CSI Capital Markets Day – August 3, 2022

Jack Nielsen:

Good morning and welcome to the Cardiovascular Systems' Capital Markets Day. It's great to see so many familiar faces here, here in our headquarters. We really do appreciate you making the effort to travel to Minneapolis to come and see us. For those of you online, we really appreciate you taking the time during a busy earning season to spend a couple of hours with us, and we really look forward to seeing you in person really soon.

Today's meeting is being webcast, and in consideration of those joining us online, we kindly ask that everyone in the room, please silence your electronics. Today's prepared remarks are expected to last about 90 minutes.

Presenting from CSI today are going to be Scott Ward, chairman, president and chief executive officer. Matt Cambronne, vice president in research and development. And Jeff Points, chief financial officer. We're also joined in the room by several members of the CSI management team.

Last night, we issued a press release announcing fourth-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 information that we think investors will find useful. Scott Ward and Jeff Points will begin today's meeting with a brief review of our fourth-quarter financial results and fiscal '23 guidance. We will then immediately transition to the Capital Markets Day portion of the meeting.

For those of you in the room, we ask that you hold your questions until the completion of the prepared remarks in about 90 minutes, and those of you joining us via webcast, you're invited to use the question submission function on the website. Your questions will be addressed by management also at the end of today's presentation. This morning's meeting will end no later than 11:30 Central Time.

And then, just finally in closing, I do need to read the safe harbor statement. During today's meeting, 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 in operations, financial condition, and prospects, which we will discuss during today's meeting. CSI disclaims any duty to update a revised 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 and earnings supplement both contained reconciliation tables to GAAP results. I will now turn the meeting over to Scott Ward.

Scott Ward:

Thank you, Jack, and good morning, everybody. It's great to see everybody here. It's great to see a full room. Also, many thanks to those of you that joined us last night for our product fair. I hope you really enjoyed the opportunity to handle our products, get to meet our people, and really have the opportunity to see that this vision, the future for this company is very bright and that the products that we talk about are very real and they're de-risked and really we're well on our way towards our next evolution of growth here at CSI.

As Jack mentioned, we're going to start today with a review of our fourth-quarter financial results, and I'm really excited to tell you that I think we had a really strong quarter. Hopefully, you've had an opportunity to review the fourth-quarter earnings press release that we issued last night. Our business continued to gain momentum in Q4, and with $62.5 million in revenue, we grew 11% versus Q3. On a sequential basis, and in line with our expectations, we did see an acceleration in our sales. Despite the headwinds caused by labor and contrast shortages, we achieved strong growth across all our business segments with our US peripheral and coronary atherectomy franchises, growing %9 and 16% respectively. Peripheral was up 9% versus prior quarter, led by 27% growth in the OBL segment and 36% growth in ISDs. We think that the strong growth in the OBLs was slightly boosted by a small backlog of patients from Q3 and the growth in our peripheral ISDs was driven by accelerating adoption of JADE balloons. Importantly, our peripheral revenue per procedure continued to expand and we delivered about $110 per procedure in Q4. Hospital executives and other med tech companies have all reported that hospital procedures have been slow to recover and concordant with that trend, the hospital segment of our peripheral business was flat to prior quarter. The labor shortage and turnover in the healthcare workforce, as well as the shortage of imaging contrast media in some regions of the country have constrained procedure volumes, particularly for some of our lower-acuity patients. Those with intermittent claudication, for example.

Now, turning to coronary, we experienced a solid resurgence with strong sequential growth of 16%, benefiting from COVID recovery in a modest competitive rebound, as we started to regain market share in the treatment of calcified coronary lesions. Physicians have now gained experience with IVLs and we're beginning to see the treatment algorithms for vessel preparation, sort out into swim lanes for the use of scoring balloons, IVL, and orbital atherectomy. So, as experience grows and more physicians align with these algorithms, we are seeing increased utilization of orbital atherectomy. We believe that the normalization of these treatment algorithms and increasing adoption of intravascular imaging will create momentum for our coronary business during the coming year.

Coronary ISDs grew 37% to $3.9 million. The limited market release of our Scoreflex NC scoring balloon has been very well received, and we are targeting a full market release in the first half of our fiscal year '23. In addition to the strong sequential growth in Q4, we are encouraged that the key operating statistics in our business continued to demonstrate strong demand for our products and really position us for continued growth into fiscal '23.

Performance metrics like new accounts, new customers trained, new contracts, all really exceeded our expectations once again in Q4. So, looking ahead, there is actually generally positive news

to report on the reimbursement front as changes for calendar '23 were announced by CMS. We do see that the reductions in the Physician Fee Schedule were right in line with our expectations and the proposed reimbursement for outpatient procedures or OPPS suggests a blended improvement of 6.25% next year. So, on a weighted average basis, our reimbursement would actually improve next year by about 1%, if these proposed adjustments actually go into effect, effective January 1.

Finally, our international franchise continues to outperform expectations. International growth increased 36% over prior year and 14% versus Q3. We enter fiscal '23 with strong adoption of orbital atherectomy in Japan and accelerating market share in Europe, Asia Pacific, and Canada. We are now commercial in 30 countries outside the United States, and we have over 1000 physicians that have been trained on orbital atherectomy. We continue to make great progress in our efforts to broaden and diversify our product pipeline. We're going to talk about that a lot more today.

And as I mentioned earlier, we initiated the limited market release of our Scoreflex scoring balloon, and we achieved 510(k) approval for the 2.0 Max Crown ahead of schedule. This device will enable market expansion to the above the knee mixed plaque market, and we expect full market release in the second half of fiscal '23.

We also achieved our key product development milestones for our Propel pVAD device. We completed the first in-human experience in March, and we recently submitted the IDE for the early feasibility study, which we now expect to begin in our Q3. In addition, we remain on track to achieve our key milestones for our thrombectomy and IVL products in fiscal year '24 and '25, as well as the everolimus drug-coated balloons and the Propel pVAD launching in fiscal '27. Matt Cambronne, our vice president of research and development, will share more details about these products later this morning.

So, with really strong execution in R&D and with a compelling rebound in sales, we have renewed momentum in our business. We're excited about the prospects for a strong fiscal '23, and we look forward to sharing more information with you about that this morning. I'm now pleased to introduce Jeff Points who will provide you with additional information and details regarding our fourth-quarter financial results and our guidance for fiscal '23. Jeff.

Jeff Points:

Thank you, Scott. Good morning, everybody. I'll now provide a brief review of our Q4 financial results. As Scott noted, Q4 revenue of $62.5 million represented sequential growth of 11% compared to Q3, which is very much in line with our expectations. We experienced strong sequential growth in each of our business segments and the rebound in our Q4 results is due to procedure recovery, focus commercial strategies, and the launch of new products.

I would note that Q4 performance last year was the strongest of the year, for most med tech companies including CSI, making this our toughest comparable quarter. As a result, this morning, I will focus my comments on the improvements we've experienced from Q3 to Q4, as we believe this was a more relevant trend as procedure volume stabilize and we emerge from the pandemic. For additional details, including year-over-year comparisons, please refer to the earning supplement deck on our website.

Fourth-quarter worldwide coronary revenue increased 15% sequentially to $21.8 million. In the US, coronary revenue increased 16% to $17 million led by 11% growth in unit sold. Coronary support products increased 37% to $3.9 million. Outside the US, coronary revenue increased 14% to $4.8 million as a result of continued strength in Japan, combined with the successful launch of coronary OAS in Europe. Fourth-quarter worldwide peripheral revenues increased 9% sequentially to $40.7 million. In the US, peripheral franchise revenue increased 9% led by a 27% increase in OBL revenue and a 1%

increase in hospital revenue. US peripheral revenue also benefited from a 36% increase in ISD revenue, which totaled $1.8 million.

Turning to expenses, gross profit margin was 74%. Margins were favorably impacted by a reduction in the estimated amount of older generation pumps that need to be replaced under the program established in the prior year quarter. Operating expenses totaled $55.7 million. SG&A increased 12% sequentially primarily due to higher sales compensation related to the increase in overall revenues, increased marketing activity related to conference participation, and the launches of our peripheral support products.Compared to last year, SG&A was about flat. R&D expenses decreased to $8.8 million. We ended the quarter and fiscal year with $160 million in cash and marketable securities and no long-term borrowings.

Looking ahead to fiscal '23, we anticipate full resolution of the imaging contrast shortage in September and a gradual improvement in US hospital procedure volumes, during the course of the year. We believe that continued market recovery combined with improving commercial execution, competitive momentum, new product introductions, and international expansion will accelerate our growth in fiscal '23. We note however that the macro environment is quite unsettled right now and the COVID pandemic is not over, so uncertain market dynamics may persist that could impact our fiscal '23 forecast. With that in mind, we forecast fiscal '23 revenues to be in a range of $255 to $265 million representing an increase of 8% to 12%.

Turning to expenses, we anticipate gross margins will be in a range of 72% to 74%, as our continued focus on reducing direct and indirect costs will offset an increase in revenues of lower margin products, nominal price erosion primarily in OBLs, and higher freight costs.

