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CSII - Cardiovascular Systems Inc Analyst Day

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PRESENTATION

Jack Nielsen - *Cardiovascular Systems, Inc. - Senior Director of Corporate Communications & IR*

Good morning, and welcome to CSI's Analyst Day meeting. I am Jack Nielsen, Vice President of Investor Relations and Corporate Communications. Members of management presenting this morning will be Scott Ward, Chairman, President and CEO; Rhonda Robb, Chief Operating Officer; and Jeff Points, Chief Financial Officer. And in the audience from CSI we have Alex Rosenstein, General Counsel and Corporate Secretary, and Julie Feuerherm, Corporate Communications Specialist.

Last night we released fourth quarter and fiscal 2018 financial results. We will begin today's meeting with a review of those financial results. We will then immediately transition to the Analyst Day portion of today's meeting.

Prepared remarks are scheduled for approximately two hours. We kindly ask that you please save all your questions for the Q&A period at the end of the prepared remarks. This meeting will end no later than 12 noon today.

Before we begin, I'd like to remind you that in today's presentation we will make forward-looking statements. These forward-looking statements are covered under the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995 and include statements regarding CSI's future financial and operating results or other statements that are not historical facts.

Actual results could differ materially from those stated or implied by our forward-looking statements due to certain risks and uncertainties, including those described in our most recent Form 10-K and subsequent quarterly reports on Form 10-Q. CSI disclaims any duty to update or revise our forward-looking statements as a result of new information, future events, developments, or otherwise. We will also refer to non-GAAP measures, because we believe they provide useful information for our investors. Last night's release and today's presentation both contain reconciliation tables to GAAP results.

I will now turn the meeting over to Scott Ward.

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

Thank you, Jack, and good morning, everyone. It's great to see a full room here. Thank you so much for coming and joining us. We really, really appreciate it.

Hopefully, as Jack said, you all had an opportunity to review our fourth quarter and fiscal year 2018 earnings press release that we issued last night. CSI ended the year with a record fourth quarter. Revenue of $59.2 million increased 6% compared to third quarter, and was up 12% year over year.

In addition, we generated $3.7 million of net income in the fourth quarter and $1.7 million of net income for the full year. This is obviously a very important milestone for our company, demonstrating that we have established a high-growth and profitable business model in a very competitive marketplace.

Fourth quarter revenue reflects the progress that we have achieved with the key growth initiatives that we deployed throughout the year, including our increased case coverage; focused coronary sales representatives; execution of long-term, volume-based contracts; the introduction of new products; and our commercial launch in Japan.

We believe that increased case coverage from our clinical specialists is really driving growth in our current accounts and improving productivity in sales. As we highlighted in the past, we are committed to providing superior procedure support in the cath lab, and in fourth quarter we were present in 67% of our cases, and that represents a 53% increase from Q1.

Looking at our business compared to Q3 we saw strong sequential growth in both peripheral and coronary. The peripheral business grew 5% compared to Q3, driven largely by strong sales in office-based labs. Our strategy to target OBLs with volume-based contracts and improved case coverage resulted in 15% quarter-over-quarter growth in OBL revenue.

Our coronary business increased 10% compared to Q3. We are seeing strong organic growth in coronary arising from increased adoption at our current accounts and significant growth from large accounts, those that perform over 500 PCI procedures per year.

The focused efforts of our coronary sales reps and a strong market response to the new GlideAssist feature were the primary growth drivers in our coronary business. We launched GlideAssist in Q3, and this new feature improves the efficiency and ease of use of orbital atherectomy. Using GlideAssist, the operator can maneuver the orbital crown through tortuous and angulated vessels and reach lesions that are otherwise really difficult to access. This feature increases market penetration by allowing the treatment of patients that otherwise may not be candidates for an atherectomy procedure due to their very complicated anatomy.

Although we remain in a limited market release for introduction of OrbusNeich coronary balloons and our ZILIENT peripheral guidewires, Q4 sales of those products generated approximately $350,000 in revenue. The successful introduction of these products to select new accounts validates our belief that we can generate incremental revenue and improve sales rep productivity by offering high-quality procedure support products that will potentially be used in every case. We look forward to the full market launch of our balloons and wires later in Q1.

The launch of coronary orbital atherectomy in Japan also contributed to our fourth quarter growth. In fourth quarter sales to our exclusive distributor Medikit represented just under $1 million of revenue. We are pleased that our launch in Japan is proceeding according to plan, with the enrollment of new accounts and patient procedures occurring right on schedule.

We also continued to make strong progress in the execution of our key development and clinical research milestones. For example, we now have nearly 90 sites enrolled and over 400 patients enrolled in our ECLIPSE clinical trial.

In peripheral we will share the two-year follow-up data from our LIBERTY 360 study at the Amputation Prevention Symposium in Chicago. That meeting occurs on August 8. As you may recall, the results of the LIBERTY trial have been very favorable. The 18-month follow-up data that we shared earlier this year showed high freedom from major adverse events across all Rutherford classes, and a sub-analysis of patients treated with orbital atherectomy revealed that nearly 92% of the Rutherford 6 patients were free from amputation at 18 months.

These results demonstrate that treatment algorithms incorporating orbital atherectomy can lead to amputation-free survival for high-risk critical limb ischemia patients. We look forward to sharing the two-year data from LIBERTY 360 at the AMP conference, and we plan to release the results of an economic analysis derived from LIBERTY later this fiscal year.

So, in summary, we remain very encouraged by the progress we are achieving across our company. Our new leadership team is really hitting its stride. We've enjoyed stability across our sales organization and the morale in the field is high. We're winning again, and as a result we've sustained sequential growth now over the course of the past three quarters. The successful introduction of product line enhancements like GlideAssist, our new balloons and wires, and the launch of orbital atherectomy in Japan will provide new and growing revenue streams that are expected to accelerate our growth trajectory going forward.

Naturally, we are very pleased that we finished fiscal year '18 strong, and we have proven that we are operating a profitable business model. Looking ahead, we will continue to operate with positive cash flow, but I expect that our profitability will continue to fluctuate around breakeven as we accelerate investments in research and development and we experience the normal variation of seasonality in our business.

So, Jeff Points will now provide a summary of our fourth quarter results and introduce our fiscal 2019 guidance. Jeff.

Jeffrey Points - *Cardiovascular Systems, Inc. - CFO*

Thank you, Scott, and good morning, everyone. I will now share details on our Q4 progress and sales performance in our peripheral and coronary franchises.

Fourth quarter revenue of $59.2 million represented a 12% increase compared to last year and was slightly above the high end of our guidance range. We sold nearly 18,800 devices during the quarter, generating 91% of revenues. Reorder rates remain strong, representing 99% of revenue.

Coronary revenue increased 22%, to $16.1 million. In the U.S. coronary units sold increased 11%, while ASPs slightly increased. In Japan revenue from the fourth quarter was $960,000. Excluding Japan, coronary revenue increased about 15%.

Peripheral revenue increased 8%, to $43.1 million. Peripheral units increased 15% year-over-year and over 7% compared to third quarter. Revenue in both hospitals and office-based labs, or OBLs, increased about 8% year-over-year.

We continued to drive revenue and take share in the OBL side of service. Offering long-term contracts to new and existing customers that include volume-based discounts along with providing increased case support has been well received. As anticipated, the success of these volume-based contracts modestly reduced peripheral ASP.

Similar to Q3, consolidated peripheral ASPs declined in the mid-single-digit range compared to the year-ago period. However, higher production volumes combined with manufacturing efficiencies and targeted product cost reductions helped offset the lower ASPs in our peripheral business. As a result, gross profit margin remained very strong, at 81.7%, and was the same as the year-ago period.

In total, operating expenses of $44.6 million increased $2.3 million, or about 5%, but was slightly below our forecast due to timing of projects.

SG&A increased about 5% versus revenue growth of 12%. Consistent with previous periods, we intend to grow revenue at a faster rate than SG&A.

R&D expenses increased about 6% due to new product development and increased enrollment in our ECLIPSE clinical trial. We would anticipate this trend to continue. You will hear more about our planned R&D investments later this morning.

Fourth quarter net income of $3.7 million, or $0.11 per share, was about $1 million better than forecast due to higher gross margins and lower operating expenses. Adjusted EBITDA was a healthy $7 million.

At quarter end our cash balance was $116 million, an increase of approximately $7 million during the quarter.

That completes my prepared comments on fourth quarter results. I will now discuss our guidance for the full year of fiscal 2019.

Consistent with the majority of companies in our peer group we are no longer going to provide quarterly guidance. Today we will provide guidance for fiscal '19, and later in our presentation we will give you a sense of our financial goals for fiscal '21 and fiscal '23.

With that in mind, we are forecasting fiscal '19 revenue to be in the range of $240 million to $250 million. This represents revenue growth of approximately 11% to 15%. From a high level we forecast continued growth in our domestic peripheral and coronary atherectomy markets. Increases in case coverage combined with line extensions and product improvements like GlideAssist are being well received.

In addition, we began introducing long-term contracts to our OBL partners midway through fiscal 2018. As I just mentioned, we saw a nice increase in volume as the benefits of those contracts take hold. We expect this to continue, and we will seek additional opportunities to drive volume and take share in the fast-growing OBL segment throughout fiscal 2019.

We believe fiscal 2019 revenue will also benefit from the full market launches of PTA and PCI support products. This will commence later this quarter, after our sales force has been trained on each of the products.

Finally, international revenue and OEM products are expected to contribute $7 million to $8 million this year with the continued launch in Japan, recently announced distribution agreement with OrbusNeich, and full launch of our wires and balloons. Rhonda will provide more details on the specifics of these revenue drivers later this morning.

For fiscal 2019 we expect gross margins of about 80%. We are excited about our international plan and our full launch of OrbusNeich coronary balloons and ZILIENT peripheral guidewires. However, they are lower margin segments that have some effect on overall margins. Product cost reductions and manufacturing efficiencies will continue to be a primary focus in our plan to sustain very attractive gross margins in fiscal 2019 and beyond.

We expect a net loss for fiscal 2019 equal to 1% to 2% of revenues. Our increased investments in product development, clinical research, and establishing an international presence are the primary drivers of the net loss. Later this morning we will discuss in more detail our strategy surrounding these significant investments and how they impact long-term growth.

Adjusted EBITDA and cash flow are expected to be positive during fiscal '19.

Keep this in mind as you build out your quarterly models, and, while I said we are discontinuing the practice of providing specific quarterly guidance, we will, however, provide some color today and in the future on quarterly conference calls, especially to remind everyone about the seasonality of our business cycles and key events that may or may not be unique to CSI.

For instance, our Q1 is historically our slowest quarter of the year, mainly due to a seasonal slowdown in cath lab procedures. In fact, if you look at the sequential revenue from Q4 to Q1 over the past several years you'll notice that our first quarter revenue was typically well below the revenue reported in Q4. As a result, our bottom line is impacted heavily and slowly improves throughout the year.

For those in the room, I'm sure you'll have some follow-up questions, and I'll be happy to answer those during the Q&A session later this morning.

I'll now turn the meeting back to Scott Ward.

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

All right, thank you, Jeff. So, I think you can see that we exit FY '18 as a strong and financially stable company. We are really driving market-leading performance now with orbital atherectomy, and we're executing on many of the initiatives that will accelerate our growth in FY '19 and beyond.

With that we're going to conclude our results looking back and we're now going to kind of get to the exciting portion of the presentation where we're going to look ahead and get on with describing our key strategy in our Analyst Day.

As Jeff said, we know that you have questions regarding fourth quarter and fiscal year '18. I just ask for your patience that you save those questions until the end of the session.

So, we can get started. I think, as many of you know, over the past 6 to 12 months we have been working on our business plans and strategies to really better serve our patients and to build our company. Throughout this process we have collaborated closely with our board of directors, with many business advisors and many key physicians around the world. It is my pleasure today to introduce two of the world's preeminent interventional cardiologists who have joined us, Dr. Martin Leon and Dr. David Kandzari.

Dr. Leon is a Professor of Medicine at Columbia University and Director of the Center for Interventional Vascular Therapy at New York Presbyterian Hospital and Columbia University Medical Center. He is also the Founder of the Transcatheter Cardiovascular Therapeutics Conference and Chairman Emeritus of the Cardiovascular Research Foundation. Welcome, Marty. Thanks for joining us.

Dr. Kandzari is the Director of Interventional Cardiology at the Piedmont Heart Institute and Chief Scientific Officer for Piedmont Healthcare in Atlanta. David is a leading clinical researcher and a prolific educator in interventional cardiology. He has extensive regulatory experience, having worked previously at FDA and serving as an ad hoc member of the Circulatory Devices Panel. Welcome, David. Thank you for being here.

So we are really thrilled that both of you are able to join us this morning and to provide your perspectives on our strategy and our markets.

So this is our agenda for today. I'll begin with a brief overview of our business and our key growth strategies. Dr. Leon will then address emerging trends in the treatment of complex peripheral and coronary artery disease. Rhonda will provide a detailed look at our key initiatives to drive market-leading performance with orbital atherectomy as well as our plans to accelerate our growth through geographic expansion and innovation in our coronary and peripheral product portfolio. Dr. Kandzari will also join Rhonda to discuss certain segments of our product pipeline, and he will share some case studies showing the interventional procedures used to treat complex coronary patients.

