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Cardiovascular Systems, Inc. (CSII)

Q2 2022 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Good morning, welcome to today's Cardiovascular Systems, Inc., Fiscal Year 2022 Second Quarter Earnings Conference Call. My name is Candice, and I will be your operator for today's call. All lines will be muted during the presentation portion of the call. We have an opportunity for question-and-answer at the end. [Operator Instructions]

I would now like to pass the conference over to our host, Jack Nielsen, Vice President of Investor Relations. Jack, please go ahead.

John E. Nielsen

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

Thank you, Candice. Good morning, and welcome to our fiscal 2022 second quarter conference call. With me today are Scott Ward, CSI Chairman, President and Chief Executive Officer; Rhonda Robb, Chief Operating Officer; and Jeff Points, Chief Financial Officer.

Earlier this morning, we issued a press release announcing second quarter results. You may find a copy of this release on our Investor Relations section of our corporate website. Here you may also find an earnings supplement that includes additional details on our performance and outlook. 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 includes 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 conditions 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 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 welcome to the call. Today, we reported Q2 worldwide revenue of $59.1 million, representing a 1.3% sequential increase but a decrease of 7.8% versus the prior year. This revenue performance reflects another quarter where our business continued to be pressured primarily by lower procedure volumes related to hospital capacity issues and staffing shortages caused by COVID-19.

Our recovery from the Delta variant was suppressed by the arrival of Omicron in December. Consistent with past surges, the impact was more acute in the peripheral claudication segment of our business, which is deemed more deferrable and is more susceptible to the long-term havoc created by COVID. We now know that staffing turnover and shortages caused by COVID have had a chronic dampening effect on the entire peripheral vessel preparation and atherectomy market.

The latest market data from independent sources indicates that the peripheral vessel preparations and atherectomy procedure volumes are down 10% to 12% versus the prior year. The good news is that we continue to believe this is temporary, and that many of these procedures will be regained as the Omicron surge fades, the healthcare system recovers and patients return to hospitals and clinics for long overdue interventions. It is difficult to predict the exact timing, but we expect a backlog of cases to gradually flow through our accounts at some point after this latest wave recedes.

We are also encouraged that the fundamentals in our business like new accounts, new customers trained and new contracts all improved sequentially in Q2 and we continued to gain share and achieve strong growth in our international markets. In addition, we achieved sequential growth in our US coronary business in Q2, and we believe that we are recovering some market share. We expect this to continue as cath labs and physicians return to the consistent use of atherectomy in their standard daily clinical practice.

We believe we have the preeminent sales force in the US market. The work we do improves the quality of life, prevents amputations and saves lives for thousands of patients every year. Our morale has remained strong and our employees have diligently supported our customers and patients throughout this latest surge.

So, even though COVID has caused us to adjust our near-term outlook for this fiscal year, we are excited about our future and we expect to return to growth supported by improving market dynamics, our innovative product pipeline and expansion [audio gap] (00:05:06) large and fast-growing markets. In a moment, Rhonda will provide additional information regarding our commercial progress, but first, Jeff will provide you with additional details regarding our second quarter financial results and our revised revenue guidance.

Jeff?

Jeffrey S. Points

Chief Financial Officer, Cardiovascular Systems, Inc.

Thank you, Scott. Good morning, everyone. Financial results for Q2 were as follows: Worldwide coronary revenue increased over 4% sequentially to $20.2 million, while also increasing slightly from the prior year. In the US, coronary revenue grew sequentially at 3% from Q1 and decreased 7% to $16.7 million over the prior year period. Outside the US, coronary revenue increased 60% over the period year period to $3.6 million as a result of continued strength in Japan, combined with the launch of Coronary OAS in Europe.

Worldwide peripheral revenues were flat sequentially at $38.9 million, while decreasing 11% compared to the prior year. In the US, peripheral revenue was also flat sequentially, while decreasing 12% compared to last year.