Turning to operating expenses, strong sales execution, new product introductions, and international expansion during fiscal '23 will yield leverage in SG&A spend. R&D spend will increase as we make significant development and clinical investments in our product pipeline. We anticipate total R&D spend to equal 16% to 17% of revenues during fiscal '23.

On the bottom line, we forecast a fiscal '23 net loss equal to 9% to 11% of revenues and adjusted EBIT a near breakeven. This year, we intend to provide annual guidance and plan to supplement that with nonquantitative commentary each quarter as needed. With that in mind, I will remind everyone that our fiscal first quarter is typically our lowest revenue quarter of the year, due to lower procedure volumes in the July and August timeframe. This seasonality typically results in Q1 revenue that is approximately 5% to 6% lower than Q4. As a result, Q1 typically results in the largest quarterly loss of the fiscal year. We anticipate that our financial results both on the top and bottom line will improve sequentially as we progress throughout the fiscal year. I will now invite Scott to provide his closing remarks. Scott.

Scott Ward:

Great. Okay. Thanks Jeff. Before we get started with our presentation, I'd like to just provide some final comments regarding our guidance and growth expectations for the coming year. Guidance assumes no new COVID headwinds, a gradual improvement in US hospital staffing shortages, and the full resolution of the imaging contrast shortage in September. With these provisos, we expect organic revenue from our core OAS franchise to grow kind of in the range of 8% to 10%. This would include mid-single-digit growth in the US peripheral and coronary atherectomy business with some benefit during the second half of the fiscal year from the full market release of our 2.0 Max device. This also assumes continued growth of approximately 25% in our international markets.

We expect ISD growth in the mid 30% range with strong adoption in peripheral, and as I noted earlier, we generated about $110 of incremental revenue per procedure with our peripheral support

products in Q4. So, in addition to that, the introduction of other new peripheral ISD products like our Shepherd Guidewire and the ViperCross Microcatheters are expected to elevate our ISD revenue to approximately $200 per procedure as we exit the fiscal year.

In coronary, we look for continued growth in ISDs, as we introduce Scoreflex, the NC24 balloons, and we also launch our complex coronary microcatheters. These launches are going to happen throughout the course of the fiscal year, and these new products are really expected to have a favorable impact on revenue growth in fiscal '23, but the full benefit of all of those new products really will come through as we pass into fiscal '24.

So, in summary, we look to achieve about eight to 12% revenue growth this year, driven by mid-single-digit revenue growth in our domestic atherectomy business, about a 30% plus increase in support product revenue, and approximately 25% growth from international. Now, this concludes our prepared remarks regarding our Q4 results and we will now transition to our Capital Markets Day.

Just to repeat, this is our safe harbor statement and our financial and regulatory disclaimers. For those of you that joined us here last evening and had the chance to interact with our leadership and with our engineers and employees here at the company, I think one of the things that you may have noted is that what we are most proud of at CSI is our commitment to our patients.

Over the past couple of years, organizations and institutions around the globe have been tested and challenged, to change and adapt and really respond to this incredibly dynamic and ever-changing environment that we've all seen, and I am really very proud of our team here at CSI. Our greatest asset is our people, and our team has really responded to these challenges with incredible strength and resilience and creativity. The source of that motivation and enthusiasm is a deep commitment to the mission of this company, to save limbs and to save lives every day. Employee engagement at this company is very high and each and every one of our employees is committed to making the world a better place.

Coronary and peripheral artery disease are a leading cause of morbidity and mortality in the developed world, and we are proud that over 700,000 patients worldwide have been successfully treated with orbital atherectomy. Our mission, which is engraved in stone just outside the door here, shapes our values and guides our judgements from the way we manufacture our products all the way up through our boardroom.

Today, we will describe the next phase of our plan to play an ever-greater role in the care of patients with complex coronary and peripheral artery disease. And our board has been heavily engaged in the development of this plan every step of the way. We have a really strong independent board composed of really great leaders that bring different skills and perspectives, which are actually really helpful in guiding this company. The board is supportive, but they also hold management accountable for the leadership and operating performance of CSI.

CSI today has a really strong foundation, and as a small med tech company, we have a tremendous opportunity to create shareholder value. We have over 700 employees, including approximately 100 engineers and scientists, and our products and pipeline are supported by a robust portfolio of intellectual property, with over 230 patents issued and just over 105 patents pending.

In 2018, we launched a strategy to globalize our company and we are now serving patients in 31 countries around the world with a vibrant distribution channel that is really delivering strong growth. In the plan we described in 2018, we also stated that we would deliver 10% growth in our core business and about 20 new products by 2023. As you know, we fell short of our growth goal as we encountered some pretty severe headwinds caused by COVID, competition, and reimbursement changes particular in the OBL side of service. At this stage, we're cautiously optimistic that the pandemic is declining and we

have adjusted our business strategies to now restore growth in our core OAS business, while we improve commercial execution and focus.

Our R&D pipeline has really delivered, over the course of the past four years. We launched nearly 80% of the products that we had planned and we've built an impressive flywheel of new platforms that will diversify our company and really drive our growth in the years ahead. So, this is really the difference between 2018 and now. In 2018, we were a single product, single geography company, and our product line was limited to atherectomy. Since then, we've been executing a strategy to leverage our atherectomy business, to drive increased revenue per procedure from the sale of support devices, while we also established a global footprint. So, this plan was more technology-focused with a really high dependence on atherectomy.

In the plan we will present today, you will see that we are taking a more patient-centric approach, building on the foundation that we've established with atherectomy to launch now a broad portfolio of new products for complex cardiovascular disease. In this next phase of our evolution, we will stay focused on our complex coronary and peripheral patient population with a new product portfolio that addresses larger and faster growing markets, while we grow and protect our core orbital atherectomy franchise.

We have learned a lot about our core OAS business, and we have new leadership in place with Rob Beverly leading our peripheral business, and Harrison Boyd leading our coronary business, and of course, Chris Volker, continuing to lead our international business. With this new focus, we are now better positioned to improve our commercial execution, deliver on our core growth initiatives, capture growth from our near term product pipeline, and drive higher revenue per procedure from the sale of our ISD devices. Our strategy to globalize CSI has also really been very successful and we expect OAS adoption in international markets to remain strong.

We are really excited about our new product platforms. For those of you attending in person who joined us at the product fair last night, I think you would agree that these products are really quite advanced in their development and will really transform our company. With opportunities in thrombectomy, Intravascular lithotripsy, drug-coated balloons, and hemodynamic support, we will advance the standard of care while we expand our total addressable market from about $2.2 billion today to $18.8 billion in 2027. So, with modest growth in our core business and the execution of this new product portfolio, we are confident that we will deliver strong growth in the years ahead. And with attractive gross margins, we will deliver sustainable profitability as we complete our clinical trials and launch our new product platforms.

We really have an exciting future and we look forward to telling you more about why we have so much confidence in this plan, so here is today's agenda. We have about a one-hour presentation as Jack said, and I'm going to tell you more about our plans to grow and protect the core business in just a minute. /I'll be followed by Matt Cambronne, our vice president of research and development, who will describe our product portfolio in more detail. And then, Jeff will update you on our financial outlook.

After some short closing comments, we'll take Q&A and most of our senior leadership team is here to answer your questions. I'm really proud of this senior leadership team. We've assembled an incredibly strong group here at CSI, with really deep experience in medical technology and cardiovascular medicine. So, in addition to Jack and Jeff and Matt, we've got actually all of our senior team here. I'm not going to introduce everybody, but I do want to introduce Dr. Jeff Chambers. Dr. Chambers is our chief medical officer and Harrison Boyd. Harrison is our vice president and general manager of peripheral. I'm sorry, of coronary. Rob Beverly, our vice president and general manager of peripheral. And then, Chris Volker seated next to Harrison is our vice president and general manager of international. Hopefully, I got all that correct.

With that, we're going to transition to our core OAS business now, and it's my pleasure to take you through the progress we've made in each of the important segments of our business. As you heard in our Q4 earnings report, we finished fiscal '22 with $236.2 million in revenue. Our core OAS business is composed of three groups, including our US peripheral business, which contributes about 66% of our revenue, our US coronary business contributes about 27% of our revenue, and international, which has grown to $16.4 million in revenue over the past several years contributes approximately 7% of our revenue. Orbital atherectomy has really transformed the care of

... Of complex cardiovascular disease. Since 2007, over 700,000 patients have been treated with orbital atherectomy. The burden of calcified cardiovascular disease really demands an aggressive response, and we play an important role in providing care for these patients.

Our brand is built upon our commitment to provide the highest quality products, services, and relationships to our customers and we derive significant competitive advantage from our US commercial sales organization. With approximately 200 quota carrying sales reps and a large staff of clinical specialists, we have the preeminent sales channel in the United States, and we support our customers with deep clinical acumen and a strong commitment to medical education. We have established a strong foundation in the peripheral and coronary vessel preparation markets. We have a proprietary core technology in OAS, we serve a large market characterized by a high unmet medical need, and we partner with physicians to care for some of their toughest cases, including patients with critical limb ischemia and complex high-risk coronary artery disease.