Jeff Points will describe how we will broaden our value streams and the quantitative characteristics of our business plan, including our financial goals for FY '21 and '23. After a few brief closing remarks we will then host a very quick Q&A session with Dr. Leon and Dr. Kandzari, followed by a more detailed Q&A session with CSI management.

So over the past three years CSI has sustained a 10% compounded annual growth rate. However, as you all know, our growth has not been linear, and we have had our share of challenges. But we have built a financially sound and stable business. We have a proprietary core technology in orbital atherectomy. We serve large and growing markets. And we partner with physicians to treat 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, and we are extending our leadership position through trials like LIBERTY 360 and ECLIPSE. We have a robust sales organization in the U.S., with approximately 200 quota-carrying sales representatives and 85 clinical specialists. We have developed deep clinical acumen in our sales organization, and we derive significant competitive advantage from our clinical case support and medical education programs. We are very committed to medical education, and we have trained over 2,500 physicians in just the past two years, including more than 100 physicians in their fellowship medical training.

CSI is a mission-driven organization, and I am very proud that each and every one of our employees is committed to saving limbs and saving lives every day. The mission shapes our values, guides our judgment, and motivates our employees. Coronary and peripheral artery disease are a leading cause of morbidity and mortality in the developed world. There are over 370,000 deaths annually in the U.S. from coronary artery disease and over 2 million patients with critical limb ischemia.

The profound burden of complex coronary and peripheral disease demands an aggressive response, and we play an important role in improving the quality of care for these patients. We are a patient-centric and customer-focused organization, and we strive to be partners in healthcare,

collaborating with our customers to deliver the high-quality products, services, and relationships that are required to assure the best possible outcomes for their patients.

We have built an incredibly strong leadership team, with deep expertise in medical technology and a proven ability to scale and grow businesses in interventional cardiology. On average our leadership team has over 18 years of experience in med-tech, and collectively we have a strong track record of successfully driving commercial execution, developing new markets, and building product portfolios that have improved the quality of care for patients with cardiovascular disease.

This team is supported by a high-performance organization. As I have said, the foundation of our culture is our mission, and the values that shape our company are confidence, passion, innovation, accountability, and pace.

We are the market leaders in the treatment of calcific peripheral and coronary artery disease. We have over 700 employees, including 80 engineers and scientists, and our core technology is supported by a robust portfolio of intellectual property, with 227 patents and about 190 patents pending.

We generated $217 million of revenue in FY '18, and you can see that our revenue mix reflects our focus on orbital atherectomy, with sales almost exclusively in the U.S. market. This focus has served us well, and we have built a very strong platform for growth. As I said earlier, over the past 3 years we have sustained a 10% growth rate and 80% -plus gross margins. Our cash balance and adjusted EBITDA have both improved by $56 million. With net income of $1.7 million in FY '18, we have proven that we have a profitable and scalable business model. So we have a strong foundation that we can leverage to build a contemporary cardiovascular company.

Looking ahead, we want to broaden our value streams, and our goal is to sustain a 15% to 18% growth rate. We intend to leverage SG&A while we increase our investment in research and development. Over the next couple of years we will continue to operate around cash flow breakeven, but we are committed to achieving and sustaining profitable growth over time. We will continue to protect and grow our core business by focusing on product enhancements, superior clinical support, medical education, and the generation of medical evidence that demonstrates the safety, efficacy, and efficiency of our products.

Over the next 5 years our goal is to sustain our peripheral growth at or just above the market and to grow our coronary franchise in the mid-double digits. In total, we believe that we can sustain a 10 percent plus growth rate in our core business in the United States.

Global expansion will further accelerate the growth of our core business. As you know, we launched our business in Japan in February, and, as I said, Medikit, our distributor in Japan, is performing well and our launch there is right on schedule.

In addition, last week we announced our global distribution agreement with OrbusNeich. OrbusNeich is a well-established interventional cardiology company with a full portfolio of stents, balloons, and catheters intended for use in peripheral and coronary procedures. This is an attractive agreement for CSI, because we have the opportunity to leverage the existing OrbusNeich infrastructure, and, as a result, we can focus our efforts and our investment on training new accounts, developing the market, and taking market share.

During the next 3 years we plan to launch our orbital atherectomy business in Southeast Asia, Europe, and the Middle East. Our goal is to achieve $25 million to $50 million in revenue from international sales in FY '23.

We plan to invest over $250 million in research and development, and this will fuel the launch of 20 new products over the next 5 years. A focus on unmet medical needs will shape our innovation strategy. We will remain focused on vessel preparation, plaque modification, and procedure support for the treatment of complex cardiovascular disease.

We intend to launch a full line of products in peripheral that will address customer requirements for disease burden, patient care in different sites of service, and a broader range of price points. For example, today we are announcing that we have entered into a collaborative development agreement with the Aerolase Corporation to develop an innovative vascular laser system for use in peripheral applications and also in coronary in-stent restenosis procedures. Rhonda will address our laser project in a few moments.

In coronary, we will expand our product offering to address the needs of complex, high-risk patients. Over the next 5 years we will launch products for in-stent restenosis, chronic total occlusions, and PCI support. Today we are announcing our intention to develop and commercially launch a hemodynamic pump specifically designed to provide temporary circulatory support for high-risk PCI procedures. The product design leverages our core technology and uses an externalized motor with a variable-speed, in vivo pumping mechanism. This device is simple, it's easy to use, and it's designed specifically for use in the cath lab. Rhonda and Dr. Kandzari will address our PCI support pump and our program in a bit more detail, as well. Our goal is to achieve $70 million to $100 million in revenue from these new products in FY '23.

So, taken in total, we believe that our key growth initiatives can deliver a 15% to 18% growth rate over the next 5 years, delivering $435 million to $500 million of revenue in FY '23. This is an ambitious plan, but we are confident that we have the competence, capacity, resources and the customer relationships required to succeed.

Now I would like to introduce Dr. Martin Leon to provide a clinician's perspective regarding complex coronary and peripheral artery disease. And so, Marty, if you could come on up. Appreciate that.

Martin Leon - *New York Presbyterian Hospital and Columbia University Medical Center - Director of the Center for Interventional Vascular Therapy*

Well, first, Scott, thank you very much. I see a lot of familiar faces in the room. It's the first time I've been at NASDAQ, so this is interesting. I'm a New Yorker by choice, by birth, by history, and in pretty much every other way. Scott has asked me to be a little bit informal and a little bit descriptive, so I do have some slides, but I also want to just make some comments.

I've had the opportunity to know and work closely with both Scott Ward and Rhonda Robb for more than 20 years. So I'm here fundamentally because of my respect for the work that they've done, for my excitement in terms of the model that they're creating, and to be supportive of what I think is continued growth initiatives in angioplasty, vascular angioplasty. Many of you know that I've taken a side trip to structural heart disease recently, but we can't forget that the central focus has always been vascular intervention.

I began my career, I'm almost embarrassed to say, I was involved in the third angioplasty done in the United States in 1978 when I was a fledgling clinical associate working with Kenny Kent at the very back of the table holding a guidewire. And I grew up understanding some of the limitations of balloon angioplasty. I became interested in new device angioplasty in the mid-1980s working with people like Khalil Palmaz. We developed a variety of interesting laser sources, got interested in rotational atherectomy, intravascular ultrasound.

And then in the 1990s we talked about the concept of multi-device lesion-specific angioplasty, recognizing that we could see the artery, understand what the composition was, and perhaps design a more scientific way of remodeling the artery. It's a great concept and I think was very interesting, but the reality is most operators had difficulty using those early-stage devices. There were more complications than we care to admit.

And then stents became really the central focus of vascular intervention, certainly in the coronary tree, and it overwhelmed all these new devices, starting with bare metal stents and then of course when we got into drug-eluting stents. So that brought forward an era of dramatic expansion and growth of interventional cardiology, which had some good elements and bad elements. The good elements were that we certainly provided access to more patients, but we also grew a generation of low-volume international operators around the United States who were accustomed to doing relatively few procedures because they had a device, a stent, which was kind of the great equalizer. It was relatively easy to use. And everything else basically was cast aside.

So that has continued, to a certain extent, and it reached its plateau, of course, in the 2000s, 2007, '08, when many of you will recognize that interventional cardiology, certainly in the coronaries, not so much in the periphery, there was a bit of a swoon. People started complaining about too many stents. And the reality was perhaps they were a little bit overused, particularly in simpler lesions. So there has been a bit of a stagnation in the growth of coronary intervention over the last several years as a remnant of those observations.

But, interestingly, it happened at the same time that we're seeing a dramatic population change, where we're dealing with older patients. Older patients have complex disease. They have calcified vessels. They have more heart failure. They require more hemodynamic support. And that population is dramatically growing at the same time that we've kind of lost our urge to do angioplasty the way it needs to be done to service that

more complex patient population. So we're in another one of those transition phases where now we can, I hope, emerge from what has been kind of the past era of coronary and vascular intervention into a different era that will allow a prolonged, at least I believe, and sustained growth in vascular intervention to better service what is a much more complex patient population than we've seen before.

So we've kind of entitled this, and these slides really are just guideposts, the contemporary era of PCI. And what I mean is that in the early days we thought of ourselves as truly being proceduralists. We were referred patients. We did procedures. They went back to their physicians. They were managed. But we focused on the devices and on the procedure itself, the index procedure experience, as being the main component of what we do as interventionalists.

What we've learned over the past decade, and a lot of this happened, I believe, in the era of structural heart disease, that there's much more to this, and that we have to think of ourselves as not just doing a procedure with a device, but dealing with therapies and being more clinicians and being able to plan procedures, being able to have access and expertise, training, evidence, to be able to decide what needs to be done and then to provide a therapy that is sustaining.

So when Scott and Rhonda talk about limb salvage and talk about preventing amputations, we're not talking about the procedure anymore. We're talking about the natural history of a disease. And I think that these therapies have to be more directed towards what happens to patients over a longer time frame, not just the 6-month or 1-month restenosis horizon that we were conditioned to thinking about.

So that, to me, is the more modern or contemporary era of percutaneous cardiovascular intervention. And as an outgrowth of some of the work that was done, first with the SYNTAX trial, and then thereafter certainly with TAVR we got conditioned to realizing that we can't be working in territorial silos. We always had the tension between surgeons and interventionalists. Now we don't just tend to work with, we are obligated to work in a more team structure. So every major program that you see will have people that have special expertise, that spend time talking to each other, working together to try to create a synergistic environment in the best interest of patients.

So for coronary vascular treatment certainly there are the clinical cardiologists who have to make the diagnosis, and with new diagnostic techniques like CT-FFR, for instance, I think even the diagnostic pathways and referral pathways are going to be changing. Of course, the interventionalists, and there are many different coronary interventionalists, and different grades, and we'll talk about that in a moment.

The surgeons, for sure, are still involved, although their role in coronary intervention is going to be somewhat diminished. As you'll see, the bypass surgeries will continue to certainly be an important procedure, but not one that will be done in the same frequency as it had in the past.

The imaging specialists are pretty important, we think, so intervascular imaging we think still has a role. And with that I kind of include physiology, so imaging and physiology as a guidance tool I think is going to be an important contribution. And I was just helping to grade the late-breaking trials for TCT this year. There are going to be 3 fascinating presentations on new ways to look at imaging that will be presented in the main arena at TCT. I'm embargoed, and it's not going to be announced until tomorrow, so I can't tell you what, but imaging is making a significant return. And in doing so it almost obligates you to pay attention to what you see and to react by having the ability to use certain devices that are more appropriate under certain circumstances.

Heart failure, as you all know, is huge, and it's now really become infused or embedded in what we do with interventional cardiovascular disease. We're in fact developing a whole track, a whole program of interventional heart failure at Columbia and starting to train people who have heart failure expertise and interventional expertise, because managing these patients is extraordinarily difficult, and it gets into a whole different range of understanding physiology, hemodynamics, and, again, the long-term management of these complex patients with heart failure, recognizing in this country alone we spend $30 billion a year just on drugs for heart failure, most of which I believe don't work very well.

And then there are many other subspecialty experts.

On the peripheral side, the team is a little bit difficult. Of course you have interventionalists. There's a lot of crossover between the coronary and the vascular interventionalists. David is a good example of that. Vascular surgeons who have acquired endovascular skills. To be honest, vascular surgeons do more interventional endovascular procedures than they do open surgery these days. Podiatrists, certainly in the setting of dealing

with things like critical limb ischemia, wound care, endocrinologists with diabetics, and of course primary care physicians. So the team's a little bit different. The extension of what you need to do requires that you be embedded in those environments with those kinds of physician groups to be able to identify the patients and provide rapid and appropriate care.

We talk about complex and high-risk coronary disease. We developed about 3 or 4 years ago an acronym that I still don't like. It's called CHIP. CHIP stands for complex, high-risk interventional patients and procedures. And it really identifies a group of patients that we think have been relatively neglected. In fact, we can identify without question at least 100,000 patients in the United States alone, which is as much as 10% of the current interventional practice, that are simply not being treated. And then if you look within the patients that are being treated, there are all kinds of ways that we think those treatments can be enhanced.