Turning to expenses. Gross margin was 69.4% for the quarter, excluding a onetime charge of $2.8 million related to the voluntary recall of our WIRION embolic protection system, gross margin was 74.3%. Q2 gross margins also reflect lower OAS volumes and an increasing mix of ISD and international revenues. Operating expenses totaled $49.6 million, which was about flat with last year. Net loss was $9 million or $0.23 per share. We ended the quarter with $176 million in cash and marketable securities and no long-term borrowings.

Turning to our outlook, our sales have been constrained by Omicron since the surge began in December, and this trend has continued into February. Based upon forecasts from public health experts, we expect that hospital capacity constraints could begin to ease in late February, and our procedure volumes may gradually begin to improve in mid-March.

As a result, we expect domestic revenue to decline sequentially in the third quarter and gradually improve in the fourth quarter. Although the timing and magnitude of the recovery is difficult to predict due to the dynamics introduced by labor shortages, we do expect sequential growth to resume in fourth quarter. To accommodate the new constraints posed by Omicron and the related staffing shortages, we are adjusting our guidance for the fiscal year ending June 30, 2022 as follows; revenues of $235 million to $245 million, gross margins of approximately 73%, net loss in a range of 15% to 18% of revenues, and an adjusted EBITDA loss in a range of 4% to 7% of revenues.

To close, we are hopeful that Omicron will be followed by a period where COVID is less disruptive and we will get back to consistent sequential growth.

I will now turn the call over to Rhonda, who will provide our 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 Q2 and share some of the key performance drivers for the back half of fiscal 2022. In the US, peripheral revenue declined 12%, and as Scott noted in opening comments, the entire market for vessel preparation has declined 10% to 12% versus last year. We believe that the market decline is due to patient behavior, incidental COVID and chronic staffing issues. As a result, many patients are being medically managed for longer periods of time.

As such, we believe, and our market research corroborates, that there is a backlog of patients that need to be treated. We do believe that some of these procedures will be recovered and we are working with our customers to prepare for a rebound. However, the pace of the recovery is difficult to predict. The recovery is likely to progress more rapidly in our OBLs where the barriers to increasing procedure volumes are much lower. Throughout the

pandemic, the OBL site of service has proven to be more resilient than the hospital setting, and the migration of peripheral patients to the OBL site of service continued in the quarter. OBL volumes increased 7% sequentially and now represents 51% of our peripheral procedures.

We are pleased that the market dynamics in the OBL setting have stabilized and our sales organization has recaptured market share since Q1. Although it is still early in OBL coping with COVID, we are not seeing much impact from the PFS changes implemented on January 1. Our OBL customers are not happy about these changes, but they are striving to drive efficiencies and we're supporting them with a series of programs and initiatives that will build and support high volume OBL accounts that are focused on the care of critical limb ischemia and other forms of complex PAD.

Our customized [ph] outpatient repurchase program (00:10:34) will include procedural education, inventory management, volume-based pricing program, clinical support, claims assistance and other initiatives that will transcend future reimbursement changes and assure efficient and effective care for our patients in the OBL setting.

Customer education has always been a key core competency at CSI and we are focused on training new physicians and adding new accounts. In Q2, we trained 61 new physicians and 52 new peripheral accounts adding to our future pipeline of OAS users in the US.

Sales of our peripheral ISDs increased to $1.2 million in the quarter following the successful launch and adoption of the JADE balloon. We are launched into approximately 25% of our US PAD accounts and expect this to ramp considerably in the next two quarters given the significant number of large contracts secured and effective January 1. JADE balloons represent a significant opportunity to increase our revenue per case to approximately $100 per OAS by the end of our fiscal year.

Turning to coronary, our US coronary revenue grew sequentially 3.1% to $16.7 million. This is an important step-up following the launch of coronary everolimus last February. Over the past year, [indiscernible] (00:12:01) where the device would fit in their treatment algorithms. And as that trialing is now drawing to a close, we are driving a rebound in our coronary business as cath labs resume the use of atherectomy for the treatment of lesions with intimal and nodular calcium, heavy stenosis, eccentric and diffuse lesions and multivessel disease. Of course, these are typically OAS cases and we are encouraged that our customers are returning to the consistent use of atherectomy in their standards of daily clinical practice.