We have the strongest medical evidence in the market with over 7,000 patients studied in more than six large scale trials that have generated over 325 peer-reviewed manuscripts. And we are extending our leadership position through the conduct of trials like our ECLIPSE clinical trial. ECLIPSE is the largest randomized trial ever performed to study vessel preparation for calcified coronary lesions. We currently have approximately 1,850 patients enrolled in this trial, and we hope to complete enrollment in our fiscal '23. We have outstanding clinical data supporting the use of orbital atherectomy for calcified coronary artery disease, demonstrating safety with low rates of procedural complications, efficacy with a 3.4% TLR rate after one year of follow up, and efficiency with a very high rate of procedural success. We also have impressive evidence supporting OAS in peripheral arterial disease with low rates of major limb amputation at three years, even for patients with critical limb ischemia.

So let's take a deeper look now at each of our businesses. And in our peripheral business, we are evolving to become a broad-based peripheral arterial disease business. We are focused on restoring growth in our core OAS business by driving market expansion, expanding our product portfolio, and accelerating our revenue generated per procedure. There are numerous catalysts for market expansion and growth. We'll strive to improve our commercial execution. We're going to expand our reach into the ATK mixed plaque market. We will increase our focus on BTK and on the CLI segment of the market. We're going to broaden our call points with greater emphasis on the vascular surgeon. And we will continue our best-in-class medical education programs focused on training over 200 new peripheral customers per year in the United States.

We're really pleased that the reimbursement environment continues to stabilize. In June, CMS issued the proposed rules for 2023. And as I said earlier, on a weighted average basis, reimbursement for CSI procedures will actually increase by about 1% if the rules are implemented as proposed. The CPT code revisions for lower extremity revascularization are not on the September CPT panel agenda. So once again, this probably delays any changes in that until 2025 or later. As we've stated, this has become now a really manageable situation and we're executing initiatives that will transcend these reimbursement changes that are potentially pending in the OBL site of service. We're launching our COR program, which is our strategy to provide comprehensive resources that are required to support high

volume OBLs. These resources are really intended to support sites that are focused on the care of more complex PAD patients and also those patients that have critical limb ischemia.

As I stated earlier, the products that we have launched over the past few years still really have great potential to drive growth for us in the future. CSI is the only company that offers radial and pedal artery access. The low profile are of our device allows physicians to use these alternative sites of access, which can improve safety and cath lab efficiency by enabling patients to quickly ambulate, oftentimes within about one hour after the completion of a procedure. Additionally, our exchangeable series can enable full leg revascularization by leveraging the versatility of orbital atherectomy to treat a wide variety of plaque morphology from the small vessels below-the-knee to mixed plaque above-the-knee. And with the launch of our 2.0 Max Crown, we will now enter the mixed plaque ATK market, which expands our TAM and atherectomy to include this roughly $200 million incremental opportunity.

Finally, we will continue to gain momentum from the success of our interventional support devices. By leveraging our full portfolio of ISDs and the scale of the PAD cases that we support, we think there is a lot of runway to drive growth by accelerating our revenue per procedure. By FY27, we are confident that we can generate about $400 of incremental revenue per procedure for peripheral balloons, wires, and catheters.

So in summary, we believe we can achieve an 8% compounded annual growth rate in our US peripheral business, and about $230 million of revenue in FY27 with mid-single digit growth in our core OAS, and approximately 40% growth coming from ISDs. Headwinds could include the pace of COVID recovery, increased competitive pressures, and further constraints on OBL reimbursement. Tailwinds would include additional opportunity generated from our full portfolio, accelerating procedure volumes driven by the increased prevalence of PAD, and improvements in hospital reimbursement. Turning to coronary, we are striving to restore growth in our core OAS business with greater focus on winning back our cases, leveraging the increasing adoption of imaging to drive market expansion for vessel preparation, expanding our medical evidence with ECLIPSE, improving our commercial execution, and accelerating ISD growth with differentiated new products like Scoreflex and our NC balloons.

So I think we all know that IVL has really expanded the vessel preparation market, increasing the types of lesions and the number of physicians who can treat moderately calcified coronary lesions. Over the past year, physicians have gained greater experience with IVLs, and it has become more apparent now that scoring balloons, IVL balloons, and OAS really serve unique market needs. So we are beginning to see these treatment algorithms for vessel preparation sort out into swim lanes. And as more physicians align with these treatment algorithms, we will focus on assuring orbital atherectomy is the treatment of choice for properly selected patients.

Increased adoption of intravascular imaging is also an important catalyst for OAS market expansion and growth. We know that imaging leads to a 28% increase in vessel preparation and it improves PCI outcomes. So as you can see on the slide, imaging really enables physicians to accurately detect calcium and clearly identifies the morphology of a calcified lesion, such as a concentric or eccentric calcium, and you can see the presence of a nodule or a fibrous plaque. So armed with this type of information, the physician can choose the right technology to optimize lesion treatment, and we have found that this type of case planning really increases the use of orbital atherectomy.

So we will continue to improve our commercial execution by increasing our focus on high volume centers that selectively treat more calcified lesions, and our high adopters of imaging for the diagnosis, treatment, and assessment of calcified lesions. We will continue to be a strong sponsor for professional education to increase the capacity of physicians treating complex calcified lesions and we will continue to leverage our full portfolio of ISDs. Our strategy to leverage the presence of our sales force and accelerate our revenue per procedure through the sale of ISDs has really been very successful.

And now with the launch of our Scoreflex balloon as well as our line of specialty catheters for chronic total occlusions, we are confident that we can drive this opportunity to approximately $2,000 of revenue per procedure by FY27.

So in summary, we're confident that we can grow our coronary OAS business in the mid-single digits and supplement that with strong growth from the sale of ISDs in the mid-20% range. In total, we estimate that our coronary business will achieve an 11% compounded annual growth rate over the course of the next five years, finishing FY27 with around $100 million in revenue. Headwinds may include the pace of COVID recovery and increased competitive pressures, with tailwinds for the business including additional growth from our portfolio of ISDs, increased adoption of imaging, and incremental upside from the results of the ECLIPSE clinical trial.

Finally, I want to quickly address our opportunities in international, where we are rapidly increasing scale, and we have achieved strong growth in a highly competitive market. As you know, we are focused on the sale of orbital atherectomy for coronary indications in our international markets, and we've delivered very successful launches in Japan and in the EU. In fact, our EU launch is keeping pace with our launch in Japan, so we are really excited about the progress we've made in opening new accounts and building a strong foundation for CSI in Europe.

We think we're on pace to sustain a 24% compounded annual growth rate over the course of the next five years, and we're confident that we can build a $50 million business in international. All of this growth will come from the sale of OAS devices. Headwinds in international are like those in the US, but we have significant potential upside as we enter the market in China, launch orbital atherectomy for peripheral in Japan, and leverage the full CSI portfolio globally.

In closing, our goal is to sustain 10% growth in our global core business with US peripheral and coronary OAS growth in the mid-single digits, international in the mid-20s, and ISD growth in the mid-30% range. Importantly, we have a strong foundation to support the next phase of our evolution as we develop an innovative portfolio of new products that will diversify our revenue streams and position our company as a leader in the treatment of cardiovascular disease.

I'm pleased now to introduce Matt Cambronne, our vice president of research and development. Matt has been with CSI for over 15 years. He's a terrific leader, and he will present our product portfolio. Matt.

Matt Cambronne:

Great. Thank you, Scott. Good morning, everyone. It's a pleasure to have you with us here today and I'm really looking forward to walking you through our product pipeline, which we're incredibly excited about. So I thought it'd be appropriate to revisit the view that you see here because I think it does a nice job of really highlighting the magnitude that we see with these new platforms that we're pursuing. As we are creating the strategic vision for this product pipeline and assessing which new markets to pursue, there were three key variables that factored into our process. Number one, we wanted to pursue markets that we felt represented some of the largest growth potential in cardiovascular MedTech. Number two, those markets had to align well with our existing sales channel, which we really consider to be one of our greatest assets. And number three, we felt it very important that we had the right technical core competencies in place to develop competitive solutions here, whether those core competencies be internal to CSI or through partnerships with external entities.

So those were the considerations that landed us with the four platforms that we'll review today. And of course, those are thrombectomy, intravascular lithotripsy, everolimus base drug coated balloons, and mechanical circulatory support. We believe that these are four of the most attractive spaces in MedTech today, and we think that any one of these alone has the potential to transform the trajectory

of our company; but combined, we really see this as creating something special. And you can see that reflected in the addressable market detail that's shown here, $2.2 billion today to nearly $19 billion when we include these new markets.