So there are a little over 2 million PCI in developed markets, U.S. and elsewhere. We estimate conservatively that about a quarter of those patients could benefit from some form of accessory treatment other than just putting a stent in. The complex coronary disease continues to frustrate us. It makes these procedures much more complicated. When I start my day and I look at the coronary cases versus, for instance, the TAVR cases, for relaxation we go in and put a valve in. To do a coronary case these days, complex, calcified, bifurcation, left main disease, the complex CTOs, these are really difficult patients to treat.

And we're dealing with a patient substrate that is, again, older, with many more commodities, who have lower ejection fractions and heart failure, where you need to have the ability -- in order to use the tools that you are required, you've got to have the ability to support the patients, which is why we believe that circulatory support is going to be important in the future. It's important now, but I think that it can be improved in terms of what is available and more specific for the cath lab.

Certainly vascular disease is part and parcel of what we do. I don't even think it's looming. It's truly a global epidemic. I think you all know that about 5% of U.S. adults over the age of 50 have some form of peripheral arterial disease, and if you're a diabetic that number increases to 1 in 3. So there are millions of patients in developed markets that have PAD that is largely not treated, many times because it doesn't express itself clinically till a much later stage in the disease. You don't have the acute sentinel event like an acute MI in most patients, so you're dealing with endstage disease in the very beginning.

So I think the tools you need need to be a little bit different than what we use in the coronary tree. So atherectomy and calcified lesions, a lot of thrombosis and thrombus removal potentially being important, not working as much with fixed metallic scaffolds as with other devices that might release drugs to reduce late recurrence. It's a different approach, because the disease itself is extremely heterogeneous, and it's riddled with calcification, which can occur in various portions of the artery, which, again, result in a variety of considerations in terms of how you remodel these arteries in terms of being able to improve flow and improve viability of the distal limbs.

So when we tried to define this concept of CHIP, we had the Venn diagram that looked something like this, where we recognized that these were patients that have greater comorbidities. Many of them are surgically ineligible. A lot of the patients that get referred to us are from surgeons, who say we just can't treat this patient because he's had multiple operations, he's got more diffuse disease, his ejection fraction is too low. It's those patients that have complex anatomy, and I've alluded to some of that, and we'll discuss that in a moment. That certainly continues to be a frustration for us, and many patients who have issues with hemodynamics and ventricular function.

There is a mini-revolution going on with CTO therapies. There have been large, randomized trials justifying the treatment of unprotected left main disease, I was a PI of a study in bifurcations of almost 1,000 patients. Now you're hearing the ECLIPSE trial in over 2,000 patients in calcified coronary disease, and many other lesion substrates that we worry about.

And we have new tools. Certainly we have echocardiography and CT. CT is becoming more and more used, and you'll see CT-FFR as being a big issue in the future. There's IVUS, OCT, physiology. There's a whole concept of doing FFR using angiography that is being interestingly developed right now that may have an implication.

These patients can have valvular disease. They can have cardiogenic shock. Many of them are going to require various forms of mechanical circulatory support. So this is the world that we're living in if we are choosing to treat these patients. And our feeling is that we have to assume the responsibility

of doing that, and we need partners who are going to be responsive to our ability to be able to manage these patients and to provide the tools and the training so that physicians can become more expert and get the kinds of results that we expect or in fact should insist on.

You've heard about the ECLIPSE trial. This is a pretty breakthrough trial. I was shocked that CSI took this on, because it's a big project. Any time you do a 2,000-patient randomized trial in interventional cardiology I'm all in. It's great. These are difficult studies to do. They already have over 90 sites involved and engaged, over 400 patients enrolled. This study is going to get done. It is being driven by many of my colleagues, who are very passionate about this.

This is a randomized trial looking at calcified coronary disease trying to look at the incremental benefits of doing orbital atherectomy in these patients with both clinical and a very important subset analysis looking at specific anatomic differences that can be imparted by incorporating orbital atherectomy as a component of doing angioplasty in these patients. So this is an important study.

So when I think of where we're going in the future and I think about the development of any new device in interventional cardiovascular medicine I always think of the clinical imperatives. I've tried to suggest to you that in this era of a more complex, aging population we're dealing with anatomic aging, which usually reflects itself in diffuseness of disease and calcification. We're dealing with the appearance of new comorbidities. We're dealing with concomitant cardiovascular diseases, like valvular heart disease and especially heart failure with hemodynamic compromise. So to manage these patients becomes a very, very different affair.

So the clinical imperatives I think are growing in this population of patients, but in order to be able to achieve this we need new technology, and the commitment that CSI is making to develop a whole series of new devices that could further, from an incremental standpoint, advance what we currently have in the cath lab to manage these patients, we need training, and we need evidence. And I think if we put these together I think we'll develop durable therapies that will be -- some will be combinations of devices. Some will be combining imaging and devices. But I think it'll be in the best service of our patients.

So as I think of coronary and peripheral patients over the next 5 years, what I would expect is that there will be an increased awareness. I think I'm seeing now social media is powerful, and the ability to be able to educate patients as to what's available is very interesting. So I think the cardiovascular community needs to be educated regarding the clinical imperatives and the marked value of treating these patient populations.

In order to do that we need to expand training, and I think the commitment that CSI is making to training physicians to be able to cope with all of these new tools and make the right decisions is extremely important. So it's a combination of skills, techniques, and treatment algorithms that need to be developed. We've already started that. There are many training courses ongoing. That needs to be accelerated and amplified.

We need to get the evidence, because unless we have evidence it's going to be difficult for us to convince a variety of communities as to the need of doing these procedures. So this clinical evidence, to me, is one of the best forms of marketing, and I think it needs to support the treatment and value propositions we're talking about.

Now, everything doesn't have to be a randomized clinical trial. There are many ways to accumulate evidence. So there are going to databases, registries, there are going to be all kinds of things, but it's got to end up in the published literature. It's got to be discussed by so-called experts. It's got to be debated, and it's got to have the ability to have dialog. And without evidence it's difficult to extend that dialog.

And, finally, I think you need more innovation. And some of it's going to be iterative, and iterative is really good. It's fine. It doesn't always have to be something new. But I think you need to be responsive to what's needed in the community. So having a different form of hemodynamic support device that would be more responsive to the cath lab is meaningful. Having a lower cost, solid-state laser that allows you to do the things that we used to do 20 years ago with much different laser sources I think could be meaningful. So I believe that the iterative changes are as important, so innovation is still there.

So, with those perspective remarks I just wanted to give you a sense as to where interventional cardiology has been, where I think it's going, and how a company like CSI making a focused commitment to being able to develop therapies, products, treatment algorithms, training, education

will resonate with the interventional cardiology community and I think will help to sustain meaningful growth in what we do with vascular intervention. Thank you.

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

Thank you, Marty. Thanks for that overview. It was just terrific. Marty's been obviously a good friend and is, along with Dr. Kandzari, a very important advisor to CSI and has really been, as you can tell, very formative in our thoughts as we've developed the vision and the direction for our company going forward.

I'm not sure that Dr. Leon can stay. We're hoping that you can stay through the Q&A session. It's possible that he may have to leave. I know that you're trying to get back to rounds. So we'll try to move along here.

But it's my pleasure now to introduce Rhonda Robb. As many of you know, Rhonda joined CSI as our Chief Operating Officer in January, and Rhonda has very quickly assumed responsibility for not only developing this strategy but also preparing and planning now for the execution of this strategy. So it's my pleasure to introduce Rhonda, and Rhonda's going to take us through our strategies to drive long-term, sustainable growth. Rhonda.

Rhonda Robb - *Cardiovascular Systems, Inc. - COO*

All right, thank you, Scott, and thank you so much, Marty.

At CSI we are indeed building a contemporary company that is moving forward with our customers, and this is an exciting new era for CSI, and I'll lay out in more detail what that looks like over the course of the next half hour.

An important aspect of our strategy is to stay -- as Scott presented, our growth drivers are focused in 3 areas, expanding leadership in our core orbital atherectomy business, expanding our core to new geographies, and innovation, and as you'll see today we'll be feathering in new revenue streams into our business to increase predictability and growth. Our growth goals are ambitious, and we expect to reach $435 million to $500 million in annual revenues in FY '23. This will more than double the size of CSI, and we will grow at a compound annual growth rate in the 15% to 18 range.

An important aspect of our strategy is to stay very focused on the disease states and the customers that we serve. Aligned with our mission, we will continue to stay laser focused on the complex coronary and peripheral patients. As Scott noted earlier, these are sizable and growing markets with significant unmet medical needs.

While focused, our strategy is to expand our leadership presence beyond orbital atherectomy in serving these customers and their patients. We are uniquely positioned to do so with our core competencies, customer relationships, and clear opportunities for innovation in these markets.

I'll start first today with CSI's core orbital atherectomy business. This is the foundation that CSI was built upon, and this foundation will remain a key growth driver into the future. Our core orbital atherectomy business will sustain 10%-plus growth through FY '23 in further developing and penetrating our core markets.

There are several initiatives in place to protect and grow CSI's core business and market-leading position that include continued innovation in product line extensions; targeted site-of-service strategies; evidence development; delivering value through expertise; and an excellence in CSI quality and manufacturing. I'll provide some detail on each of these in the following slides.

Continuous innovation of our core technology is a priority at CSI, and we recently launched a new capability on the coronary Diamondback 360 called GlideAssist. This is an important development that enables a slower speed of 5,000 rotations per minute, making a significant difference in slowly and atraumatically getting around more tortuous and angulated anatomies. This results in smoother tracking, with the ability to remove and reposition.

This is really important, because it may actually increase market penetration, allowing the treatment of patients that otherwise may not be candidate for orbital atherectomy due to complicated anatomies. And we're certainly seeing this play out commercially very early in the launch. More patients are being treated.

In the first half of FY '19 we will be launching ViperWire Advance with Flex Tip. This is a unique Nitinol core design wire with a shapable tip that provides an additional solution for navigating and treating complex coronary lesions.

We will also launch our next-generation pump. This is a device that manages the saline-based fluid during the orbital atherectomy procedure. This pump keeps pace with the requirements of the evolving cath lab environment while focusing on safety, fast and simple setup, and ease of use.

On to radial, the radial access site has emerged as a really important route of access, particularly in the coronary world, now accounting for more than 40%-plus of the cases in the United States. This is because radial offers the benefits of lower complications with faster ambulation for patients. CSI just recently launched radial for peripheral as an access route that is complementary to the tibial and pedal routes of access. This solution is a unique core competitive advantage for CSI. It leverages our unique 5-French diameter that enables a radial approach while also offering an extended length of 200 mm for above-the-knee applications.

We will be also launching additional tools for support in radial cases, first an exchange catheter in summary of 2018 to facilitate ease of use. We will also continue to expand our portfolio of radial support devices through OEM distribution agreements, as we have with OrbusNeich.

The radial approach offers our customers and their patients many significant benefits, including increased and faster ambulation, which can result in fewer vascular complications and greater efficiencies in workflows, which means shorter length of stays and the ability to do more procedures in a day. This is extremely attractive for OBLs, for example.

Finally, radial access further positions CSI as a valued procedural partner to lead in both the hospital and the lab-based setting.

As with our peripheral approach, on the coronary side we will also continue to expand our bag of PCI support products. This makes a big difference in CSI's value for customers in their cases, and it bolsters our reps' productivity.

This last year we started with the OrbusNeich balloon portfolio. In FY '19 we will be adding a microcatheter as well as a scoring balloon, enabling CSI to have a very competitive and market-leading PCI portfolio for complex coronary and peripheral patients.

Also within our core business we have a strategy to drive deeper case penetration by serving more patients. In our core peripheral orbital atherectomy line we will be adding two new crowns. One is a 1-mm solution for sub and chronic total occlusions. The other is a larger crown intended for larger vessels like the iliac, a sizable patient population, innovations like this enable CSI to treat the broadest range of vascular beds for full vessel preparation.

A new development in our core business is our new peripheral exchangeable platform. This platform is designed to serve up to 50% of peripheral patients that have multi-vessel disease throughout their legs. This important innovation is unique in that it facilitates utilization of multiple crowns during a single case, where today an operator would need to pull an entirely new device to treat a different lesion in a part of the anatomy.

The exchangeable platform will enable both patient and economic benefits, enabling potentially more patients to be effectively treated in a single setting as well as a more cost-effective solution for the practice. This platform in the future will enable new business models and new product configurations to meet the unique needs of sites of service and geographies. Our U.S. launch of the exchangeable platform will start in late fiscal 2019.

Another way of driving performance in our core business is to have very targeted and customer-focused approaches for the different sites of services that we serve. In peripheral the market has experienced more procedural dispersion. In particular, we will continue to see continued movement of procedures to the OBL. For these segments we will continue to deploy long-term contracts with price-value commitments to drive share.

In addition, we will increasingly look at technology price points to drive share and to deliver customers either more advanced or more basic technologies given their patients' needs. In addition, we will continue to deploy an adaptive sales model with increased utilization of highly efficient and effective competent clinical specialists.