We continue to serve a high demand for customer training in coronary atherectomy. In Q2, we began training over 200 fellows, certified 101 new users and opened 11 new coronary accounts in the US. We look forward to working with these physicians to complete their certifications in the months ahead and are excited by the enthusiasm we are seeing in the expanded utilization of our product. Our training pipeline remains strong and is an important indicator of future growth.

During Q2, we sold $751 to support [indiscernible] (00:13:12) for every coronary OAS sold. This was roughly flat with Q1 but was over $200 higher than the prior year period. In total, sales of coronary support products were $2.7 million in the quarter. We still have a large opportunity here since this product group is relatively new and we continue to make our customer base more aware of our product offerings.

We are also expanding our coronary ISD portfolio and following the recent FDA, PMA approval, we are in the process of launching the Scoreflex NC Scoring balloon in the United States. This balloon creates a focal stress pattern to facilitate safe and controlled plaque modification. Scoreflex NC has the highest rated burst pressure in

the United States and is indicated for the dilatation of a de novo stenotic coronary lesions and in-stent restenosis. Scoring balloons represent a growing $50 million market in the US and we believe Scoreflex NC backed by compelling clinical data will continue to be well received.

Turning to international, we are really pleased with our Q2 international results with revenue growing 62% to $3.7 million. We continue to gain share in competitive atherectomy and IVL accounts with strong progress in Japan and Europe. Like the US, we continue to serve strong demand for physician training and certification in our international markets. We certified over 70 coronary interventionalists outside the US and launched our coronary device in six countries during Q2. And we remain on track to be commercial in over 30 countries by fiscal yearend.

During the back half of fiscal 2022, we expect continued strong revenue growth despite COVID as we drive adoption and launch OAS in several new countries. We are on pace to deliver $15 million to $16 million in revenue in FY 2022.

In closing for Q2, we strengthened the fundamentals of our business with strong progress in new customers trained, new accounts, new contracts and new product launches. And of course we're also pleased with our share gain recapture and strong growth in international markets.

I'll now turn the call back over to Scott.

Scott R. Ward

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

Thank you, Rhonda. We are obviously operating in a very dynamic environment, which is really so defined by COVID, but we are encouraged by our performance in Q2, as you just heard from Rhonda with a lot of very favorable outcomes on many of our leading indicators. So despite all the chaos, we really do have some great opportunities and we're making strong progress in our efforts to transform CSI into a multiproduct, multinational company capable of delivering consistent and profitable growth.

Looking forward, we will continue to protect and grow our core orbital atherectomy business while we expand globally and develop a robust portfolio of new products. Over the next 18 months, we plan to introduce new products to serve our customer base, drive higher revenue per procedure and expand the use of orbital atherectomy.

In the near-term, we will launch the Scoreflex NC which will be the first non-compliant coronary scoring balloon in the US. And next fiscal year, the 2.0 Max, which is a large vessel crown that will expand our offering to treat soft and mixed plaque in the larger vessels above the knee. And we will also launch an innovative line of coronary microcatheters for accessing chronic total occlusions.

Longer term, our pipeline includes several products representing some of the fastest growing segments in the market, including everolimus drug-coated balloons for coronary and peripheral applications, a pVAD for high-risk PCI and IVL balloons for peripheral and coronary artery disease. And I'm happy to report that we're making really great progress on each of these programs.

Last quarter, we announced the first in-human experience for the coronary drug-coated balloon. Our R&D team recently completed several important development and preclinical milestones for our pVAD device. And we expect to conduct our first in-human clinical experience with that device in an OUS trial later this fiscal year. And

most recently, we announced the development of IVL balloons for the treatment of peripheral and coronary artery disease.