So with that, we'll walk through what the pipeline looks like in total over the next five years. You can see FY23 is going to be led by our next generation atherectomy platforms and ISDs. We have the 2.0 Max Crown OAS on the peripheral side, which is going into full market release during the first half of FY23. And then in the second half of the year, we have our next generation coronary device launching, which we're branding as the Diamondback Precision. On the ISD front, we launched Scoreflex, the OrbusNeich scoring balloon, in midyear FY22. And it's done extremely well, and so we'll expect momentum to continue to build for Scoreflex as we go through FY23. And then in late FY23, we expect to commercialize our first line of catheters for complex coronary lesion crossing, which we'll ultimately aim to indicate for use in chronic total occlusions or CTOs.

So that's what the upcoming year looks like, and then from there we'll start to get into our new strategic platforms. So in terms of time for the new ventures, we'll expect that the peripheral vascular thrombectomy is going to be first to deliver. We expect to close our transaction with Innova Vascular late in FY23, and then proceed to initiate commercialization in the early part of FY24. We will initiate a clinical trial to expand our indication to include DVT in FY24. And finally, the pulmonary embolism indication will follow a clinical trial that Innova will run, and we expect to acquire that indication in late FY25.

On IVL, both coronary and peripheral indications will require pre-market clinical trials, which we expect both to start in FY24. The peripheral trial will be quite a bit smaller than the coronary, so we expect to commercialize peripheral first in the second half of '25, and the coronary and the second half of '26. And then as you get into DCB and MCS, which deliver in the latter half of this plan following completion of their pivotals, we'll expect the DCB platforms to commercialize first in the first half of '27 with peripheral running slightly ahead of coronary. And then finally we expect to commercialize our MCS device with an indication for high-risk PCI in the latter half of FY27.

Okay, so now we'll transition into the specific programs. And before we get to the new ventures, I wanted to take just a moment to walk through some of our more near-term products that are within our atherectomy and ISD portfolio. Again, we're excited about these in this next year.

So starting in atherectomy, we're in the early stages of our market release of the 2.0 Max devices. As Scott described, this is a larger grid crown which is available on all three of our peripheral platforms, and it's intended to serve the mixed plaque above-the-knee segment. And thus far, our commercial experience has been very positive. We're expecting to move from limited launch into a full market release in the second quarter of this year.

We also have the new coronary platform, which is now under FDA review. This will be branded as the Diamondback Precision, and this is a device that uses a modified drive shaft, which will improve the one-to-one motion, resulting in more predictable handling and greater treatment efficiency when used. As you saw on the previous slide, we expect our PMA supplement on this product to be approved in the third quarter of this fiscal year.

Turning to ISDs, we launched our OrbusNeich Scoreflex scoring balloon right about the midpoint of last fiscal year. This is the first non-compliant scoring balloon in the US. It also has the highest rated burst pressure of any specialty balloon at 20 atmospheres. And with about two quarters now under our belt, we really think this product is hitting the mark with our physicians. Feedback has been very positive. It's exceeded our commercial expectations and we expect it will continue to build momentum throughout '23.

And finally, we have our CTO Toolkit program. This program comprises a portfolio of devices that include an antegrade and retrograde microcatheter, guide extension catheters, and dual access catheters. This kit is being designed to target the most challenging to cross lesions and coronary interventions. The initial clearance will be for broad coronary and peripheral use with indication expansions specific to chronic total occlusions following clinical trial. From a timing standpoint, all three of these products are 510(k), and we'll expect to gain that initial clearance in the fourth quarter of this year. So overall, as you can see, there are a number of new products in the near-term that we're looking forward to bring to the market.

Okay, so now let's jump into our strategic platforms, first with thrombectomy. And here, we'll be focused on venous thromboembolism, or VTE, which consists of both deep vein thrombosis and pulmonary embolism. And as we think about the opportunity in this space, historically, VTE has been treated with the range of therapies including prescription medication, catheter-directed lytics, as well as aspiration. But the challenge has been that as clot ages, it becomes harder to treat with these legacy therapies. And as a result, that's where the market over the past few years has really started to shift towards mechanical clot retrievers in combination with manual aspiration, and that will be our area of focus.

So here's our estimate of the market and how we see it growing in DVT for FY22. We believe that pump-based aspiration systems still represent the largest segment of the market. That's followed by mechanical clot retrievers. And excluding stocking, we estimate that clot retrievers did in the neighborhood of $110 million in the US, but we expect that mix to shift considerably over the next five years. We see mechanical clot retrievers growing at a 20% CAGR to nearly $300 million in FY27, at which point we expect it to be the largest segment in that market. In PE, mechanical systems with manual aspiration have already commanded the leading market position at approximately $220 million annually, and we expect that momentum to continue to a 15% CAGR over the next five years.

So this is an overview of the system that Sanjay Shrivastava and his team at Innova Vascular have in development. It consists of two devices. The first is a manual aspiration catheter, which works in concert with a second, which is a mechanical clot retriever that uses a laser cut Nitinol cage to capture and retrieve thrombus. In terms of indications, we expect Innova will receive 510(k) clearance for the first peripheral vascular indication. CSI will then have the exclusive option to acquire and commercialize under that indication.

Shortly into our commercial experience, we plan to conduct a post-market study with the goal of expanding to DVT. In parallel with our work in the peripheral vascular, Innova will be running a pre-market clinical trial to gain PE indication. And when they acquire 510(k) clearance for that PE indication, we also will have the exclusive option to acquire and commercialize there as well.

In terms of configurations, we'll have aspiration catheters with diameters ranging from 12 to 24 French, with straight and curved configurations. And finally, we'll clot retriever baskets in 10 and 14 millimeter expanded diameter sizes. In terms of competitive advantage, our aspiration devices have a low profile, a nice thin wall, navigable design with atraumatic tip. We think recovering the spectrum of sizes and configurations to meet the needs of both peripheral vascular and PE. The retrieval basket has a laser cut design that's been optimized for capturing and retrieving clot. It also has radiopaque marker bands to make it highly visible under fluoroscopy. And finally, we think CSI brings a lot to the table in this space as well. We have a large and well-established sales force already in place calling on these ICs, IRs, and vascular surgeons. And we think this technology is highly complementary to what we already have in our portfolio. And then to wrap up thrombectomy, this is what we're looking at from a regulatory and clinical strategy. All three indications, the peripheral vascular, DVT, and PE, will be achieved through the 510(k) process. The PV indication will not require a trial. As mentioned, DVT will require a post-market

study and the PE will require a pre-market study, which will be run by Innova. And then from a timing perspective, we're expecting to commercialize the peripheral vascular in early FY24 and have the DVT and PE indications in late '25.

All right, so we'll move into intravascular lithotripsy. And as I'm sure many of you know, lithotripsy as a medical technology has been widely adopted for a number of decades. More recently, of course, the technology has been miniaturized with use in vasculature, starting in the peripheral arteries then expanding to the coronary arteries. And one of the real key points for us to address today is that we view IVL and atherectomy as both having a role to play in treating the spectrum of calcified disease.

We think atherectomy is the appropriate tool for longer, diffuse disease, eccentric or nodular calcium. And of course there are many lesions that can't be crossed directly with a balloon, so we think atherectomy is the right tool there. We see IVL as being effective for treatment in less diffuse, circumferential calcium, and more crossable lesions. We also think it's an important tool for physicians who in general might be less focused on treating highly complex disease.

In terms of the market opportunity, it's grown rapidly over the past two years. We expect that growth to continue over the next five years. And by FY27, we anticipate the US peripheral market to be somewhere between $150 and $200 million in revenue, and we expect that coronary will be between $600 and $700 million.

Here's an overview of our IVL system. It will consist of a console-based generator, a disposable connector with firing button, and a portfolio of balloon catheters. We are simultaneously developing catheters that will be indicated for use in the coronary as well as peripheral space. And in the peripheral space, we'll offer portfolios to treat lesions above and below the knee. And below, you can see the plan for our configurations, which we think cover the appropriate use case range in terms of balloon lengths and diameters.

In terms of competitive advantages, we believe there are a number of opportunities for us to improve upon the incumbent technology. We expect our catheters to have a reduced crossing profile and overall enhanced deliverability, which we see, really, as a need in the market today, especially in the coronary space. We also plan to offer a wider range of balloon sizes. And we believe that we can improve the number of pulses per catheter by a significant margin, which we think will allow for a more efficient and cost effective treatment.

And finally, we intend to simplify the sterile field interaction with the disposable connector and trigger and also improve upon the durability of the balloons to further mitigate the risk of rupture. In terms of what CSI brings to the table, the call points for IVL really are sweet spots for our sales force, both in the coronary and peripheral. And as I said earlier, we believe IVL is highly complementary to our existing portfolio. And as we commercialize, we think we'll be uniquely positioned in the market as the only company who can treat the entire spectrum of calcified disease. Turning to the regulatory and clinical front for IVL, we have been in discussions with the FDA on our strategy and we're planning to conduct two pre-market trials to support approval of our system. For peripheral, we're run a combined ATK/BTK study. We think this will be about 120 patients and results will be used to support 510(k) submission. We expect to start this trial in the first half of FY24 and finish in FY25, ultimately gaining 510(k) clearance in the back half of '25. Development of the coronary system is running in parallel to the peripheral, and we expect to start with the coronary trial right about the same time as the peripheral in FY24. It will be a larger study, sample size at around 400 patients. It's also a PMA submission, so the path to commercialization will stretch out a bit further, so we'll expect to launch in the back half of '26.