In coronary we're actually seeing greater procedural focus and conversion as volumes are being driven by accounts that are specializing in performing complex PCI procedures. Here we were pursuing more of a dedicated coronary rep focus, also with a highly competent clinical specialist model where procedural support is valued. Our model is customer focused and enables us to deliver devices and support, including educational excellence and expertise, that addressed the value drivers across the sites of services and their varying needs in the space.

Transitioning to evidence development, CSI has led the field by developing a wealth of clinical data, with more than 5,000 real-world patients enrolled, with more than 7,000 lesions assessed, and more than 600 physicians engaged in our broad study portfolio across the coronary and peripheral space.

Dr. Leon covered ECLIPSE earlier, and we are proud to be sponsoring ECLIPSE as one of the largest randomized, controlled trials underway in interventional cardiology. We're thrilled with the reception to CSI's leadership in this trial, investments, and execution that will establish a new standard of care in vessel preparation. Enrollment is well underway, with more than 400 patients enrolled to date, and completion of the 2,000 patients in our approximately 100 sites is expected in the next 18 to 24 months.

The LIBERTY 360 trial is the largest contemporary real-world experience, with various endovascular strategies across a full range of peripheral arterial disease in CLI patients, and it has demonstrated clear benefits of intervention in the treatment of patients with peripheral arterial disease. CSI is and will continue supporting customers with strong, unique data that they can use to improve the quality of care while also decreasing costs.

This study has also had a positive influence on guidelines development. In particular, the 2016 AHA/ACC guidelines are now calling for an evaluation by an interdisciplinary team before an amputation is performed in a patient with CLI. This is significant for the field.

Looking forward, 2-year data from LIBERTY is expected to demonstrate continued high freedom from major amputation overall, and the data are to be presented at AMP in early August. In addition, the study has been collecting data on economics associated with the treatment of these patients, and presentation of that data is slotted for later 2018.

Finally, CSI will be launching a new study of orbital atherectomy in below-the-knee patients later in 2019. More to come on the specifics of this trial in the coming months.

In our core business we've also had considerable focus on excellence in quality and manufacturing. Through continuous improvement in our manufacturing initiatives, sourcing, and supply chain we are driving volume-driven leverage, labor productivity, lean, material cost reductions and pursuing increased vertical integration. This in turn is driving scalable and continuous cost of good reductions to protect our margins from likely ASP declines over the next 5 years.

Now I'm going to transition to CSI's plan for expansion into new geographies, with an update on Japan, expansion of our global distribution network, and planned cadence for commercialization into targeted geographies. New geographies will provide in the range of $25 million to $50 million in new revenue in FY '23.

In Japan there is a significant unmet today, with more than 40,000 patients living with severe calcium, the calcific burden there being significant. We're seeing through the early months of our launch that physicians really value vessel preparation. Medikit will remain our exclusive distribution partner, and they are doing an excellent job, with a very safe and effective rollout that is progressing on plan.

We started with our coronary microcrown, and the new coronary plus crown with GlideAssist and ViperWire Flex will be launched in early calendar 2019. We will also be expanding into the peripheral segment, and enrollment of CSI's peripheral study in Japan will also begin in 2019.

As you've seen, we've signed an exclusive international distribution agreement with OrbusNeich. Our plans include considerable expansion globally to accelerate growth from our core orbital atherectomy business. Japan has been a tremendous success, and now with the distribution agreement with OrbusNeich we will pursue launching CSI into Europe, the Middle East, and throughout Asia, starting this fiscal year.

OrbusNeich is a global interventional solutions provider with a footprint in over 60 countries, a strong customer following and share position in the geographies in which they are present. This company has a strong leadership team, with distribution presence in coronary and peripheral cath labs, with a portfolio of balloons, stents, and specialty products, including strong relationships with KOLs specializing in complex procedures.

This relationship will enable CSI to focus on customer training and customer relationships while leveraging the global infrastructure that OrbusNeich has in place. Critically important here is that this agreement will enable us to move more quickly to bring CSI products to the customers and the patients around the world.

The timing of our access in the international markets beyond Japan will start in the first half of our fiscal '19. With early focus on Europe, Middle East, and Southeast Asia, longer term we will be looking at expansion into Canada and China, again, resulting in revenue range between $25 million and $50 million in FY '23.

As you heard from Scott earlier, we are also investing heavily into research and development, and I'll share today some important new developments in the portfolio that will drive our long-term growth potential. For example, we will launch 20 new products by 2023, enabling meaningful portfolio expansion to more broadly treat complex coronary and peripheral patients.

Innovation will drive $70 million to $100 million of incremental growth in fiscal '23, with a steady cadence of launches through that time frame. We will develop premium and low-cost platforms that can be paired to multiple therapeutic mechanisms, sites of service, and markets. We will balance the portfolio across the short, mid, and long term to develop products to meet the needs of the global marketplace. Notably, we will be expanding beyond our core of orbital atherectomy. Our goal is to become recognized across our markets and industry as leaders in innovation.

The market opportunity for complex and high-risk coronary patients is considerable, and these are just U.S. numbers. Our strategy is that CSI will continue to innovate on our core while expanding the product portfolio with additional PCI support products, products for chronic and subtotal occlusion, instant restenosis, and a new temporary hemodynamic support pump designed specifically for the cath lab physician and patient needs in complex PCI cases.

There is a clear and significant opportunity for a temporary circulatory support system specifically designed for PCI hemodynamic support, and CSI will bring an innovative yet simple and easy-to-use system to the mainstream. CSI will be able to take our proven orbital atherectomy system, leverage our external motor control and spinning wire competencies with our existing capabilities and capital for this hemodynamic support device. We can spin a wire with great control and precision at a rate that is needed to drive an in vivo pumping mechanism at the end specifically designed for PCI support.

The program is well underway, and we have completed early-stage animal trials. We expect human experience to start in calendar 2020, with a clinical pathway likely to follow predicate devices.

I would now like to turn it over to Dr. David Kandzari, from Piedmont Heart Institute, who serves as an advisor and national PI for the CSI clinical program. Dr. Kandzari.

David Kandzari - *Piedmont Heart Institute - Director of Interventional Cardiology*

Well, good morning. As with Marty, this is a privileged opportunity to be here. I've worked alongside Scott and Robin for more than a decade as a colleague in the healthcare industry, as a chief medical officer, as a regulator at times in my career as a clinical investigator. My center is one of the leading centers, along with Columbia Presbyterian, in the ECLIPSE trial, and I've helped the design and conduct of the trials for the Sapphire and the forthcoming ScoreFlex balloons. And then also as an interventional cardiologist I perform several hundred coronary and procedures each year.

As an aside, too, I'm not from New York. I'm from a Third World country called West Virginia. And so this is an exciting opportunity for me to be here for the first time. Marty, in New York, has not been before, as well. We have had a great friendship throughout my whole career.

And this is a welcomed opportunity to expand on many of Marty's comments and introduction for the themes of high-risk percutaneous coronary intervention and where we're heading specifically with the utilization of catheter-based hemodynamic support.

Since the introduction by the 510(k) approval pathway of the Abiomed Impella catheter-based circulatory support system in approximately 2007-2008, we've realized in the interventional cardiology community and you in the financial community an exponential increase in catheter-based mechanical circulatory support in the United States itself. And this exponential rise in the utilization of this technology in clinical practice has paralleled the use of other medical circulatory support technologies that include extracorporeal membrane oxygenation, or ECMO, that involves greater degrees of circulatory support but with larger catheters, a limited applicability to a patient population, and fraught with many complications, but also including more permanent mechanical circulatory support devices such as left ventricular assist devices.

And I'm certain that, too, for Columbia Presbyterian Hospital this is representative of our experience in Atlanta. My center ranks ninth in the United States for the greatest complexity of patients by the case mix index, and Marty and I both, as physicians attending this weekend and this past week in the critical care units see an emerging number of patients who are treated and sustained on circulatory support for either cardiogenic shock related to acute myocardial infarction, for advanced heart failure, or for patients undergoing very complex percutaneous coronary revascularization.

And further, as indicated in a nationwide inpatient sample database in the right-hand panel, the utilization of these technologies, and specifically percutaneous circulatory support temporarily, for example, with the Impella technology, has risen again exponentially for the applications of cardiogenic shock, for acute myocardial infarction, for high-risk percutaneous revascularization, even amidst debate in the medical community regarding the levels of evidence to support these indications as well as inconsistent results from clinical trials.

But more specifically and most recently from the experience in the United States of the American College of Cardiology's NCDR, National Cardiovascular Database Registry, of which I'm one of the steering committee members, the most recent data that we've realized just from the fourth quarter of 2017 represents, against a background of an annualized rate of utilization of the percutaneous LVAD technologies, a quite remarkable increase over the past 3 years for the applications specifically in these data represented for patients undergoing percutaneous revascularization.

And more specifically, while this represents a patient population to date in high-risk PCI of approximately 2% to 3% of the entire patients undergoing revascularization in the United States, the data also provides us some insight into the application of these technologies in routine clinical practice.

And more specifically, in comparison to historical time points, the utilization of the Impella technology, for instance, is becoming increasingly more commonly used at the time of the percutaneous revascularization procedure. It's placed in the patient prior to the beginning of the revascularization procedure and then most commonly removed after completion of the procedure itself. This represents in some ways a directional trend distinct from previous years in which the device was used in some instances as a bailout procedure in the instances of complications or hemodynamic compromise, and less commonly, too, in patients coming forward to the cath lab with the device already implanted.

Nevertheless, when we consider the applications of circulatory support for high-risk intervention, the objectives of circulatory support do vary upon the clinical indication. For example, in the setting of acute myocardial infarction, which is presently under ongoing investigation, the use of a catheter-based circulatory support device like Impella or other forthcoming technologies is intended to reduce the workload of the injured heart and promote healing of the injured myocardium.

In contrast, however, for patients with cardiogenic shock either related to myocardial infarction or to advanced decompensated heart failure, the objectives in this instance may be slightly different -- still to restore cardiac output, to (inaudible) the blood pressure and hemodynamics for the patient, to sustain end-organ perfusion, and yet at the same time to permit a bridge to decisionmaking for these patients as to whether the patient should be a candidate for left ventricular assist device implantation, for perhaps cardiac transplantation, continued medical therapy, or high-risk revascularization.

And yet specific to coronary intervention and percutaneous coronary intervention the objective for hemodynamic support is to maintain blood pressure and cardiac output during transient episodes of balloon occlusion or stent occlusion in the coronary artery that for most patients who are clinically stable may have no dire consequences, but in patients with very little contractile reserve or the heart or for patients with very advanced heart failure, and/or with very complex coronary anatomy, these technologies may be potentially life-sustaining, and in instances of even transient balloon occlusion or ischemia may have very dire consequences.

And, further, the advantage of these technologies may permit us in one singular setting to achieve what is becoming an emerging concept of completeness of revascularization, one that is recognized as enabling interventional cardiologists to treat more -- to achieve more complete revascularization of the patients. Completeness of revascularization is well emerging and being recognized as an indicator of improved outcome with percutaneous revascularization and may provide greater parity to, for example, that of surgical revascularization, as well.

Just to level set our discussion, then, and some case examples of utilizing these technologies, patients just treated at our institution over the past 2 weeks, we have at our institution a great utilization of hemodynamic support. Every 3 days 1 patient at least undergoes ECMO cannulation for circulatory support, and our utilization for catheter-based support even transiently for high-risk PCI is also quite commonplace.

To level set our discussion, however, in the left-hand panel is an angiographically fairly normal coronary artery structure. Our arteries twist. They turn. They give off multiple branches. But they're generally wide and smooth. And the contractile function of the heart in the right-hand panel is represented by robust squeeze or contractility of the heart.

But this is not the case in a 54-year-old gentleman treated last week at our institution who has a very sick ventricle where the ejection fraction is less than 15%, as exemplified in the right-hand panel, hardly moving whatsoever. The pressures in the heart are exceptionally high. And in the left-hand panel these are not normal, angiographically normal arteries. Instead, the patient has very severe disease, high-risk anatomy, with a very high-grade lesion in the proximal left anterior descending artery.

And, further, even under fluoroscopic guidance we see this black marking throughout the coronary arteries, emblematic of very severe calcification, as well. This is a patient for whom routine standard balloon and angioplasty stent catheters are not applicable, but rather an armamentarium or a portfolio or a toolbox of technologies that include balloon catheters that are deliverable through complex anatomy, atherectomy technologies that can permit expansion of the balloon catheter and delivery of the stent technology, advances in drug-eluting stents, for that matter, and the application, as Marty implied, of intravascular coronary imaging, along with percutaneous hemodynamic support.

In this particular case for this patient, who also is, as Marty also introduced, a surgical turn-down patient -- these patients are becoming increasingly commonplace at high-volume institutions. They are so much common, yet they are not represented in societal guidelines or in appropriateness criteria. There's very little data published on these patients. The reasons for why these patients are turned down for surgery are not always so commonplace. And this is in fact an issue that we are currently studying at Piedmont Hospital, Mid-America eartHeartHeart

Heart Institute, and Columbia University and 23 other centers across the United States in a trial called OPTIMUM.