So I think you can see that we've assembled an impressive portfolio that diversifies our growth platforms and expands our total addressable market from about $1.8 billion today to over $12 billion in the future. We have a great team. Our greatest asset at CSI is our people, and we have made strong progress in the execution of our product pipeline. I'm confident that we will overcome our near-term challenges and restore growth to our business while we transform CSI to become a leading innovator in the care of patients with cardiovascular disease.

I would like to thank our CSI employees for their continued resilience as we continue to deliver 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 the CSI, and we will now take your questions.

So Candice, if you would please repeat the instructions, that would be great. Thank you.

QUESTION AND ANSWER SECTION

Operator: Thank you. [Operator Instructions] [Technical Difficulty] (00:19:03-00:19:18) Our first question is from Mathew Blackman from Stifel. Your line is now open. Please go ahead.

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

Q

Good morning, everybody. Thanks for taking my questions. I've got a few here. Maybe just to start, you've mentioned a couple of times that you think you regained share in the quarter versus the first quarter. Can you maybe just talk a little about the competitive environment in the second fiscal quarter and how you thought about competitive headwinds in the new guidance range? And then I have a couple of follow-ups.

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

A

Yeah. Thank you, Matt, and good morning. The – I think where we probably made the most important improvement is in our coronary business, where you noted that we grew sequentially quarter-over-quarter, we are also seeing that the trialing now of IVL balloons is really drawing to a close, and at least in many of our accounts. And I think in those accounts that trialed early in, let's say the IVL launch, we now are beginning to see a recovery of our procedures in those accounts that is really coming back about to our normal pace.

So we're excited about that. Our organization is doing a great job and continuing to work closely with our customers, educating them on the proper lesions in which to use orbital atherectomy, and we're also seeing as a result of that as physicians are returning to adopting our device on a regular basis. So good news there.

I think as we look forward, we do expect to see continued improvement in that coronary segment in the second half of this fiscal year. We are, as we've talked about before, we continue to anticipate some potential competitive headwind as it relates to the launch of IVLs for the above-the-knee segment in peripheral. Although we now think that'll be fairly muted as we've got just a short amount of time its early days, but we haven't seen a large impact from IVL in the ATK segment. That may progress over the course of the second half. If it does, we don't think it will be a large impact, but it is a change in the competitive dynamic.

And I think that addresses your question Matt. If I haven't fully addressed it, please ask a follow-up on that.

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

Yeah. No. I think you covered it, Scott. Appreciate it. And then maybe one for Jeff, and then I'll squeeze in one for Rhonda. Just from the P&L guidance, the full year gross margin guides at 73%. I don't think implied you get back to the, what's called the mid-70s that you hit in the first quarter. So is that all volume headwinds as we think about the back half gross margin, are you seeing any upward pressure on cost, supply chain, things like that?

And then maybe to sneak this one in for Rhonda on the large crown. It sounds like timing maybe slipped a bit into next fiscal year. I think you were previously saying later this fiscal year. So did I hear that right? And as we think about commercialization, so the commercialization of the large crown, is that plug-and-play or account is going to have to get recertified, retrained? Just any help on that front would be appreciated. Thanks.

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

Great.

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

Yeah. Matt, thanks for the question on gross margin. As we look to the back half of the year, that is really if we compare to kind of the original guidance we provided, that difference is really all volumes at this point. If we get back to normal volumes, we would be kind of in that mid-70 range and it'll be a little bit lower here in the back half and that's just because of the lower volumes.

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

And Matt, thanks for the question. So for timing on the large vessel, now we're calling it the 2.0 Max, we expect we're working very closely with the FDA and that's going really well. We expect to have actually approval later in the quarter. So realistically kind of the timing for launch will be kind of that early FY 2023 timeframe. So that's the status update there.

And when you say plug-and-play, I mean I think yes, to a degree, it will work with our existing handles. We will, of course, train and educate as we always do with that device, but I think it's going to be a really straightforward launch into a huge market that will give us access to ATK procedures, which are about 60% of the atherectomy procedures out there.

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

All right. Thank you so much.