Moving along to drug-coated balloons. And here, we see the peripheral ATK

... market in the US is just under 200 million today and growing with a CAGR about 15% over the next five years. On the coronary side, we're looking, at least for now, exclusively at an ISR indication or in-stent restenosis. And of course, we don't have any approved devices in the US today, but we expect we'll see approvals in the next couple of years and that those approvals will help to drive that market to north of 150 million in revenue by FY27. In terms of our focus, we've partnered with Chansu Vascular Technologies, or CVT, led by Philippe Marco, who previously developed the Stellarex balloon platform. CVT is developing a portfolio of everolimus-based DCBs. The portfolio will consist of a range of rapid exchange devices for the treatment of coronary ISR, as well as a range of over-the-wire devices indicated for above-the-knee peripheral arteries. So, we're very excited about this opportunity.

We think we'll be one of the first to the US market with a limus-based DCB. We think within the limus family, that everolimus is the most proven drug, as demonstrated by the stent data over the past several years. The product that CVT is developing is unique and that it doesn't use a bioresorbable polymer, or nanoparticles, to deliver the drug to the tissue. And finally, similar to IVL, we think these products fit extremely well into our existing sales channel, which is very experienced with these call points. In terms of the regulatory and clinical pathway, CVT is underway with its European first-in-human studies, both in the coronary and peripheral space. In fact, they've now completed enrollment on the coronary side and are making good progress on the peripheral. Both these studies have a six-month endpoint and they'll be followed by an IDE Submission and Pivotal Trial, which will be used to gain PMA approval from the FDA. We expect that approvals will come in the first half of FY27, with peripheral running slightly ahead of coronary. So, we'll wrap with mechanical circulatory supporter, MCS, and with MCS, we're focused on our high risk protected PCI patient population. So, in terms of the US market today for protected PCI, it's about 340 million, and we expect that to grow at a 15% CGAR over the next five years and increase to approximately 700 million in FY27. One of the things that makes this space so attractive is how untapped it is. You can see here by our estimates, there are about 14,000 cases being performed in the US today. If you compare that to the total addressable market, you can see the delta between the two is tremendous, and it gives you a sense for just how underpenetrated this market is. So, here's an overview of our system. It will include a disposable catheter which contains our micro axial flow pump. It will contain a reusable console. Also, along with it will be a custom delivery guide wire and introducer kit.

In terms of our competitive advantage here, we believe our system will combine optimal cardiac output with ease of use and a low-profile design, which is deliverable through a 12-Fr access sheath, and has a very low end catheter profile of just 7-Fr. We'll plan to price this system at a level that we think will make this technology more accessible across the healthcare network. Similar to the other platforms that I've discussed today, we think MCS is highly complimentary to our existing product offerings and fits well within our existing coronary sales channel, which is well-versed in supporting the most complex BCIs already today. And finally, from a regulatory and clinical perspective, we recently completed our first-in-human experience with this system back in March in Europe. We're now planning to conduct a US-based early feasibility study, which will start in the first part of our third quarter of this fiscal year. We'll then come out of that EFS with the data we need to make final adjustments to our system algorithms and design.

From there, we'll proceed into final design verification of the system, complete the clinical trial design with the FDA, and submit our IDE for the pivotal trial. Pending that trial design, we think that positions us to commercialize late in FY27. So, I've taken you through a lot of information in a short period of time, so what's the takeaway? If I can leave you with one thought, I'd like that thought to be a vision of what CSI looks like in FY27. Peripheral will not only be serving our customers for the broad treatment of PID, but also for deep vein thrombosis and pulmonary embolism. In coronary, we believe we'll be uniquely positioned as the company for treatment of coronary disease. We'll have atherectomy

balloons, catheters, a crossing toolkit, an IV system, drug-coated balloons, and mechanical circulatory support for high risk PCI.

We'll be participating in markets that represents TAM of nearly $19 billion. We'll be highly diversified. We'll be competing with a highly trained and experienced sales force. In our opinion, will be one of the most formidable companies in cardiovascular med tech. With that, I'd like to thank you for your time, and I'll now turn it back over to Jeff Points, our Chief Financial Officer.

Jeff Points:

All right. Thank you, Matt. As you've heard throughout the morning, we have a very exciting future here at CSI. From a financial standpoint, I'll cover several topics in detail, but let me first provide the highlights. First, peripheral and coronary OES revenue, combined with ISDs, international, and our product pipeline combined to grow revenue 17% on average over the next five years. Second, we currently have attractive gross margins over 70%, and plan to improve margins over the next five years upon the launch of our new platform products. Third, as we pursue some of the largest markets in the medical device industry, we are going to significantly invest in product development and clinical research. And finally, as we launch the platform products, we are excited about attaining a significant level of sustainable profitability late in the plan period. Let's move to the financial summary. Earlier this morning, we discussed, in detail, our financial guidance for FY23.

We believe that continued market recovery combined with improving commercial execution, competitive momentum, new product introductions, and international expansion will restore revenue growth in FY23 to range between 8 and 12%. FY23 is a transition year, as we begin to make key investments in the development and clinical research that is required to move our new platform products forward. As a result, our anticipated net loss is between 9 and 11% of revenues. As we move forward to FY25, we start to see a significant amount of revenue from our thrombectomy DPT and PE products, along with our IVL peripheral product entering the market at that time. Revenue from these new platform products will encompass 8% of total revenues in FY25. We continue to benefit from mid single digit growth in our US peripheral and coronary businesses, while international growths over 20% annually on a consistent basis.

Overall, our revenue estimate for FY25 ranges from 325 to 350 million growing at a 13%, three-year CAGR. We expect to maintain consistent gross margins over the next few years as product cost reductions and the benefit of higher volumes offset any inflationary impacts, ASP erosion, and an increasing mix of lower-margin revenue sources. Our net loss improves in FY25 as we are continuing to invest heavily into our product pipeline. Profitability is expected as we achieve approximately 400 million in revenues later in the plan period. By FY27, our business transformation continues and new platform products represent 27% of total revenues. By this time, we anticipate fully entering the market for thrombectomy DBT and PE, IVL peripheral and coronary, and DCB peripheral and coronary. Although some of these products launch later in the plan period, they all represent very large, high growth markets where we believe we can generate substantial revenue in a very short period of time. As a result, we anticipate global revenues to range from 500 to 550 million in FY27, representing a 17% five-year CAGR.

Gross margins are expected to improve from current levels as each of the new platform products are expected to have higher margin profiles. We expect to be profitable and have positive adjusted EBITDA in FY27. Here, we have summarized our markets that we either play in today or will play in moving forward. The lower growth markets consist of peripheral and coronary atherectomy, while moderate growth markets in which we currently participate include international atherectomy and certain ISDs such as balloons and microcatheters. The high-growth markets, which are all growing

above 15% annually, are all future markets we plan to enter, beginning with our thrombectomy products. We are very excited about the prospect of commercializing into each of these markets over the next several years.

It's important to recognize our basis of assumptions used in our financial projections. First off, the projections assume that inflation begins to come back to normal levels during FY23. This will help manage component costs and operating expenses that are assumed throughout the plan. Secondly, please note that revenues from the product pipeline products have only been modeled to launch in the US. If any of these are launched internationally during the plan period, this could represent upside to the plan. The projections do not assume major impacts from COVID, such as a major disruption in our supply chain, a new COVID variant materially impacting procedure volumes, or worsening staff shortages. The projections also do not contemplate a global recession, additional reimbursement changes, and, of course, all projections exclude new M&A activity. I touched on gross margins earlier, but noted on this slide are the associated headwinds and tailwinds. Headwinds include inflation and freight costs, ASP erosion, and an increased mix of lower margin ISDs and international revenue. Tailwinds include a continued focus on reducing OAS product costs, increasing volumes, and the new platform products that carry higher margin profiles.

We expect margins to improve towards the end of the plan period, when most of the new platform products have been launched. We will continue to be major investors in research and development, the development and clinical research associated with participating in these major markets is significant, and those expenses begin to ramp up in FY23 and continue to increase through FY25 at levels of 15 to 17% of revenues. In FY26, we start to see this level of R&D investment level off and the percent of revenue is closer to 14 to 15%. Expenses that are driving the higher spend in the early plan years are investments in clinical trials related to our product pipeline, along with entering international markets with our OAS products. Development costs associated with our MCS device will also be significant and span across all plan years.

Tailwinds include the outsourcing of development costs for the new platform products and completing patient enrollment in the eclipse trial this fiscal year, which will offset some of the increases later in the plan period. We will begin to see improvements in SG&A expense sequentially starting at FY23. Over time, SG&A spend will be leveraged down to 55% of revenues, from from 72% that we experienced in FY22. This leverage will occur as we launch new products, commercialize our new platform products, and increase revenue per case with ISDs. Note that in preparation for the commercial launch of our PE thrombectomy system in FY25, we will be adding a new channel of sales representatives. From a capital allocation standpoint, our strong cash position of 160 million provides the resources necessary to fund all new platform product development and associated clinical trials. We will remain disciplined in our spending and prioritization to ensure each of the pipeline projects remain on track. Our balance sheet remains strong and we maintain a $50 million line of credit that is available to us as needed moving forward, while our banking relationships are strong and provide optionality as necessary.