But specific to this patient, who again was one -- was someone who otherwise was represented with very limited therapeutic options, we are able to perform orbital atherectomy. This is the Diamondback catheter being advanced throughout the calcification of the left anterior descending artery, and then very -- in short, with successful stent placement in both the left main artery, the left anterior descending artery and the left circumflex artery, we achieve a normalized angiographic result; one that is confirmed with intravascular imaging, again demonstrating the complete expansion of the stents and appropriate geographic coverage of the stent to ensure a long-term durable result for this patient.

And this is a procedure that, as I've implied, is performed with this hemodynamic catheter here, the Impella technology, that's inserted at the beginning of the procedure and then removed at its completion.

Similarly is a patient who, in his late 70s, is emblematic of complex coronary revascularization, and in many ways thematic of the direction that high-risk interventional cardiology is moving forward. This is a 77-year-old active businessman who was not a surgical candidate for an aortic valve replacement and therefore underwent treatment previously with the self-expanding transcatheter aortic valve. However, this makes it especially

challenging, too, in many ways, to perform coronary revascularization, this patient also being very symptomatic with heart failure and ischemic chest pain symptoms, having a very diseased ventricle, but also extensive disease involving all 3 major epicardial coronary arteries.

This is a procedure in which historically, even if we were to treat this patient, it would not only represent high risk for consequences, but we would perhaps not be able to treat all of the existing disease in one singular setting, given the limitations of the ischemic burden introduced to the patient, given the volume administered to the patient with contrast, et cetera.

And yet, again, even through a transcatheter aortic valve, we can place the Impella catheter in this particular instance to treat circumflex disease and left anterior descending artery disease. And in this instance, we achieved complete revascularization of the left anterior descending artery, the diagonal branch, and then also into the circumflex artery as well, exemplified in the right-hand panel.

And then at the same setting, at the same singular setting, we can move over to treat very -- to treat disease in the right coronary artery and therefore achieve complete revascularization, something that would be analogous to surgical revascularization in a patient for whom that was not a therapeutic option.

When we think about hemodynamic support technologies that are at least presently commercially available in clinical practice in the United States today, by no means is there a class effect, and these technologies differ with regard to the amount of hemodynamic support they provide, whether it is biventricular or univentricular support, and as well as the degree of myocardial protection.

Extracorporeal membrane oxygenation, or ECMO, for instance, provides complete circulatory support and may be a life-saving endeavor, but on the other hand it is fraught with complications, including not only vascular and bleeding complications because of the large catheter caliber, but also the technology places a great deal of forward pressure, or what we term "afterload," on the already failing ventricle of the heart.

But it's perhaps the latter 3 items or elements that are especially relevant to interventional cardiologists in an endeavor to standardize the procedure to broaden the applicability of this technology to operators with more variable skill sets, in many ways analogous to what, as Marty implied, the stent had done for interventional cardiologists more than 20 years ago.

And these issues relate to the ease of use and the applicability of the use of the technology, not simply from the operator's perspective but from the cath lab processes of getting the technology quickly into the room, getting it set up, getting it inserted into the patient, with having the applicability of using this technology in patients for whom, at present, their anatomy or their vessel calibers currently do not permit the use of technologies that include even the Impella technology. And specifically, there is a need for reducing the caliber of these technologies to make this available to a broader underserved patient population.

This issue of vessel caliber and ease of use also translates into complications. A recent national database, for instance, specific to the Impella technology has suggested that the risks of bleeding complications may exceed 10% and the risk of the need for in-hospital transfusion exceeds 15% to 17%.

And so, there remain still, to date, opportunities for iterative development for this technology for the introduction of an additional technology for hemodynamic support for high-risk PCI, and there are unresolved dilemmas and unmet needs specific to this issue.

One of them relates to the amount of hemodynamic support that may be required for high-risk coronary intervention. Technologies at present, to date, range in providing support of 2.5 liters per minute to up to 5 or greater liters per minute. Full circulatory support is generally assumed to range between 4 to 5 liters per minute. But most interventional cardiologists performing these procedures recognize that for high-risk PCI, the need is approximately 2.5 to 3 liters per minute to achieve complete revascularization in a very safe and effective manner.

Ease of use and accessibility I've already introduced as one of the current limitations even with the existing Impella technologies as well, and there also remains a great need to inform patient selection. This has been one of the limitations in the context of clinical trials because anecdotally we all have experiences in which these technologies have been truly lifesaving, and yet it is very challenging in many instances to demonstrate this in a clinical -- in the context of a clinical trial.

To date, there have been risk models introduced to inform patient selection largely based on either singular-center anecdotal experience or, alternatively, on consensus opinion. These models have, at least to date, not been externally or prospectively validated, and therefore, there remains a strong need to further develop the evidence basis with regard to the use of hemodynamic support in high-risk PCI.

And here remains, too, the opportunity for CSI, in my opinion, along with introducing a new technology, to advance the evidence basis. I think that it is open to criticism both on social media as well as in the medical literature with regard to the limited amount of evidence that we have to date with existing technology and the sponsorship of such studies with percutaneous hemodynamic support in high-risk PCI to date and the opportunity for CSI then to come forward and help develop that evidence base to inform patient selection, and through the investment of resources and personnel to help support medical education, would be welcomed.

And so, altogether, the technology that Rhonda had introduced and will be forthcoming is one that is not only a welcomed addition to the portfolio for high-risk PCI, and again representing an emerging number of patients treated in the United States and, to date, a far still yet underserved patient population, but it will be a welcomed opportunity to advance the science as well.

Thank you.

Rhonda Robb - *Cardiovascular Systems, Inc. - COO*

All right, thank you, David. That was an excellent presentation of just kind of the current state of the space, unmet needs, and certainly CSI's direction supports everything that you've articulated here for complex coronary cath lab patients and for your practice.

All right, I'm going to shift gears now and review the peripheral side of our portfolio. The CSI core strategy here is to develop a full line of products to address the heterogeneity of peripheral arterial disease burden, the increasing rate of procedures in the OBL, and unique needs of this site of service, while also serving the hospital segment. Core aspects of our portfolio that we will be investing in and building out will be further developments in radial, accessing more patients through small- and large-vessel crowns, the new exchangeable platform that we discussed earlier, peripheral arterial disease support products, and a new laser solution for soft plaque and in-stent restenosis.

Today we announced a unique development agreement with Aerolase for the co-development of a new laser atherectomy device for physicians to use in more effectively treating multiple forms of arterial disease. This agreement will leverage Aerolase's innovative proprietary laser technology, which is FDA-cleared for dermatology and medical aesthetic uses, and is supported by leading physicians in those fields. The collaboration project aims to create a significant innovation and ultimately improvement in the quality of care for patients suffering from peripheral arterial disease and in-stent restenosis.

We're excited to enter this market, one that is complementary to where CSI exists today, with a state-of-the-art innovative laser. We will start with soft plaque and ISR in the peripheral segment and then expand into the coronary space.

Serving this segment is entirely synergistic in that it leverages our existing sales channel and strong customer relationships. We are pursuing a disruptive approach given the size of the power source, going from today's 650-or-so-pound system to an approximately 25-pound system. It's like comparing a washing machine to the size of a carry-on piece of luggage.

With Aerolase, there is a robust IP portfolio with protected solid-state and air-cooled technology. We will differentiate on procedural efficiency. This will be a small system that turns on fast and does not require a special power source. It will simply plug into the wall. Finally, the system will be designed to be an economically friendly system for hospitals and for OBLs. Our development with Aerolase is well under way, and we're targeting first-in-human use in 2021.

So here's a summary of how our investments that we've reviewed today, the major programs we've discussed, ladder up over the next 5 years, creating an inflection point in revenue for CSI in FY '21 and resulting in the range of CSI achieving between $430 million and $500 million in revenues in FY '23.

I'm going to close now with a slide that Scott showed earlier. What I presented herein today and their respective investments will enable us to significantly broaden our value streams with a goal to achieve a 5-year 15% to 8% (sic) [18%] compound annual growth rate. CSI has the financial strength and talent to execute; investments to protect and grow our core-differentiated business; distribution partners, along with CSI's expertise, training and education competencies to meaningfully expand in the global market; and our commitments and investment in innovation will fuel the launch of 20 new products over the next 5 years to enable CSI to serve broader patient segments in both the coronary and peripheral space. This is a plan that is very ambitious but achievable, and we are uniquely positioned with our core competencies, customer relationships and clear opportunities for advanced innovation in these markets.

Now I would like to turn the program over to Jeff Points, Chief Financial Officer for CSI, to review CSI's growth summary and financials.

Jeffrey Points - *Cardiovascular Systems, Inc. - CFO*

Thanks, Rhonda. Good morning, everybody. I will now review CSI's current financial position, our platform for growth, the broadening of our value streams and our financial goals over the next 5 years.

As Scott and Rhonda have previously mentioned, CSI has built a strong and stable business model. As evidenced on the charts above, CSI is well capitalized, with over $116 million in cash available, while continuing to generate cash flow from operations. We also have a $40-million line of credit as needed for financial flexibility.

CSI's historical 4-year revenue growth rate is 12%, while focused on a single technology and single geography. We have built a strong core business and are the established U.S. market leader in peripheral and coronary atherectomy. We have stabilized the bottom line and established operating discipline into the organization, improving adjusted EBITDA by $56 million from 2 years ago. CSI also achieved its first full year of profitability in fiscal '18, showing that our core technology can support a growing, profitable business model.

Our gross margins have continued to improve the last several years, even as we experienced mild price erosion in our peripheral market. Gross margins are an area that CSI compares very favorably to peer companies, along with several other financial categories such as revenue per employee and all liquidity metrics.

CSI has plans to grow our business through geographic expansion and innovation. Rhonda touched on the fact that we launched coronary orbital atherectomy in Japan in February with Medikit, and also that we recently signed an agreement with OrbusNeich to distribute our products in Southeast Asia, Europe and the Middle East. We're excited to partner with both groups and have a goal of achieving $25 million to $50 million in international revenue in fiscal '23.

As Scott mentioned, CSI plans to invest over $250 million the next 5 years and approximately $50 million in fiscal '21 on product development and clinical research. These investments are focused on the introduction of 20 new products by fiscal '23, and also generating medical evidence that supports the use of our products. $50 million in fiscal '21 R&D spend is nearly double from the $27 million that we spent during fiscal '18. All of our organic growth investments are funded internally and have been included in the plan.

CSI remains committed to continuing leveraging down SG&A spend as a percentage of revenue over time. The amount of leverage may be limited in the near term by our initial investments in establishing an international presence; more specifically, training new accounts under our distribution agreement with OrbusNeich.

Lastly, our strong and stable financial position allows CSI to be very opportunistic within our product portfolio. Our plan as presented is entirely focused on organic product development. However, we will consider external opportunities that we believe improve patient care and increase shareholder value.

Our value streams will continue to broaden over the 5-year plan. As you're aware, we reported $217 million in fiscal '18 revenues; 1% of that revenue, or $1.8 million, related to international revenue. As we move forward in executing our plan, an increasing amount of revenue will be derived from new sources, including international and new products. In fiscal '21, we estimate that 12% of overall revenue, roughly $35 million to $40 million,

will be from international and new products, with that amount doubling to 24% of revenues in fiscal '23. Adding additional revenue streams enhances the stability of our financial performance moving forward.

Our fiscal '21 goals include generating $300 million to $350 million of revenues, which equates to a 3-year growth rate between 11% and 17%. This includes growing our base business at 10%, which includes peripheral growth at or above the market rate of mid- to high-single digits and coronary growth in the mid-teens. The balance of the growth is derived from international and new product sources.

Gross margins are expected to remain attractive at 78% to 80% as lower-margin segments such as international and OEM products contribute to higher revenue growth. The CSI team remains focused on targeted product cost reductions and manufacturing efficiencies. This, combined with higher production volumes, allows us to sustain attractive margins even while experiencing modest ASP reductions.

As mentioned earlier, we plan to heavily invest in R&D to drive long-term sustainable growth. In fiscal '21, we expect R&D spend of $50 million, which is 14% to 17% of expected revenues. We anticipate adjusted EBITDA to be 8% to 10% of revenues in fiscal '21, while net income will approximate 3% to 5% of revenues. As we continue to execute on our plan, we are committed to driving higher levels of profit over time.

In conclusion, we have built a strong and stable organization that is choosing to make key investments to drive long-term revenue growth. We're confident that our key growth initiatives can deliver a 15% to 18% growth rate over the next 5 years, delivering $435 million to $500 million of revenue in fiscal '23.

I will now turn it back to Scott for his concluding remarks.

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

That's great. Well, thank you, Jeff, and thank you as well, Dr. Leon and Dr. Kandzari, for those excellent presentations, and Rhonda, for your review.

I can't tell you how excited I am to be here today to finally have the opportunity to share this vision and share our plan with you in full. It's been a busy couple of years, as I think you can tell, but we are -- we're very excited to finally have had the opportunity to provide full disclosure to you now on the direction of this company and where we take -- where we plan to take CSI as we build this company going forward.