Operator: Thank you. Our next question comes from Michael Matson from Needham & Co. Michael; your line is now open. Please go ahead. Unfortunately, your question – there is no audio in your question. Can I ask you to reregister, please, Matthew (sic) [Michael] (00:24:44)?

Our next question is from Chris Pasquale from Guggenheim Securities. Your line is now open.

Chris Pasquale
Analyst, Guggenheim Securities LLC

Q

Thanks.

Operator: Please go ahead.

Chris Pasquale
Analyst, Guggenheim Securities LLC

Q

Thank you. Rhonda talked about the initiatives you guys have underway to help your OBL customers cope with reduced economics in that setting. With OBLs now accounting for the majority of your US PAD mix, what impact do you expect that to have on your own business? Should we assume some incremental pricing pressure over time as they take advantage of volume discounts and the like or do you expect to be able to maintain stable trends, even as you help them become more efficient?

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

A

Yeah. Thanks, Chris, and good morning. I think that we expect now our OBLs to stay fairly consistent and actually to return to the good strong growth rate that you've seen in the past. I would note that our OBL segment has always been – had more difficult pricing pressures. And that most likely will continue. We've seen pricing erosion there in the mid-single digits typically. And I would anticipate that we'll continue to see that going forward.

Chris Pasquale
Analyst, Guggenheim Securities LLC

Q

Okay. And then [ph] can you give us an update (00:26:14) on the WIRION filter after the recent recall, but what's the path to getting that product back to the market? How should we think about timing there?

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

A

Yeah. So the timing on that is still a bit to be determined. We have now just completed the recall or we're just about complete with it in terms of bringing back the devices. We will be making improvements in that device. We'll be improving the retrieval catheter and some of our use procedures. And as we assess that, we'll then be in a better place to give you a better sense of timing. We'll probably be able to do that next quarter.

Chris Pasquale
Analyst, Guggenheim Securities LLC

Q

Thanks.

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

A

Thank you.

Operator: Thank you. Our next question comes from Danielle Antalffy from SVB Leerink.

Danielle Antalffy
Analyst, SVB Leerink LLC

Q

Hey, good morning...

Operator: Your line is now open. Please go ahead.

Danielle Antalffy
Analyst, SVB Leerink LLC

Q

...everyone. Thanks. Hey, good morning, everyone. Thank you so much for taking the question. Rhonda, I have a question for you and then Scott a question for you. On the Max product, ATK I appreciate it's a large market opportunity, but also more competitive and I guess just would love a little bit more color on the rationale behind investing in this product. Is it more about the breadth of the portfolio, strength into your competitive positioning, do you think this is a higher growth market than maybe I had been assuming? So just a little more color there would be great.

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

A

Sure thing. Yeah. Thanks, Danielle for the question. Much appreciated. I mean it is a large market, and as I mentioned in my earlier comments that it constitutes about 60% of atherectomy procedures. We currently do perform procedures in ATK today, but with this device we'll have better access to a new plaque morphology that we typically don't treat with OAS today and that's soft and mixed plaque. So we're looking forward to it. It's going to be a new market. It leverages our existing platform, so it's actually really pretty efficient for us to develop this and get it launched because it does work with our existing handle. And so from that standpoint, it's really a cost-effective way for us to access a really big market.

Danielle Antalffy
Analyst, SVB Leerink LLC

Q

Got it. Okay. Thanks for that. And then Scott, question for you or Rhonda maybe this is for you too on the coronary side of things. Great to hear that you're regaining share. I guess one of the things that we've been hearing in our due diligence here on vessel prep in general is that the market has been expanding. And now that the trialing seems to be coming to a close at your accounts at least, what are you seeing from IVLs into the market from a market expansion perspective and just getting more patients to undergo vessel prep than prior to IVL? Anything to – of note there, I know COVID complicates things, but just curious even anecdotally what you're seeing? Thanks so much.

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

A

Yeah. Thanks Danielle. We are most definitely seeing IVLs expand the market. I think they are broadening to a completely different customer group that historically maybe has not treated calcium in the past. I think that is actually having a beneficial impact on the market as those efforts are raising the awareness of calcium, and also making it evident that severely calcified and even moderately calcified lesions should be treated before stents are placed. And that hasn't always been the case. So definitely improved awareness.