We expect to be in funding certain new platform product transactions starting in the second half of FY23 and continuing through FY25. To close, let me reiterate that we are excited about the opportunity to grow our core business in the coming years. That growth, combined with our robust product pipeline, will provide a 17% five year CAGR by FY27. Our gross margins have remained attractive and will improve over the plan period. We are going to make significant investments in product development and clinical research in order to bring this plan to reality. And finally, as we begin to launch some of the new platform products, we expect to attain a significant level of sustainable profitability late in the plan period. In conclusion, we believe in this financial plan and are confident in our ability to achieve it. At this point, I'll turn it back to Scott for his closing comments. Thank you.

Scott Ward:

So, thanks, Jeff, and Matt, thank you for that presentation, as well. We are really confident about this plan. I hope you can see that we're really excited about the future for this company. I've just got a few closing comments and then we'll get on with the Q&A. So, this is just a quick summary of how we will win. It carries on, really, from Jeff's presentation, but you can see that in FY23, we will continue to drive growth in our, our global core business, we'll launch three new products, we'll achieve rapid growth from the sale of ISDs. We'll continue these initiatives in '24 and '25, and we'll supplement our growth during that time with the launch of our thrombectomy platform for DVT and for pulmonary embolism. We'll also launch our IVL balloon for peripheral indications during that timeframe. As we progress into FY26 and 27, we will launch three important new platform products, including our drug-coated balloons, the coronary IVL, and our propel mechanical circulatory support system for high risk PCI. We'll deliver sustained profitability and as our business scales over time, we will become a leader, really, in complex cardiovascular medicine.

Our growth will accelerate and with steady performance in our core global businesses, combined with the successful execution of our product portfolio, we're confident that we can deliver mid-double digit growth and 500 to 550 million of revenue in FY27. Of course, we are not looking too far ahead, and we're not doing that too fast. We fully recognize that our journey starts now and with strong commercial execution and the achievement of several important product development and clinical milestones that are scheduled for completion here this fiscal year. So, those are really important metrics, and we're very mindful of that, and those will be demonstrating the progress that we've made against this plan. So, going forward, we are committed to meeting the needs of all of our stakeholders. We will be guided by our mission. We will be focused on complex peripheral and coronary artery disease, we will be dramatically expanding our TAM with new product platforms, and we'll be serving over 250,000 patients worldwide by FY27. So, with that, I thank you all for your attention, and we will now take your questions.

We're going to get organized so that we can take questions online. We'll also take questions from those of you here in the room. For those in the room, we have a microphone that Julie will bring around and hand to you as you ask your question. I'd remind you and just ask you to introduce yourself, provide your name, the firm you represent before asking your question. So, with that, I think we can go ahead and get started. All right. Questions? Mike, right over here.

Mike Matson:

Hi, I'm Mike Matson, Needham & Company. I have a few on the pipeline, I had some of the disclosures you made today. I guess starting with the thrombectomy products, what gives you confidence that the mechanical devices are going to capture share or take a bigger part of that market than the pump based devices? If you look at what's happened in stroke, it almost seems like it's gone the other way, where the pump-based aspiration devices have taken over that market. I know it's maybe a little different type of market, but maybe you can talk about that a little bit. Thanks.

Scott Ward:

Yeah. Thanks for the question, Mike. Certainly, we have real confidence in our mechanical thrombectomy device. The device that is being produced at Innova has several really important competitive advantages, and Dr. Chambers, maybe I'll ask you just to take the microphone there and share your thoughts regarding our thrombectomy platform.

Dr. Chambers:

Yeah. Thank you. So, I'll address your questions in a couple ways. First, I'll talk about the market and the shifts in the market, and then about the device a little bit. So, if you look at the history, and I'm sorry to go back a little bit, look at the history of everything as it evolves. So, you figure coronaries, we started with thrombolytics that were give it externally, and that had problems. People had bleeding, strokes were the biggest part of that. It also takes time and its percentage of success is lower. So, in the coronary business, we've moved to thrombectomy, or direct intervention, to take care of that. We're seeing that in the PE world right now. So, for years, the first thing that showed benefit was lytic catheters directly in the pulmonary arteries. The problem with that is you have to sit in the ICU for 12 hours, there's a risk of bleeding, so we've eliminated that. So, nowadays, at least in the program at our hospital, people come in, we diagnose their PE, we bring them to the cath lab, we use the mechanical thrombectomy, remove the clot, restore flow.

Immediately, these patients get better. Their oxygen levels go up, their pressures and their lungs go down. And these people, I'm discharging the next day. I'm putting them on an oral anticoagulation, discharge the next day. So, similarly with peripheral, you have the same thing. When you give a lytic catheter, you have to have the patient flat on their back, they're in an intense monitoring environment, and there's a risk of bleeding. Anytime you give a lytic, there's a risk of bleeding. So, we can eliminate that with mechanical thrombectomy. You go and you move it, it's faster, it's easier, safer, and more effective, so we meet all the criteria. So why haven't we seen that yet, the complete changeover? It's really product development. So, we need the tools that we can do the job quickly, efficiently, and with a high success rate. So, we're very excited about a thrombectomy catheters that we'll be able to achieve those goals.

Mike Matson:

Okay. Thanks. I guess within mechanical, though, you have two types, you have a mechanism that goes and pulls it out and then you have the pump-based aspiration, a penumbra-type product, so I'm trying to understand why. I think what that slide was saying was that you think that the actual stent retriever type pulling the device out would take over some share from the pump-based penumbra-type products.

Dr. Chambers:

Oh yeah, for sure. Thank you for the clarification. So, if we go one step further into the pump versus mechanical, let's start with PE first. You're trying to pull a clot out that's very big and the pump-based devices are small. They're not effective, they just can't get enough of the clot. When new products develop, everybody tries them and figures out where they work, they're not really working in PE, because they can't effectively remove a large enough thrombus burden. I think we'll see the same thing in the leg. So, we have pump-based devices that work okay in the little tiny vessels, but as you get to progressively larger vessels, they're just not as effective, in the more mechanical works, as well.

Secondly, this clot is of various ages. So, the fresh clot, you can remove pretty easily with anything, but right now, we're seeing a mixed clot that's formed, and the pump-based devices just won't touch that. So, we have the ability to do, essentially, an endarterectomy, where we remove the clot from the wall, mechanically, and then we can remove it from the body. So, it's going to treat a larger segment of patients more effectively and restore more flow.

Mike Matson:

Okay, got it. That's all cool, thanks. And then, I guess a similar type of question on the DCBs. So, it seems like you're developing everolimus-based DCBs, and I know there was the paclitaxel scare that happened, but it seems like the pendulum has swung back a little and the docs aren't as scared about the paclitaxel

anymore, and by the time you get these things to market, there's just going to be even longer term data on those products. So, how do you really capture share? What's your point of differentiation? Are you going to run head-to-head trials against those paclitaxel balloons?

Scott Ward:

Yeah. So, let me address that you guys, I'll just interrupt the conversation that you're having. So, in our everolimus drug-coated balloons, the real competitive advantage there, as you've described, is our moving from paclitaxel to a limus-based product. We do think that the limus- based products, in particular, as you look at the drug-eluting stent market, which is now dominated, obviously, by everolimus and limus-based drug-eluting stents, that the advantage of the pharmacology and pharmacodynamics of everolimus significantly may enhance the safety and efficacy of these treatments for peripheral lesions, as well as coronary lesions. So, you are correct, we're going to be entering what is, potentially, a very competitive peripheral market, but in the coronary market, we may be the very first limus drug-coated balloon to come to market. We have a really strong franchise in Japan and we're closely advised by a lot of our Japanese interventional cardiologists, who now have been very heavy adopters of drug-coated balloons for the treatment of small vessels, bifurcated lesions, in-stent restenosis, and other coronary cardiovascular lesions, to the point where now, they're estimating 30 to 40% of PCIs being conducted in combination with a drug-coated balloon.

So, we think there is a tremendous opportunity there. As we look at our commitment to providing a full range of products to our physicians, for both peripheral and coronary artery disease, we think it's important, in our portfolio in total, to be able to offer the balloons, wires, and catheters, the atherectomy systems, the access systems like the microcatheters, also, the drug-coated balloons that can be used to treat these patients, and ultimately, as well, mechanical circulatory support to support those cases. So, we're really trying to provide that full range of products that, ultimately, can assure that we are an important player in the treatment of this complex cardiovascular disease. Other questions? Mike?

Mike Matson:

Thanks.

Scott Ward:

You're good for now? All right. Just pass it right over to Matt.