So as I conclude, I'm just going to really emphasize just a few points. First, and I suppose really perhaps stating the obvious, is that this business plan that we've outlined today is really going to transform CSI from being a single-product, single-geography company to now being a multiproduct, multinational company that is really focused on some of the most compelling unmet medical needs in interventional cardiology. I think you can tell that we take our role here very seriously. We play a very important role in improving the quality of care for complex patients and we serve very large and growing market segments.

We have the opportunity to leverage a strong core business with reliable revenue streams that -- and gross margins that will generate the resources we need to invest in a compelling organic growth strategy that we believe will create disproportionate shareholder value.

Our brand is built upon providing physicians with the highest-quality products, services and relationships. We will continue to derive competitive advantage through our focus on quality, innovation, medical education, superior clinical support in the cath lab and robust medical evidence supporting the safety, efficacy and economic benefits of our procedures.

Of course, our greatest asset is our people, and I believe that we now have the leadership, we have the talent and experience required to succeed. CSI is an incredibly mission-driven organization, and our employees are focused on saving limbs and saving lives every day. Our team is exceptionally motivated by this plan, and as you might imagine, morale is running very high throughout our entire company.

Finally, as Jeff presented, we are financially strong. We are sustaining double-digit growth. Our core business is generating in excess of $200 million in annual revenue with strong gross margins. We are cash-flow breakeven, even marginally profitable. We have over $100 million in cash. We have no long-term debt. And we're really well positioned now to invest really over $250 million in research and development over the next 5 years.

As Jeff said, we are positioned to achieve double-digit growth through FY '21, and then we see a convergence of key milestones, including some new geographic market launches, the completion of clinical trials and new product introductions that will further propel our growth for years to come. For a small-cap medical technology company, we have a tremendous opportunity to create shareholder value.

So on behalf of our entire team, I want to thank all of you for being here today and for joining us. We really appreciate your presence in joining us in the room, as well as all of you that have joined us on the webcast. We do appreciate your attentiveness throughout this entire presentation, and we look forward to updating you on our progress in the quarters and the years ahead.

QUESTIONS AND ANSWERS

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

We will now proceed with the Q&A session, and we'll start with our physician panel. So Dr. Leon and Dr. Kandzari, if you could please join me here at the table. And for those of you in the room, I would just ask that for Q&A, please use the handheld microphone for the benefit of all of those on the webcast. I will facilitate this as best I can. I can see there's already some hands in the air. So let me get started, and Danielle -- where are you going first? Okay, well, let's start with -- Danielle had her hand up here.

Danielle Antalffy - *Leerink Partners LLC, Research Division - MD, Medical Supplies and Devices*

Good morning. Danielle Antalffy with Leerink Partners. Quick question for both of you, actually. If you could talk a little bit about OrbusNeich and your view in their reputation within the interventional cardiologist community, just to better understand how they're viewed and how incremental they could be to CSI.

Martin Leon - *New York Presbyterian Hospital and Columbia University Medical Center - Director of the Center for Interventional Vascular Therapy*

So maybe we'll start, age before beauty, David.

David Kandzari - *Piedmont Heart Institute - Director of Interventional Cardiology*

I don't even know about the beauty part.

Martin Leon - *New York Presbyterian Hospital and Columbia University Medical Center - Director of the Center for Interventional Vascular Therapy*

I've known OrbusNeich for several decades. They're not known in the U.S.; this is an Asian company. I visited their manufacturing facilities; I know the founder, Teddy Chien, very well; I know the family very well; and I know what their capabilities are. They're highly respected in terms of balloon angioplasty and certain other accessories of that ilk in Asia. The introduction of the 1-millimeter balloon in the U.S. -- I wouldn't describe it as revolutionary, but it's been extremely substantive. Every major lab that wants to use and treat advanced angioplasty needs to have that balloon because it is that differentiated. So very high-quality balloons, high-quality accessories. They do have a very different drug-eluting stent program, which is separate from this. Extremely well respected in Asia from the standpoint of their marketing and sales group and well known in many, many of the Asian companies with a significant penetration in Japan. So a lot of their R&D is down in Florida, in Fort Lauderdale. In fact, I've worked with them on -- in developing some of their DES programs. They've got some highly talented engineers that are developing some very innovative accessory devices along the lines of microcatheters, guide extensions, dual-lumen catheters, that I think are the kinds of accessories that you will be needing for complex angioplasty. So in terms of partnership, I think you get the immediate boost of truly competitive, high-quality balloons, plus other multiple accessories that I think have a low bar for FDA approval and that can enter and fuel the advanced-angioplasty marketplace. Plus, a very nice group to work with, and if you're talking about a global organization, it gives you an entree into Asia, which I think could be very meaningful.

David Kandzari - *Piedmont Heart Institute - Director of Interventional Cardiology*

Just to add on to that, I -- my experience with OrbusNeich was fairly limited other than my exposure with them in Asia-Pacific in my past 10 to 15 years of working in that part of the world, but the -- more recently, I've been involved with them for the development and the design of the clinical trials with the Sapphire balloons. And we currently have a new scoring-balloon technology that's presently under FDA consideration as well. And just as Marty shares with you that the -- while a differentiating technology certainly is welcomed into the cath lab and is more easily to get through an inventory process, in many ways pricing is one of the big determinants, for example, for what are considered fairly standardized products like balloon-angioplasty catheters, unless you have some distinctive product. And so in this instance, it is, as Marty said, it's not a game-changing technology, but it's certainly one additional element to add to the therapeutic armamentarium. We therefore stock, now, those balloons at our institution, and we stock their whole matrix, for that matter. And it's been very well received by my other colleagues as well. But it also highlights the opportunity for leveraging that technology with another company, partnering with another company to provide a broader product portfolio that seems to be more attractive to the inventory committee, of which one of -- I'm one of those members, that we see. And also, just to amplify Marty's comments, I now have worked for the past couple of years with the group in the Miami-Fort Lauderdale area, and they have a very skilled clinical, at least from my perspective, their clinical program and their regulatory program to facilitate the introduction of these technologies in a fairly short timeline from when we started the trial with the Sapphire balloons. I expect the same with the forthcoming Scoreflex technology.

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

That's great. Danielle, I can tell you have a follow-on question, but I think I'll just add one thing to this. And outside the United States, OrbusNeich has a very large and well-established distribution channel. So they have direct and distribution relationships in about 65 countries around the world. The attractiveness of the relationship with OrbusNeich for CSI is that we can immediately leverage their infrastructure so that we can distribute orbital atherectomy through their channel all around the world, and we don't have to build that. We don't have to take the time, we don't have to make the investment. Quite to the contrary, we can leverage our investment to go in, in advance, train and educate physicians on how to use orbital atherectomy, assuring that our customers have great outcomes and building that market properly. We have a great opportunity through our relationship with OrbusNeich now to go in and rapidly take market share in peripheral as well as in coronary applications. So we're really excited about that and we think that our relationship with OrbusNeich in the U.S. is really important to bring in some of these support products, but outside the U.S. it really enables us to accelerate our growth.

Danielle Antalffy - *Leerink Partners LLC, Research Division - MD, Medical Supplies and Devices*

Okay, thank you so much. And just one more quick question for the clinicians: When we're talking about the multidisciplinary team approach, you guys are both at larger institutions. Where are we if we think more broadly in the community in implementing this multidisciplinary team approach, and where are the points of resistance as you get into smaller facilities? Thanks.

Martin Leon - *New York Presbyterian Hospital and Columbia University Medical Center - Director of the Center for Interventional Vascular Therapy*

Well, it's a great question. I mean, obviously, in academic medical centers in large private institutions that carry great volume and that lead with clinical science, it's really embedded and now in their culture. I think that part of the acceptance of this concept of a heart team really has been driven by people like Rhonda as we developed a TAVR. It really -- it was a class I indication. You couldn't do the procedure unless you had created this team approach. Now that's metastasized and it continues to metastasize to the other interventional programs. So even in smaller institutions, you may not have everything. You may not have on-site wound care or podiatry, but you'll certainly have vascular surgery talking to interventional cardiology, talking to vascular medicine, talking to referral doctors. So the teams may look a little bit different, but I really do project that in the future, in pretty much every institution that's doing intervention, it can't just be a sole operator with his bag of tricks. It has to be a team approach managing patients, planning strategies and doing the followup care.

David Kandzari - *Piedmont Heart Institute - Director of Interventional Cardiology*

I agree that the experience largely emanated out of the transcatheter valve experience with the heart team, and I don't think it's -- and that was largely also, in part, driven by reimbursement issues and external mandates. But the heart team concept, at least at most institutions either with -- where I practice or with colleagues really isn't so formalized, for example, for high-risk percutaneous revascularization, but it certainly exists. As Marty implied, our largest referrals for these surgical turndown patients are our surgeons. They're more sensitive to external metrics and scorecarding than ever before. They're busy enough, at least at our institution, with existing patients, that this surgical turndown population is becoming an increasingly common patient on a daily basis, almost, in the cath lab setting. I would say, however, to focus on, I thought, a unique point, is where are the points of resistance? And I'm not so certain that there are necessarily competitive points of resistance now across the disciplines. Our surgeons are involved in complex structural -- catheter-based structural heart procedures as well as our vascular surgeons, too. And so the point of resistance for us, in fact, is probably accommodating all of these procedures in a busy cath lab setting and finding scheduling time for everyone. That would be our point of resistance.

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

That's great. Okay, let's go back here. Brooks?

Brooks O'Neil - *Lake Street Capital Markets, LLC, Research Division - Senior Research Analyst*

Good morning. Brooks O'Neil at Lake Street Capital Markets. I'm here from Minneapolis and happy to be here. I was hoping you might talk just a little bit from a clinician's perspective on the competitive environment, starting first with orbital atherectomy and what you're seeing there, and then maybe expanding to also talk about this concept of vessel prep, vessel prep for what, and how connected are the [whats] from a competitive perspective to what's happening in peripheral and coronary artery disease work you're doing? Thank you.

David Kandzari - *Piedmont Heart Institute - Director of Interventional Cardiology*

I think we're seeing, now, a sea change in interventional cardiology just from the vendor perspective, that whether it's atherectomy technologies or even drug-eluting stents, and OrbusNeich being one example, that we're seeing more vendors coming to the commercial space than what we've had historically with 3 or 4 major strategic corporations, and that's welcomed not only from -- not simply from a pricing perspective but more broadly as we're describing from expanding the portfolio. Specific to vessel preparation and coronary applications, it's been well acknowledged that appropriate sizing, appropriate geographic coverage of vessel treatment with stents is associated with a superior outcome than visual estimates by just angiography alone. This has been well documented with the application of intravascular imaging such as intravascular ultrasound, but also in very calcific disease, which does not permit expansion of a balloon or stent, in achieving a better luminal gain, a better, larger artery, is associated with an improved outcome, both short-term and a durable long-term outcome as well. The other -- and we may see forthcoming, too, even further evolutions of atherectomy technologies beyond laser and certainly with orbital atherectomy as well for the coronary application. For the peripheral application, this is really a mainstay. The disease burden, the extent of calcification, as exemplified in one of the examples Marty had shared, is quite extensive. And here is an opportunity of topical interest for the combination of -- whether there's a synergy with drug-coated balloons and vessel preparation. In other words, if we can reduce the plaque burden and the calcification and then deliver an effective antirestenotic, antiproliferative therapy with a drug-coated balloon, avoid stent placement, this may have a special advantage.

Martin Leon - *New York Presbyterian Hospital and Columbia University Medical Center - Director of the Center for Interventional Vascular Therapy*

Just to add to David's comments, in terms of competitive advantage or competition, I think competition is good. There are obviously only 3 strategics right now -- main strategics. There are others that are -- I would call kind of semistrategics. But the product portfolio that CSI has and is building, I think, is going to be a very strong one. So in the rotational, the broad area of rotational atherectomy, they have competitive advantages over what's currently available. In something like a Scoreflex, that's a very interesting plaque-modifying technology that will have some competitive advantages over the 2 other devices that are currently available either through Boston Scientific or through Philips with its acquisition of Spectranetics. It seems to me that a lot of the strategics are focusing more on the core technology, which has been stents, drug-eluting stents and that area, and have to

a certain extent neglected a lot of the accessories. And I think that's what's going to be the strength of CSI. So I really think by focusing on these accessories in what is an expanding market, I think they're going to have a -- if this model makes sense to people, and it certainly resonates with me as a clinician, I think they're going to have a nice open space to develop.

David Kandzari - *Piedmont Heart Institute - Director of Interventional Cardiology*

And just to add to that, one other potential application for vessel preparation -- we're talking about calcification so much is also in an emerging and an increasingly frequent patient population with in-stent restenosis. And so here is a great opportunity for better stent expansion prior to the next treatment, whether one day in the United States it'll be a drug-coated balloon or the use of laser technology to achieve expansion to place another stent. This is an underserved patient population with a very high adverse event rate and one that we're increasingly seeing. As an example, in the United States 5 years ago, there were, I think, 2 centers with brachytherapy. There are now more than 35. So we're revisiting an old technology trying to throw the kitchen sink at these patients with limited option.