Strong market expansion out beyond the tertiary care centers now into more community hospitals and other areas, and also expanding the use of interventional procedures for treating calcium, let's say to less severe lesions, which – all of which has really been very beneficial, and I think is an indication of things to come as we do expect that that market expansion will continue and that IVLs in particular in the treatment of coronary lesions will continue to be adopted and done well.

Having said that, I think we also are seeing that physicians recognize and understand in their own practice that when they come across severely calcified lesions where they have a high degree of stenosis or nodular lesions where there's a lot of intimal calcium, that these are cases where they really do need to use atherectomy. And we're seeing them come back to that in their more standard daily clinical practice, which is what we expected. This is happening as you know, the trialing is kind of drawing to a close and we see individual physicians and cath labs kind of returning to their more standard practice. So, good news for us and we expect to see that trend continuing now as we head into the second half of our fiscal year here.

Operator: Thank you. Our next question comes from Mike Matson from Needham & Co. Your line is now open. Please go ahead.

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay. Can you guys hear me now?

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

A

Yes.

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

A

Yes, we can, Mike. Thank you. Good morning.

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay. All right. Good. Good morning. So, I wanted to follow up on Rhonda's comments on the OBL reimbursement changes. I guess one concern that I had around that was that it could lead to more – some increased incentive for the customers to maybe move some of the lower cost products out there. You did mention value-based pricing, which I think you have talked about in the past with the OBL setting, but can you just provide some more detail there? And is this something that's putting some additional price pressure on you?

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

A

No. I don't think it's putting additional price pressure on our business, Mike. I think we would expect to see that continuing. Just recall, and you noted this, that about three years ago, we changed our approach to office-based labs and began developing deep partnerships with select labs where we do provide a wide range of support including procedure support and inventory management, and we do volume-based pricing programs.

So, those initiatives have been in place. They're kind of built into our base. And I think that you can expect to see that continue going forward. So, I don't really envision that the reimbursement changes in office-based labs will fundamentally change the business model that we have deployed to that site of service. I would say that probably one of the things that has been fairly encouraging to us over the course of the past month is that, our OBL customers are not on salary, they're not on a hospital salary. So, their procedure volumes is what determines how they do month to month. And we do expect to see the OBLs return to a stronger performance as Omicron recedes. And at least thus far, our customers are driving towards achieving higher volumes in their practices. And that is how they're responding to these pricing challenges.

As Rhonda said, I don't think any of the customers are happy about it, but they're really striving to improve efficiencies in their practices. And we're in there working right alongside them and working with them to help them make that happen and to really increase their volumes as they deal with Omicron coming back as well as this pricing challenge at the same time. But early on at least here in January, the indications are relatively positive that the office-based labs that we work with will overcome these challenges.

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay. Got it. And then I just had a couple on the IVL news that you're developing a product there. So I guess, my understanding is it took Shockwave about two years from their first in-human to getting the product commercialized. So can you maybe comment on does that imply sort of like a fiscal 2025 launch? And is there any way to accelerate that? And then, can you just talk about coronary versus peripheral, are you going to go after both or going after one before the other?

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

A

Thanks, Mike. We will be pursuing both coronary and peripheral IVL balloons. We would anticipate our peripheral launch to occur probably late FY 2023 or early FY 2024. So that is out, let's say, 18 months to 24 months from now. And you made a note of the timing from first in-human. Of course, we have the benefit now of being second coming into this market. And recall that the peripheral approval is a 510(k) approval. We are working with the FDA now on what requirements they will see as being important for that launch. And then we'll be able to be more specific about the timing as we get greater clarity from the FDA.

The coronary clinical trial requirements that coronary approval is a PMA approval as you know, and that will likely be FY 2025, FY 2026 before we see approval for that coronary segment. We may launch outside the United States earlier than that, but that's what we would anticipate in the US.