Matt Levin:

Matt Levin with Stifel. Thanks for putting this together. If I could start with just a couple questions for Jeff. On the '23 guidance, how should we think about the margin cadence? Does the R&D step up to that 16 or 17% range right out of the gate, or is it a build throughout the year? And similar on a SG&A level, just how those two interplay.

Jeff Points:

Yeah, thanks for the question, Matt. I would expect pretty consistent R&D spend throughout the year, that 16 to 17% really consistent throughout the start of Q1 through Q4. At SG&A, we talked about the leverage, that's going to go from 72% here in FY22 and we'll see that down in the mid-60s for the year. I would expect that leverage will start mostly in Q2. Q1 will be somewhat similar to FY22, but then you'll see that leverage start in Q2 and improve as the year goes on. Did you also have a question on gross margins or not, or just SG&A and-

Matt Levin:

No, I think the gross margins were fairly explicit, unless you want to give us some cadence.

Jeff Points:

No. I think gross margins, of course, I've provided a little bit greater range now, 72 to 74%. There's certainly some macro factors that are going on right now with inflation, with freight, those sorts of things that are driving gross margins. So,

So if we continue to see some of those things throughout the year, we're going to be at the lower end of that, also depends on kind of the mix of revenues that we end up seeing. But if we see some of those abate, then I think we could be at the higher end of that so that's really kind of how we came up with that range.

Matt Levin:

And then while I have you, I appreciate sort of the longer term outlook and I'm just thinking about what this business could look like at scale with, and you can pick if it's one or two or even all of these pipeline products play out. What's the margin profile look like, EBITDA profitability? And I'm asking particularly because it seems like there's very limited incremental selling expense for most of this pipeline so there should be significant drop through.

Jeff Points:

Yeah. And that's not something we provided in the materials in 27, you can see that we did comment that at 400 million of revenue we expect to get to significant profitability. I think at that point we'll have a lot of leverage and we'll be able to get very profitable very quickly, but specific numbers in 27, we aren't going into.

Matt Levin:

Okay. And maybe one last one for Scott, I'm just curious, you talked about the evolving swim lanes, the algorithms for treatment in coronary, you have a sense of what percent of cases OAS, I will say, irrefutably treats best. Is there a way to think about that? Is that evolved? Is it still the same sort of mix of lesions that orbital performs best in?

Scott Ward:

Yeah. Thanks for that, Matt, let me go back one question. I guess as we think about margins and EBITDA going forward, I think we would agree with your supposition, that we have the opportunity to really gain a lot of leverage and that is in fact true. And I think as we look at kind of the end of this plan period, our goal would be to have CSI be consistent with peers in our market. So as you think about more traditional EBITDA leverage within the med tech industry, I think will be about right there, which would be probably in that low 20s type of range, but that certainly would be our goal. And we believe that this product pipeline certainly has the potential to deliver that.

Regarding the evolving swim lanes, the way that this marketplace shapes out, and I'm going to ask Dr. Chambers to address this as well, but the way that this market shapes out, there's probably in the range of 30 to 40% of patients that have moderate to severely calcified lesions. And across that patient population, those patients are served with scoring balloons, IVL balloons and atherectomy devices. The atherectomy devices, we believe, are most appropriately used in about 10 to 12% of that population that have these more severely calcified lesions. Our device is best used and most often used

when you have uncrossable lesions, so if a balloon can't get across, you can't use an IVL balloon or a scoring balloon, you have to use orbital atherectomy. You also have lesions that are longer, that might require more than one balloon to treat, you have lesions that are diffuse, let's say, and where the energy of an IVL could escape out of one side of the vessel and as a result, you'll have a lower frequency of fracture.

And we also see patients that have multi vessel disease, let's say, where it's just going to be a lot more efficient and more appropriate to treat that patient with orbital atherectomy. Now, our challenge has been during the past year, as IVLs have been launched into the market, a lot of sites are trialing these devices and using them across this wide variety of patients. And what you've heard me saying for the past couple of quarters is as that trialing has begun to slow down now, and we're seeing more and more of our sites begin to move towards, let's say, a more consistent treatment algorithm. What we're seeing is that these swim lanes are coming back and forming and the differentiation of the unique market needs between an IVL device, let's say, and an atherectomy device are now much more clearly defined.

So that's good news for our business and that enables us to get our cases back. Of course, our sales organization is really out there driving this and something like imaging really enhances a physician's ability to detect what type of lesion they're trying to treat. So, Jeff, I'll just see if you want to add anything to that.

Dr. Chambers:

Yeah. Scott really covered that very well, very little to add. I'll just say a couple of quick comments. Atherectomy will never go away, there are just cases you cannot treat without that technology. And like Scott outlined, that's the uncrossable long lesion severely narrowed. And then we're really developing swim lanes, so IBL is really the concentric, more focal crossable lesions and then the scoring balloons are the other segment of that moderate to severely calcified area. In- stent restenosis, as a clinician, I find a lot of times there's under expanded stents, that's a good opportunity for lithotripsy and that works well in that area.

Scott Ward:

So the only thing I would add to that, Matt, is it's incumbent on us to work with physicians to define these treatment algorithms because in a short period of time, we may very well be the only company that offers scoring balloons, IVL balloons and atherectomy. So our intent is to really be the company that supports physicians in the care of these severely calcified lesions. So thanks for that. Rob.

Rob Halley:

Rob Halley with Champlain Investment Partners. I was curious Scott, I think it was mentioned that there was thought about a lower price point on the MCS device. Would you think about the same thing in IVL or because the reimbursement's there, would you look to be more in line with the competition?

Scott Ward:

Thank you for that question, Rob. As we think about our MCS device, we haven't really defined what our pricing will be there but we do believe that the ability to penetrate that larger population of patients could be enhanced by offering a better, or let's say, a more efficiently priced procedure and that would indeed increase the adoption. I think, as we look at IVL balloons, as we look at the marketplace for vessel preparation, we're much more aligned there with probably staying within the context of the economics that have currently formed around those procedures. Largely because we provide the vessel

preparation, but what that procedure really is all about is placing a drug-eluting stent. So the drug-eluting stent, and that will still define the procedure, we are obviously a part of that, but we're not the most important part of it. At the end of the day, the drug-eluting stent and the placement of that product is the reason the patient is there to be cared for.

Rob Halley:

And just one other, if I could. There's been a lot of talk about IVL expanding the market to clinicians that aren't used to doing atherectomy, do you see some of those clinicians now that they've used IVL wanting to get trained in atherectomy so they can treat a wider variety of patients?

Scott Ward:

Yeah, we are seeing that. A lot of physicians now that have begun to realize that they can provide care for some of these more severe patients are actually now being trained in coming through. And we have a lot of our training programs are specifically designed to provide advanced training to take a physician who, let's say, has some fundamental basis in treating these patients and now train and educate them on how to perform atherectomy. And I think we focus on that in coronary, I think we generally focus on training about 200 coronary physicians per year. And that largely are our customers who have experience using IVL balloons or other devices, and now want to learn how to use orbital atherectomy.

The other area we really focus on is training and educating fellows, and so fellowship training, training physicians in their fellowship is really critically important for us. And it's important there for physicians to learn everything from scoring balloons to IVL balloons to orbital atherectomy, but we really focus there on the interventional cardiologists who are going to be dedicating their careers to treating these more complex cases and that's not everybody. And treating these patients as consequences, this patient population is oftentimes a very sick population of patients, and sometimes just interfacing with them can cause complications. So it requires a lot of training and education to be expert at this and when you talk about the really difficult cases, I think it's still very important that physicians be trained in managing complex coronary artery disease, they be trained on how to manage these complications and ultimately how to use tools like orbital atherectomy. So customer education is really critically important for us and something we continue to invest heavily in, and I think it's probably the primary factor that drives our market development. Thank you for that.

I'm going to just switch to our online questions very quickly and we have a question from Brandon Vasquez from William Blair, and Brandon is asking about our ECLIPSE trial. ECLIPSE trial is getting closer to finishing enrollment, what are the timeline expectations for a readout of that study and what kind of benefits, if any, are baked into the long term guide for this study? Thank you for that question, Brandon. The ECLIPSE clinical trial, as I said, has approximately 1,850 patients enrolled, that trial is designed to be a randomized controlled trial comparing balloon angioplasty to orbital atherectomy, we intend to enroll about 2000 patients in that study. Because of COVID, we've seen a slow down in patient enrollment, as you know, we've been running around 20 to 30 patients per month. We do expect to complete enrollment in that trial during the course of this fiscal year, there is a 12 month follow up on that trial so the trial has two primary endpoints.

The first primary endpoint is the minimum stent area, which is an acute metric, it's taken immediately following the procedure. And then there is a 12 month follow up that would be looking at clinical outcomes, in this case, target vessel failure. So the final report out on ECLIPSE will occur about 12 to 16 months following our completion of patient enrollment. If we finish patient enrollment January 1st of 2023, you could expect the report out on that then in the spring of Jan of 2024. In this current financial model that we've presented, we have really no incremental benefit from ECLIPSE or the

ECLIPSE results in that analysis. So the benefit from ECLIPSE would really be recognized by us as an improvement to the model that we presented.