Martin Leon - *New York Presbyterian Hospital and Columbia University Medical Center - Director of the Center for Interventional Vascular Therapy*

But also, lasers are not a new technology. We got involved in lasers a long time ago. We worked with Spectranetics for many years. We did the original in-stent restenosis work in the 1990s with lasers. But the technology from the standpoint of expense, size, complexity, really just did not make sense in smaller cath-lab environments, so the idea of developing a solid-state laser that is basically a plug-in-and-go device, I think, will ensure its more frequent use in a variety of settings.

Michael Matson - *Needham & Company, LLC, Research Division - Senior Analyst*

Hi, Mike Matson, Needham & Company. So just curious what you think it's going to take for orbital atherectomy to become the standard of care in calcified coronary lesions. The penetration is still pretty low. I know you're both big proponents and users, but it seems like adoption's been somewhat limited. And then I guess a related question, which is: Beyond the ECLIPSE trial, what do you think -- what kind of results do we need to see from that trial to really be a home run and drive widespread adoption of atherectomy -- sorry, orbital atherectomy? Thanks.

Martin Leon - *New York Presbyterian Hospital and Columbia University Medical Center - Director of the Center for Interventional Vascular Therapy*

But I think you need to start with evidence. I think with a 2,000-patient randomized trial, if the trial really is sufficiently convincing where physicians can relate to both the clinical benefit and the technical benefit from the standpoint of demonstrating better mechanical expansion of the stent, I think those are going to be things that will catch people's attention. It used to be the barrier to initiating a procedure with atherectomy was considerable. There were a lot more complications associated with it, the startup was not so easy, learning how to do the technique correctly wasn't so easy. Most of those barriers have been erased. If we had more clinical evidence suggesting that there's incremental benefit, I think that's going to importantly change the way physicians feel about it. And my hope is that you'll see much greater penetration.

David Kandzari - *Piedmont Heart Institute - Director of Interventional Cardiology*

Just to amplify on those comments, the advantages of orbital atherectomy to me as an operator are fairly transparent. Number one, the technology compared with more historical rotational atherectomy provides bidirectional treatment. It may have reduced complications associated with it. It permits, with a singular catheter, a broader range of treatment, and it enables us to do this with what we call 6 French guiding catheters that we can perform through the wrist, whereas rotational atherectomy often requires larger catheters to do so. And it cannot be understated the ease of use and set-up and the standardization to enable a technology to a wider group of interventional cardiologists with variable skill sets. Perhaps in some ways, pricing or simply distribution of the technology may be a limitation. I don't have insight to that. As with regard to ECLIPSE, the one important point to note about the ECLIPSE trial is that there are patients, as I shared with you in an example, where unequivocally this is a vessel that's going to need some type of atherectomy without -- to be a successful procedure. The purpose in part of ECLIPSE is to broaden that patient population to patients in whom there may be more equipoise or uncertainty with regard to, can I get away with a balloon or does this require

atherectomy? And if we can demonstrate in this group of patients, 2,000 patients, that there is a -- there is still a superior result to be achieved with vessel preparation in this case, that would further expand the application of this technology to a patient population that I would say is clearly not routinely treated with atherectomy.

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

Excellent, thank you. Let's see, we have one more question for the physician panel.

Vishnu Gogineni - *Bank of America Merrill Lynch - Analyst*

Hey, Vishnu with Bank of America. I was wondering if you could -- I was hoping you could talk a little bit about CSI's plans for a hemodynamic support pump, and would this directly compete with Abiomed's pump, and how CSI plans to differentiate itself with that pump from the existing pumps?

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

Sure. At this point in time, we are really focused on the clinical trials, the clinical program for the U.S. marketplace. We have not yet developed any intent to proceed into Japan, although we certainly will be doing that in time. I think right now what we're most focused on is getting to our first-in-human experience with that device in 2020. David, did you want to add anything to that?

David Kandzari - *Piedmont Heart Institute - Director of Interventional Cardiology*

Yes. The initial -- we've had a series of meetings with regard to the clinical trial planning and execution of this clinical trial, and I think that the initial intent of this technology is similar, to offer it through something that's more efficient, more easily accessible to patients, that is more applicable to a wider variety of patients with regard to vessel anatomy and sheath and catheter-caliber size than the existing Abiomed technology, but would still provide sufficient support for high-risk PCI.

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

Okay. Oh, all right, one more question over here. Bruce?

Bruce Nudell

Bruce Nudell, SunTrust. Two questions: One, with regard to the laser for peripheral atherectomy, how expansive could that be for atherectomy generally in that you could deal with pretty much all sorts of plaque, and given the favorable reimbursement generally? And secondly, I actually sat through an OBL set of cases, and I was -- compared to TAVR, I was shocked by the lack of preplanning and the image quality, and maybe Marty could comment on that as well. Thank you so much.

Martin Leon - *New York Presbyterian Hospital and Columbia University Medical Center - Director of the Center for Interventional Vascular Therapy*

Well, I'll let David talk about his OBL experiences. There are different ways to approach laser angioplasty. As I said, I have a 25-year history working with lasers, and I'm just -- it's very curious and provocative to me to see CSI picking up on a theme that we thought about a long time ago. The current generation of lasers really are meant to modify plaque, not really to be ablative devices in terms of volume tissue removal, because they're generally ultrashort-pulse lasers where they induce shockwave effects, and those acoustic phenomena tend to modify the plaque integrity, if you will, and certainly its compliance. So I would imagine in heterogeneous lesions like you see in the periphery, there's a real opportunity to use a laser fairly broadly as an assist device. So if the combination of ease of use, practicality, cost is compatible with what people are doing in the periphery

-- because remember, we try to stay away from stents under most circumstances, use DCBs. So the extent to which you can modify the plaque and get a good enough result with a balloon-based therapy, I think that will advance to outcomes. So I think that the laser has not nearly reached its peak or plateau, and I think there's a lot to develop in the periphery, and I also expect that you'll see return on the coronaries as well, if you have the right piece of equipment and it was designed correctly and was compatible with some of the complex anatomy that we're treating. David, I'll throw the OBL to you.

David Kandzari - *Piedmont Heart Institute - Director of Interventional Cardiology*

Well, just to expand, too, on some of those comments, is that just as you described earlier, we had, many years ago, an early experience with laser, for example, in in-stent restenosis. But there's now this renewed and this resurgence of interest in the use of laser, for example, for in-stent restenosis, and in part it's driven by an unmet need that's becoming more frequent, but it's also, in part, driven by the need for an ease-of-use technology. And so if you have a new technology like a laser that is more accessible, more routinely applicable to patients, then I think the frequency is going to increase. And specific to the periphery, the advancement of the technology where you can change out the crown sizes without getting a new device, I think, would certainly offer a new opportunity to treat multisegmental disease, which is commonplace. It's the standard more than the exception to see disease both in the femoral-popliteal segment but also below the knee. And similarly would be the case for laser, that if, with 1 technology, you could treat a broader range of lesion subsets in the same procedure, that would have specific advantage. Because just as you had described, Bruce, there has been an exponential increase in the use of peripheral atherectomy technologies over the past few years, and in part it's paralleled reimbursement changes as well. However, we're still sensitive to the cost, nevertheless, and our administrative colleagues are, too. And so the more that you could treat with singular ablative technology rather than using multiple ones in the same procedure would have advantage. With regard to OBLs, I, too, don't have much experience working in an in-hospital setting.

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

Well let me just follow on what David is describing, because I think what's really most important, if you go back and think about the presentation that Marty showed, he showed one slide that showed the really heterogeneous nature of peripheral vascular disease. And even in one lesion, you have severely -- a severely calcified component, you've got mixed plaque, you've got soft plaque and thrombotic disease. So leveraging a single device or a single solution to treat that really broad range of disease burden is difficult to do. What we've done up until now, and we've done a great job because we've been focused on severely calcific lesions, and orbital atherectomy provides a great outcome for that patient population, the essence of our strategy and as we think about laser and we think about the rest of our strategy, looking at other mixed-plaque solutions and other devices that can be used in peripheral arterial disease, is that we would provide to the marketplace a comprehensive portfolio of solutions. And the physician, whether they're in the hospital setting or the OBL setting, can choose from that portfolio to best meet the needs of their patient. Bruce, you raised another really important point, and that is case planning. We are going to be transforming our medical education approach from, let's say, product training to case planning. Dr. Ryan Egeland, who is our Vice President of Medical Affairs, describes this as, we're moving from training the hands to training the minds. And we want to train physicians in peripheral vascular disease just like we see them in coronary artery disease, to begin thinking about the nature of the lesion they're treating, the needs of that patient broadly, whether you need wound healing going on or how are you going to ensure that you get the best outcomes for that patient over time. We want to do case planning and treatment planning, therapy planning, for that patient throughout the continuum of care. So that's really where we're headed. It's a rather sophisticated combination of product; clinical support in the cath lab, in the OBL; the medical evidence to support that; and then the medical education that ties all that together. I think that's what Marty describes when he talks about a contemporary cardiovascular company, and that's really our intent. That's where we're headed, is to bring all 4 of those components together. Do we have any other questions for the physician panel? Okay. With that, we will conclude this session, then, and thank you again, Dr. Leon and Dr. Kandzari. Thank you so much for joining us today. You're welcome to stay if you can, or if you need to get back to work, you can do that, too. All right, thank you.

Okay, so Jeff and Rhonda, if you want to come on up, and we'll get started with the CSI session. Okay, so we'll switch gears a bit now, and we can talk about Q4 and FY '18 results, the strategic plan, really anything else that you would like to cover. So let's get started. We'll still -- we'll use the microphones, obviously, so first question, Danielle, again, is leading the way.

Danielle Antalffy - *Leerink Partners LLC, Research Division - MD, Medical Supplies and Devices*

Thanks so much. Danielle Antalffy from Leerink Partners. Just a question on the strategic initiatives here, and we heard a lot about the pipeline today. This is something that's new to CSI, at least relative to what we've seen in the past, so would love to get a better understanding as to how -- what has actually changed in the R&D infrastructure, R&D planning within CSI that is giving you confidence that you'll be launching 20 new products by fiscal 2023?

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

'23. Yes, thank you. So I'll let Rhonda address this because that has been, obviously, a key core competence that Rhonda brings to our company having had extensive experience scaling R&D organizations at Medtronic. I will tell you that this is -- it's new to all of you today; it's a strategy that we've been working on for a couple of years. And so over, really, the course of the past couple of years, we have had the opportunity to build the competence, build the strength in our company and to begin building the processes that are necessary to become an innovation powerhouse. We know how to do that. It doesn't happen overnight. We need to continuously build our competencies, build our skill sets and build our processes to really be successful at launching a portfolio of products. But it's a discipline that we know and understand. Rhonda, do you want to talk specifically about some of the programs you've implemented?

Rhonda Robb - *Cardiovascular Systems, Inc. - COO*

Yes. And just to start, I mean, Scott has focused on developing an exceptionally talented and experienced leadership team. And so we really have a group of leaders around the executive table that have considerable experience in the space. And so it starts here, but there's a strong base of talent at CSI. And so as we've come in, we've really done an early assessment and assimilation of the strategic plan, what the existing competencies of the organization are, looking at the competencies that are needed in the future, not just in R&D but, candidly, across the entire organization. Expansion of our clinical trials, building out of our medical education. I mean, all of those have been under considerable assessment, and now we believe we have the right plans in place. We've been adding people over the course of the last several months. And as Scott said, really putting in place some systems and structures and organizational capabilities in order for the organization to effectively and efficiently execute on our plans. So I've been really pleased with the progress and, Scott, the receptivity of the leadership team. As he mentioned, it's an incredibly mission-driven, patient-focused organization that really wants to enter into this new era of transformation for CSI.

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

It is a great question, though, because it's the essence of what we're talking about. And Brad Davis, who's our Vice President of Marketing, has taken on the role of really building a strong understanding of upstream marketing, really building out that team of people that can go out and interact with interventional cardiologists and really understand their requirements. I think to some degree that's reflected in our laser atherectomy program. We're talking about an innovative program there that really -- where we've gone to Aerolase, and Aerolase has proprietary designs now that allow them to have a solid-state laser that can be the size of a briefcase, that can plug into the wall and can instantly turn on. And while those aren't necessarily features we normally talk about in medical technology -- those sound like features in something that you would have in your kitchen, but these are really critically important because you need to have a device that's small, you can plug into the wall, that's portable and that is instant-on if you want to maximize efficiency in the cath lab. So a great example of how we develop the right types of product marketing skills, the upstream marketing skills to get out into the market, and then in our R&D organization -- our R&D organization is led by Matt Cambronne, who's our Vice President of Research and Development. He's been with CSI for a long time, has great expertise, and he now has built out a portfolio management system, as well as a product review system, that allows us on, actually, a monthly basis to continuously review, monitor, adjust to continue to drive our product development programs forward. So we're implementing the processes. We've got the right people in place. And we're excited, now, to be executing these strategies. Other questions? Over here again, Mike.