Mike Matson
Analyst, Needham & Co. LLC

Q

Perfect. Got it. Thank you.

Operator: Thank you. Our next question is from Suraj Kalia from Oppenheimer. Your line is now open. Please go ahead.

Suraj Kalia
Analyst, Oppenheimer & Co., Inc.

Q

Good morning, everyone. Can you hear me all right?

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

A

Yes, we can Suraj. Thank you.

Suraj Kalia
Analyst, Oppenheimer & Co., Inc.

Q

Perfect. So Scott, a couple of questions. The first one either for you or for Jeff, so the updated guide is approximately 20% lower than your original guide. So can you give us a breakdown of the relative impact of COVID versus IVL so that as we structure the remaining two quarters and the outlook over this calendar year, we can put the different pieces together?

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

A

Yeah, Suraj. Thank you for that question. The vast majority of the impact is Omicron and the related staffing shortages and labor shortages that are impacting the market broadly. I think as we look at our performance in January and now into early February, as you've heard from many companies reporting, we are seeing reduced procedure volumes largely due to the acute impact of Omicron.

We do expect in our markets that we will see some restoration of normal commercial activities, probably beginning in the mid-March timeframe. And then we are anticipating that we will see a slow and gradual recovery after that. It will be slower than what we've seen in the past. If you recall last year when we had that January outbreak, the market actually recovered fairly fast, and in March and April, there was a backlog of patients that were rapidly treated.

And what's different this year is that hospitals are dealing with these staffing shortages and we find that in many cases, hospitals are triaging cases, they're coming back and doing their most severe cases first. And frankly, the treatment of patients with intermittent claudication are not arriving on the high end of that priority list. So we are expecting that that will result in a slow and gradual recovery in our peripheral hospital segment. And that would largely be the patients that have intermittent claudication.

So that is some of the – basically the rationale for that guide. Naturally if the Omicron wave recedes more quickly or if these staffing shortages are addressed more rapidly, we would anticipate that our guidance may improve. I have to say though, Suraj, at this point our conclusion is there's not strong evidence that this shorting – the staffing shortage and the labor shortage that is impacting hospitals in particular, we don't think that's going to resolve quickly. We think that this is going to take some time to recover. So I hope that helps in regards to your question.

Suraj Kalia
Analyst, Oppenheimer & Co., Inc.

Q

Got it. Scott, then my second question, I'll just position it for you or Rhonda, and it's a two part question. First, what percent of your cases are being done independently onsite, i.e., just to give us an idea in terms of leveragability once Omicron disappears? And the second thing, to the extent that you can, Rhonda you or Scott can talk about this, on your IVL approach, what is the specific competitive attribute that you all are targeting? Is it [ph] emitters (00:40:49) per catheter, number of pulses per catheter, deliverability or size limitations? Because these are issues in the [ph] current platform (00:40:58). I'd love to get, again, any color you would share. Thank you for taking my questions.

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

A

Yeah. Thanks, Suraj. About two-thirds of our cases – we cover about two-thirds of our cases, so about one-third are conducted independent. Now as we have been impacted by Omicron and our reps have not had easy access to our accounts over the course of really the past couple of months that number has reduced pretty significantly. So we're not covering two-thirds of our cases at this point.

However, our sales teams have been collaborating very closely with our customers during this time, working to identify where the backlogs exist, getting prepared and really interacting with our customers to understand how can we help them best if and when this volume comes back.

There are many issues in these hospitals, for example, that the technicians that support cases in cath labs, we have seen a fair amount of turnover in that particular part of the workforce. We've got to get back in, train and educate those cath lab techs. We've got to train and educate others in the support and care network there, so that they know how to manage patients that have been treated, let's say, with orbital atherectomy or frankly that are just being treated for intermittent claudication or CLI or coronary lesions.

So our field sales organization, and the fact that we have a substantial organization, actually positions us very well to provide outstanding support to our customers in conducting these cases, but also training and educating their new staff as they're dealing with the turnover that they're experiencing. So I think we're well-prepared to deal with this. We've done it before. And if and when this wave comes back through, we'll be in a good place to manage it.