Next question online comes from Chris Pasquale at Nephron, thank you for this question, Chris. Chris asks why does the MCS device require a 12 French sheath for a seven French indwelling catheter? Do you expect it to be compatible with standard small bore vessel closure devices? Also, what flow rate are you seeing in the first in human experience? Jeff, I'm going to come to you with this in just a moment, but the way that our MCS device is designed is that our pump is larger and requires the 12 French puncture. But our indwelling catheter, which is left behind, is only a seven French catheter, which is actually very small, probably about the size of a diagnostic angiocath. So, Jeff, do you want to take the rest of that question is, do you expect this to be compatible with small bore vessel closure and what flow rate did we utilize in our first and human experience?

Dr. Chambers:

Yeah, perfect, thank you for the question. So the answer, when you put the device in, the pump is larger than the shaft so you need a larger sheath to go in. There are techniques where you can remove that but we have become proficient with large vessel closure. So typically we do Perclose or there's other commercially available devices to treat the large vessel. So I think that's been worked out and we're seeing much less complications in the vascular area. And then for flow rates, I'm going to call my colleague here, Matt Cambronne, to talk about the mechanics of the pump.

Scott Ward:

This is the flow rate used in the first in human.

Matt Cambronne:

Great. Yeah, thanks for the question, Chris. Again, our device has been characterized to produce north of three liters per minute. Again, as we get into this market, we want to talk about really the patient that we've selected here, which is the high risk patient population and being able to deliver meaningful flow for the needs of that patient versus a shock patient because they're different. And so with our device being able to support and provide meaningful cardiac power throughout that and cardiac the entire cardiac cycle is really important. And we think we've got a great functioning pump and flow rate for that to fill during diastole, which is when the coronary arteries are perfusing at the same time. Anything else?

Dr. Chambers:

No, that was perfect, Matt. I think the highlight is that we have maybe a greater ability to complete the flow through the entire cardiac cycle, two thirds of the flow, all the flow to the coronary occurs during diastole and we think we can have increased perfusion, which has some advantages.

Scott Ward:

Great, thank you. Our next question is about international and I'm going to call on Chris Volker, our vice president of international to address this. And the question comes from Brandon Vasquez at William Blair, can you talk about some of the most compelling international opportunities in international over the coming years?

Christopher Volker:

Absolutely, starts with Europe early, where were in the early days in Europe. So year ago, I couldn't say that we had sales coverage across Europe, we're now in most of the larger Western European countries and feeling good about this. We launched 16 countries in the last fiscal year, the vast majority of those were just in the last six or seven months. We're really early days in Europe so we're looking for strong growth in Europe. Japan, we've touched on, we think we have about 40% market share, we still see growth there. Peripheral, we're going to be starting a clinical study soon for Japan, and then longer term, of course, China is the big opportunity out there. So still early innings with international, for sure, and just a lot of opportunity for us really just focused on execution right now.

Scott Ward:

Thank you, Chris, and hold on to the mic. So the next question from Brandon is which regions have established reimbursement for either the core or pipeline products and if possible, can you size some of those opportunities? I don't think we could size the opportunities, but you might just make a few comments about reimbursement.

Christopher Volker:

Sure. Reimbursements, country by country, of course, and product by product, so hard to generalize. In Japan, we have a good reimbursement for coronary, jet stream's in the process of getting reimbursement established for peripheral and that actually just recently got announced and was slightly higher than the coronary reimbursement. So we were happy to see that in Japan. Europe, it's a variety of DRG based systems as well as hospital budgets, so really country by country and we're just starting to look at the market opportunities for the pipeline right now. We do see really strong interest, of course, very exciting products and we're looking forward to bringing those products globally to our partners.

Scott Ward:

Great. Okay. Thank you, Chris and Brandon, we can get you more detail on those market sizes, we'll just do that offline. I would definitely need a slide in order to take you through that. Okay. Other questions, Matt.

Matt Levin:

You've generated first in human data, you're starting to generate some EFS on a couple of the pipeline products. How do you think about maybe disclosing that data over the course of the next sort of 12 to 24 months, whether it's on the DCB, whether it's on mechanical circulatory support? Just how you're thinking about disclosing some of the early data.

Scott Ward:

Yeah. Thank you, Matt. So we will definitely be disclosing it, we're in the process now of just preparing the report of our early feasibility study. That trial was actually conducted, as you know, in Georgia, we had a very successful outcomes. We intend to prepare that information and have it presented, Dr. David Kazak who performed the procedures, we'll be putting that together and we'll be presenting those results. So we're excited to have that happen, obviously it takes time to get that organized and pull together. And we'll be presenting that probably at some time in an upcoming medical conference over the course of the next six months or so. In the case of the drug code of balloons, as we complete the follow up on those studies, we would fully anticipate presenting that in accordance with the timelines that have been laid out.

And I think the best indication for you on that, however, will be the initiation of our IDEs. As we complete our feasibility studies for the coronary and peripheral drug code of balloons in Europe, we'll be using that data to support our IDE submissions. So a successful IDE submission will reflect a successful outcome in those trials.

Matt Levin:

One follow up on IVL, we all obviously saw it last night. What's left to do to get into the five, 10K and the PMA trials from a development standpoint? What do you still have to nail down or lock down?

Scott Ward:

Yeah, we're in the stage now of moving into our design validation testing, we'll be completing our animal testing and then continuing the pre sub meetings that we have with the FDA to negotiate the content of those IDEs and the design and content of those clinical trials. As Matt Cambronne indicated in his comments, we have not yet completed those discussions with the FDA, so those conversations are ongoing and they will really be determinant in terms of identifying the clinical studies that will ultimately be performing. But I would say that that technology is fairly well de-risked at this point and we're excited to bring that forward.

Mike Matson:

Hi, just a few more on IVL. So in your projections, what have you assumed in terms of other companies entering the market? And then I mean, I understand what happened with the IPR process and whatnot, but how confident are you that Shockwave's not going to still try to file some kind of patent lawsuit against you guys with a newer patent or something else that they have?

Scott Ward:

So thank you, that's Mike Matson, by the way. So in terms of our assumptions regarding the competitive market, we are assuming that we will be the second company in the market, we also are assuming that it is possible other companies may enter that IVL market over time, most likely following us. In terms of the intellectual property, I can tell you that we are confident that our device does not infringe upon any of the Shockwave intellectual property. We, as you know, also filed three IPRs, two of those have were ruled in our favor, have been appealed and following appeal are also ruled in our favor. The third is in a process that has led up through the Supreme Court and I think I'm going to ask our general counsel just to give you an update on that. Alex introduced yourself.

Alexander Rosenstein:

Yeah. Alex Rosenstein, general counsel, the PTAB issued the three decisions back in July of 2020, two of those, as Scott said, have been appealed and upheld. The third was subject to a re-hearing that happened, I think, in October of 2020 and we're still waiting for the PTAB to come back on that, we don't have any reason to believe that the decision will change from the original one, but we would expect that process to sort of continue as the other appeals did if it goes against Shockwave as the original filing did.

Scott Ward:

Excellent, thank you. Anything else, Mike?

Mike Matson:

That's all for now, thanks.

Scott Ward:

Okay, for now. All right, good. Our next question, I'm going to take from online from Jason Bedford at Raymond James. What do you expect the PROpel pivotal trial to look like single arm or will you compare it to existing MCS therapies, either Impella or IABP? Thank you for that question, Jason. Our clinical trial design is still under discussion with the FDA, we do not yet have a final trial design with the FDA that has been completed. Just based upon what we have seen other companies do and the content of other company IDEs, we do anticipate that this will be a head-to-head trial, but the exact randomization scheme for that study has not yet been determined.

Next question comes from Chris Pasquale at Nephron. You mentioned you believe you have enough capital to support your growth goals, how much of the cash on the balance sheet is already spoken for between the pre-negotiated purchase options and potential milestone payments if you achieve your LRP? So excellent question, we do have enough cash on our balance sheet to cover all of the obligations related to the transactions that we've negotiated, as well as our projected R&D costs and the costs that we expect to incur over the course of the next few years. I can tell you, and you can calculate that probably, that will use up a fair amount of our cash but we still will have cash remaining on our balance sheet at the conclusion of that process. Jeff, is there anything that you would like to add to that?

Jeff Points:

No, I would just add that in my comments, Chris, I did note that these product acquisitions start in Q4 kind of late in FY23 and kind of continue kind of the next couple years after that end FY25. So we haven't given specifics on how much those acquisitions are, but we are comfortable kind of with our current cash position supporting our plan here. So thanks.

Scott Ward:

Thank you, Chris. Other questions? Anything else online? Any other questions in the room? Okay, very good. Then we will conclude today's session. I want to thank all of you who have joined us in person, and those that joined us online. We really appreciate your interest in CSI and we're so happy that we've had the opportunity to take you through our products, show you our pipeline and give you the chance to handle some of these devices and get a firsthand impression of really the great progress that we've made and how excited we are about the future. So thanks everyone, thanks for being here. And with that, we will adjourn.