Michael Matson - *Needham & Company, LLC, Research Division - Senior Analyst*

Hi, Mike Matson from Needham again. A couple questions for you. I guess I'd just want to start with the international opportunity here with OrbusNeich. So it seems like atherectomy has been mainly used in the U.S., and there's been some resistance, for whatever reason, in places like Europe. So can you just talk about why atherectomy hasn't been more widely adopted outside the U.S.? Excluding Japan, obviously. And then what is the reimbursement currently like? I know you have some approvals, maybe, but it seems like reimbursement could potentially be an obstacle to selling this product in some of those markets. Thanks.

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

Yes. So we're going to start with peripheral as we think about Europe. In Southeast Asia, Middle East and some of the other markets where they -- these markets use U.S. PMA approval, or recognize U.S. PMA approval to allow you to commercially market in those segments, we will launch both coronary and peripheral in those segments. We'll launch peripheral first in Europe and we'll follow that with coronary later this fiscal year. So as we think about coronary in particular, I think your question about atherectomy is a good one. And what has changed over the course of the past several years, in particular in Europe and around the world, we don't quite see that as much in the United States yet, but in markets where physicians had exposure to bioresorbable stents, physicians learned a lesson or revisited a lesson that was learned in the late '90s, and that is that vessel preparation is really critically important to avoid malapposition of stents. Because bioresorbable scaffolds could not be overexpanded, it became really important for physicians to understand the size of the vessel they were treating. And as a result, if any calcium were present or if there was anything present that would cause that stent not to be fully expanded or hang up in the vessel, it would interfere with the outcomes. So there's physicians throughout Europe that have really adopted vessel preparation and plaque modification as a standard part of their treatment paradigm now. And in fact, as we were at the Paris Course on Revascularization, the PSR meeting -- PCR meeting in May, we received a tremendous amount of interest in gaining access to our technology for these coronary indications. I think, as David had described earlier, it's -- the -- throughout -- the market conditions in Europe will probably be similar to what we see in the United States in that not all centers will be doing -- will be treating these really complex cases. But in fact, already, these patients concentrate in very specific centers where they focus on treating complex coronary lesions. So what -- our plan is really to focus on those sites and to train and educate those sites on orbital atherectomy and bring that forward. Now, in terms of the reimbursement environment, I think reimbursement can be a barrier in Europe, and in particular in certain geographies of Europe where it can change. There are other parts of Europe, though, where procedures are reimbursed on a case basis. Germany, for example, I think we'll find good, favorable reimbursement, Italy and in some of the other markets. So we will focus our efforts initially on locations where reimbursement is favorable and meets our needs, and we're really going to target medical education. So we'll think about reimbursement, but frankly, what's going to determine the success of this business long-term is patient outcomes. So we're going to make sure that every physician that utilizes our product is trained and educated by either CSI or one of our proctors so that we are assured that we'll get great patient outcomes. If we do good by our patients, the business will take care of itself.

Michael Matson - *Needham & Company, LLC, Research Division - Senior Analyst*

Okay, thanks. And just wanted to ask a follow-up question on the peripheral exchangeable platform. So can you just talk about how that works from a business-model standpoint? I mean, is it -- are you then going to charge a base price for the unit and the initial crown, and then you'd have additional pricing for any additional crowns that are used, and then how do you ensure that that doesn't -- that that's additive and it's not somehow cannibalizing, I guess, additional system sales?

Rhonda Robb - *Cardiovascular Systems, Inc. - COO*

Sure. Yes, and we kind of left the business model intentionally vague today because we're still working on looking at the different types of service needs and also different geographic needs. And I think today, we're going to start with the exchangeable platform, but that will make a sway into future portfolio development that will enable entirely new business models beyond what we're even thinking about for peripheral exchangeable. What we're trying to do, though, is address an unmet medical need where patients come in for their peripheral procedures. As I said during my presentation, 60%-plus more of these patients actually have multilevel disease that extends throughout their legs, but because of today's technological limitations and cost limitations, physicians will make the determination that oh, hey, maybe I'm not going to treat it. And that's our goal first and

foremost, is to address that. We want patients to walk away having received the therapy that they should have and not have there be a clinical or economic disincentive in order for physicians to treat. So more to come. We think that this will be favorable in terms of its overall economic solution given the current reimbursement environment, but we're not ready to disclose specific pricing configurations today.

Michael Matson - *Needham & Company, LLC, Research Division - Senior Analyst*

Okay. And finally, just a quick financial question: So I think you mentioned the OBL strategy around these contracts. I think you're 2 quarters into that. You've seen some pricing headwind. Is it the right way to think about this that that pricing headwind maybe lasts another 2 quarters, and then as you start to lap those contracts, that'll start to ease? Or is that going to be an ongoing kind of headwind? I know it's not a big pricing reduction, but it's still a little bit of a drag in the peripheral business, so. Thanks.

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

Yes. I'm not sure that I would consider it a pricing headwind. I think it's more of an opportunity for us. We have done really well with these long-term contracts in creating really good relationships now with large accounts. We're not going every place. We've brought on 20 large OBLs now that collectively do more than 500 procedures per year. So we're going to these large accounts and we're creating these good long-term relationships. You saw that even in fourth quarter, although we had some price erosion in our peripheral business, our gross margins overall actually increased. And we're 1 percentage point higher this year than we were in Q4 of FY '17. So our -- what we're very effectively doing is managing our manufacturing operations to continuously reduce our cost of goods sold, leverage volume, leverage improvements in our -- lowering our costs of materials, and that allows us to be very competitive on price. We can continue to drive the growth of our business and we can be very successful in this more price-sensitive site of service. So the combination, I think, of our manufacturing operation strategy and our focused contracting strategy in the marketplace is a very powerful strategy that is unique to us, and we intend to continue to leverage that going forward. I look at it as a great opportunity, honestly, to drive growth.

Jeffrey Points - *Cardiovascular Systems, Inc. - CFO*

Yes, Mike, just one thing to add to that is, I think it also has allowed to take share in a lot of high-volume OBLs and take those accounts and really drive additional volume with the strategy. And so it's not only been our existing accounts, but also new accounts.

Michael Matson - *Needham & Company, LLC, Research Division - Senior Analyst*

All right, thanks.

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

Thanks, Mike. Other questions? Oh, right here.

Vishnu Gogineni - *Bank of America Merrill Lynch - Analyst*

Just that -- the last question a bit more directly. What are your pricing assumptions? It's -- the core atherectomy business is 10% over the next few years. What's the pricing assumption baked in?

Jeffrey Points - *Cardiovascular Systems, Inc. - CFO*

I'm sorry, [Jason], what's the 10% pricing?

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

The pricing assumptions going forward?

Vishnu Gogineni - *Bank of America Merrill Lynch - Analyst*

Yes.

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

Well, I don't think we're putting out pricing assumptions going forward necessarily on a product-by-product basis at this point.

Vishnu Gogineni - *Bank of America Merrill Lynch - Analyst*

No, I just mean your 10% atherectomy growth. Should we assume that that's 11% volume and a 100-basis-point hit on price, or?

Jeffrey Points - *Cardiovascular Systems, Inc. - CFO*

Yes. What we'd normally expect on the ASP side, especially on peripheral, is kind of that mid-single-digit erosion year-over-year. We've got that planned. Obviously volumes would be additional -- would be higher than that. But we've experienced mid-single-digit and we'll expect that moving forward. On the coronary side, meanwhile, our ASPs are very stable. In fact, I did remark that they actually increased from last year.

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

And that's really an important point. We have always -- or at least in the few years I've been here, we have always projected low- to mid-single-digit price erosion, and that's right where we continue to perform. But what we have to do is assure that our -- that we're continuously reducing our cost of goods sold at a rate faster than that.

Vishnu Gogineni - *Bank of America Merrill Lynch - Analyst*

Okay. And you mentioned peripheral growth at or above market.

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

Yes.

Vishnu Gogineni - *Bank of America Merrill Lynch - Analyst*

When you look at the peripheral growth profile from a market perspective, how do you do OBL growth versus in-hospital growth?

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

Yes, the OBL market is growing much faster than the in-hospital segment, and has been for -- as we indicated last year at this time. The OBL market segment continues to grow very fast. In-hospital is probably still in the low- to mid-single digits and the OBL segment is much faster than that.

Vishnu Gogineni - *Bank of America Merrill Lynch - Analyst*

Okay. And just following up on Danielle's question, I've always thought of CSI as more of a sales-oriented company, and I realize many of the new products are licensed, but you're kind of pivoting here to more R&D, and so I guess the question is, have you changed the infrastructure, the size of the team? And then, maybe for Jeff, how does R&D trend over the next few years? I think you mentioned $50 million in fiscal '21. How does that trend over the next few years?

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

So Jeff, I'll let you cover that in just a moment. No, as we think about our sales organization, we haven't changed the infrastructure. We still have 200 quota carrying sales reps. We'll continue to have those. I think you -- many of you had asked us questions about why we were shifting our focus to coronary, and we had 20 focused coronary sales reps in the marketplace now. I think you now can understand why we are creating that specific focus. We continue to have a hybrid channel that supports most of our customers, where they're serving physicians who are performing both peripheral and coronary procedures. That will -- we expect that that will continue, but on a local basis, we still have focused peripheral sales reps where the market supports that, where market demand supports that, and we still have focused coronary reps where market demand supports or requires that focus as well. So the infrastructure in that sense has stayed very much the same. As we think about our strategy going forward, we're really leveraging -- we're still increasing our spending in sales, but we're leveraging our SG&A down in order to accommodate a more rapid increase in research and development spending. And we've been doing this over the course of the past couple of years. So over the course of the past couple years, we've been increasing on R&D spending, we've been increasing the size of our R&D team and we've been adding people that have the scientific and engineering backgrounds that are required to develop these products. But from my perspective, what an incredible opportunity it is to have access to a $250-million run rate over the period of 5 years to invest in research and development and drive organic growth. We have the resources we need to execute this plan, and we now have the team in place to get it done, so we're excited about that. Do you want to talk more about the specifics on R&D spending?

Jeffrey Points - *Cardiovascular Systems, Inc. - CFO*

Yes. I'll just mention, in my prepared remarks we talked about R&D going from about $27 million here in fiscal '18 up to $50 million. That's going from about 12.5% up to 16% by fiscal '21. So over the next couple years, you'll see that ladder up probably between 13% and 14% fiscal '19, and the continuing on to be about -- around 16% in fiscal '21. So as Scott mentioned, we've added to the team, and there will obviously be additional projects that'll be occurring throughout those years.

Vishnu Gogineni - *Bank of America Merrill Lynch - Analyst*

And just last one from me, the scoring balloon and microcatheter -- I apologize if I missed this -- are they internally driven or are they OrbusNeich products?

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

They're both OrbusNeich products. Yes, they'll both be coming from our partner, OrbusNeich. Next question? Yes?

Vishnu Gogineni - *Bank of America Merrill Lynch - Analyst*

Thanks. [Vishnu] with Bank of America again. I just wanted to confirm some math on the OUS revenue contribution next year. So if I assume the base business 10% and guidance alone of 15% growth, I'm backing into, like, $210 million of OUS revenue? Is that fair -- is that a fair assumption for next year and what the cadence of that incremental revenue is next year?

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

Yes, I think that's a little bit high, but Jeff, do you want to address that?

Jeffrey Points - *Cardiovascular Systems, Inc. - CFO*

Yes, so I can provide some color on that. We've talked a lot about our core business growing at about 10%, so our core business this year was about $215 million. Consider 10% growth in the core business. If you add on to that $7 million to $8 million of both OEM revenue and international revenue, that gets you to around the midpoint of the guidance. So again, going back 10% on the core, and then we've got some new revenue drivers, OEM and international, to add to that.

Vishnu Gogineni - *Bank of America Merrill Lynch - Analyst*

Okay. And then one more question on the U.S. underlying CAD -- or coronary and peripheral market growth. What are your assumptions sort of internally on underlying market growth for both coronary and peripheral in the U.S.?

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

I didn't hear your question. Would you repeat that?

Vishnu Gogineni - *Bank of America Merrill Lynch - Analyst*

Under -- just CSI's assumptions on underlying U.S. coronary and peripheral market growth?

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

Oh, sure. So the underlying growth in coronary, we think, is largely supported by our growth rate. So we still think that can be mid-double digits, mid-teens-type growth rate in the marketplace. In coronary, we still are looking at that as the mid- to high-single-digit range. I'm sorry, in peripheral. Peripheral would still be mid- to high-single-digit, and that hasn't really changed. And that probably harkens back to Dr. Leon's -- or, yes, Marty's presentation showing that this is still an epidemic that is very much upon us, and there just aren't many markets in medical technology today that are growing at that high-single-digit rate. And this is by no means the penetrated market. We've got a long ways to go to improve care in this peripheral vascular disease market segment, so.

Vishnu Gogineni - *Bank of America Merrill Lynch - Analyst*

Thank you.

Scott Ward - *Cardiovascular Systems, Inc. - Chairman, CEO and President*

Next question? No other questions?

All right, terrific. Well, just in closing, let me say once again, I want to just thank all of you for being here. Thank everyone for having joined us on the call on the webcast. My thanks to Dr. Leon, Dr. Kandzari. David, thank you for being here today. We know how busy you are and we're grateful for your attendance. And thank you, Jeff and Rhonda, for a great job.

So thanks, everyone, and have a great day.