We don't think the economics are an important factor in coronary, largely because reimbursement for atherectomy is favorable, as is right now, at least, the reimbursement for the IVLs.

So, in the coronary segment, I think we're seeing an environment that is much more defined by the appropriate indications for use for each of these technologies and economics plays a larger -- or, let's say, a smaller role. Over time, the IVL right now is a Category 3, has received a Category 3 CPT code, and that will need to be improved over time in order to, let's say, rebalance that reimbursement as we get out after the TPT, let's say, as it expires. So, that is yet to be seen and is quite a long ways in the distance.

But, nonetheless, at this point, I would say the economics are probably a level playing field in coronary. Does that answer your question on the economics, Suraj?

Suraj Kalia
Analyst, Oppenheimer & Co. Inc.

Q

Yeah.

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

A

Okay. Thank you. All right. Ryan, will [ph] progress (01:01:17) through the third question.

Ryan D. Egeland
Chief Medical Officer, Cardiovascular Systems, Inc.

A

Yeah. A, I think, you're – Suraj, thanks for the question. I think the heart of the question is really the difference in payments over time. And, I think, as you know, the new tech add-on code is really – that the criteria for that code to be met is that really quite simple. The technology needs to be new and it needs to be expensive and inadequately reimbursed.

So, as you see the evolution of payments, if you look at long-term data, ultimately, is really what determines the ability of payers to make coverage decisions. And, I think, we can only speak to OAS that over the last 10 years now, we've validated the treatment of severely calcified lesions, as Scott mentioned, and tied otherwise non-crossable lesions, and we've demonstrated TLR rates that are as low as 3% at a year, with less than 7% at three years.

And so, ultimately, as payers look to that long term clinically significant data, we feel very adequate and, in fact, very strong about the ability to show a real clinical benefit with OAS. Time will tell whether those long-term benefits are shown with the IVL.

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

A

Suraj, I hope that answers your questions. Any additional follow-up there?

Suraj Kalia
Analyst, Oppenheimer & Co. Inc.

Q

No. That's [indiscernible] (01:02:46). Thank you.

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

A

Okay. Thanks, Suraj.

Operator: [ph] At this time, we have (01:02:42) no further questions, I will now hand over to Scott Ward for any final remarks.

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

Okay. Thank you, everyone, for joining today's call. We look forward to updating many of you at the upcoming Stifel and Canaccord conferences later this month and wish you all a pleasant day. Thank you.