In terms of the competitive attributes of the IVL, yeah, our IVL will address some of the limitations of the products that are currently in the market. We will be talking more about that as we get closer to commercial launch, but I think that you articulated quite well some of the key areas of that, that need to be addressed and the areas that we will be addressing in our product.

John E. Nielsen
Vice President-Investor Relations & Corporate Communications, Cardiovascular Systems, Inc.
A

Operator, I think we're ready for the next question.

Operator: Thank you. Our next question comes – our final question comes from Brandon Vazquez from William Blair. Your line is now open. Please go ahead.

Brandon Vazquez
Analyst, William Blair & Co. LLC
Q

Hi, everyone. Thanks for taking the question. First, just wanted to follow up on kind of the backlog that we're talking about here. I appreciate the color around it. I know that staffing shortages can impact the market's ability to treat this backlog. I would think maybe the OBLs could maybe be a source of alleviating that backlog. Is that a fair statement? And if so, it seems like you guys might be in a good position to kind of benefit from that backlog coming in, so kind of curious is that a fair statement and then is that kind of benefit potentially baked into guidance or not or could that be a little upside as we move through the year?

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

Yeah. I think that the OBLs usually do bounce back more quickly, largely because the barriers to patient care and their ability to increase their volumes quickly are there, the barriers are much lower. So we may see that happen in the office-based labs. We in our current guidance are anticipating that the Omicron impact will really impact nearly all sites of service through that March 15th timeframe. And then after that we will see some recovery begin.

I think geographically this will be asymmetric across the United States. So in the south, where office-based labs are more prevalent, we may see the office-based labs in let's say Florida, Texas, that those parts of the country

rebound more quickly than in other parts of the country. So that is most definitely an opportunity and we're prepared to address that there Brandon. Did you have another follow up question on that?

Brandon Vazquez
Analyst, William Blair & Co. LLC

Q

No. That was good on that. I did have one follow up separate to that, so I'd appreciate the color there. It looks like international was a big market for you guys, and obviously COVID delayed that for a while. It seems like this may be is the first quarter where you're starting to dip your toe back into the international markets. Can you just talk a little bit about where you're kind of seeing some early momentum there? And where are you making investments in the international markets that will drive growth in the next 12 to 18 months? Thanks.

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

A

Yeah. Thank you for that question. Our international markets actually have been growing nicely despite COVID, even over the course of the, really the past four quarters. So we're really pleased with our launch of our business outside the United States, where we are taking share from IVLs. We're taking share from other atherectomy devices as well, mainly in the coronary segment, so we focus principally in coronary outside the United States. We have gained really strong share in Japan. And our launch in Europe, our coronary launch in Europe has also progressed very well.

So, we now are launched in 22 countries and we expect by the end of this fiscal year, we will get to about 30 countries. So, here is a circumstance where we have a marketplace that has never had access to orbital atherectomy before and we're able to now engage with our customers there, train and educate them on the use of this technology. They see the benefits of this technology and the care for their patients. They adopt it and incorporate it into their daily practice. So we're excited about that.

And we did, this quarter with very strong growth there, about 62% year-over-year and about $3.7 million. We are expecting to continue on about that run rate and that would lead us to probably having $15 million to $16 million of revenue in our international segment of our business this fiscal year, which would be obviously very strong growth and we're not done there. We expect that to continue going forward as we launch into these new markets and continue to grow our business there.

Brandon Vazquez
Analyst, William Blair & Co. LLC

Q

Great. Thank you.

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

A

Excellent. Thank you, Brandon.

Operator: Thank you. There are no additional questions waiting at this time, so I'll pass the conference over to the management team for closing remarks.

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

Excellent. Thank you very much. And thanks to everybody for your continued interest in CSI. We look forward to giving you another update next quarter. And with that, we'll conclude our call. Thank you.

Operator: That concludes today's conference call. You may now disconnect your lines.