Fiscal 2021 Stockholder Letter

CSI CARDIOVASCULAR SYSTEMS, INC.

To our stockholders,

Thank you for your continued support of Cardiovascular Systems.

We hope that you and your loved ones continue to successfully manage the impacts of the pandemic and that you are resuming your normal activities.

I am pleased to share with you that we ended fiscal 21 with strong momentum in our peripheral, coronary and international franchises. Despite the impact of the pandemic on the worldwide health care system we are proud that nearly 90,000 patients were treated using orbital atherectomy – a strong testament to the importance of our technology in the treatment of patients with peripheral artery disease (PAD) and coronary artery disease (CAD). Revenues in fiscal 21 increased 9.5% to $259 million.

Throughout the year, we continued to invest in our people, our systems and new product development to enable our continued success in fiscal 22 and beyond. These investments, combined with lower than normal procedure volumes due to the pandemic, resulted in a net loss position for the year. Nevertheless, we enter fiscal 22 with a strong balance sheet with over $200 million in cash and no long-term borrowings.

In total, we effectively navigated the challenges presented in fiscal 21 and today our strategy to broaden our revenue streams and accelerate growth is underway. As a result, we have arrived at an important inflection point in our growth trajectory – one that we believe can result in higher top-line growth and simultaneously advance CSI on the path to sustainable, attractive profitability, consistent with established peers in the medical technology industry.

Peripheral franchise growth

Twenty million Americans suffer from PAD. The most severe of these patients, those with critical limb ischemia (CLI), often experience severe pain and are at risk of serious infection, amputation, and premature death. Patients with CLI, which represent approximately 60% of our peripheral business, were consistently treated throughout the pandemic. Conversely, we found that patients experiencing intermittent claudication – a painful, yet less acute form of PAD – deferred evaluation and treatment during the Covid pandemic. However, as vaccines became widely available during the second half of the fiscal year, patient confidence increased and we observed a rebound in the treatment of patients with intermittent claudication.

Scott R. Ward
Chairman, President and
Chief Executive Officer

Our U.S. Peripheral revenue increased nearly 7%, driven by strong growth in the office-based lab (OBL) site of service. The volume of PAD procedures performed in OBLs has consistently increased over the past several years. These sites of medical service allow physicians to treat more patients than is typically feasible in a hospital setting. In addition, patients appreciate the improved access to care and convenience. Throughout the pandemic, we witnessed a strong migration of patients to the OBL – particularly as many hospitals restricted elective procedures. As a result, our peripheral procedures are now split evenly between the hospital and the OBL.

We believe this patient migration to the OBL may continue. However, our hospital business, which grew less than 1% due to the impact of the pandemic on the health care system, is expected to resume growth when referral channels are replenished and patient confidence increases.

We are confident that the compelling medical evidence supporting orbital atherectomy will assure that the technology remains a cornerstone in the treatment of severe calcification in all sites of service. For example, our LIBERTY 360° study enrolled over 1,200 patients and now with three years of follow up, represents the largest, contemporary, real-world experience with various endovascular procedures across the full range of patients with PAD. Notably, the physician authors of the LIBERTY 360° OAS sub-analysis indicated that OAS is safe and effective for patients with claudication or CLI, as demonstrated by the low rates of periprocedural complications, the high procedural success rates, and the high 3-year freedom from major amputation.

CSI has now supported the publication of 12 peer-reviewed manuscripts using LIBERTY 360° clinical data, including four new manuscripts published in fiscal 21. This hallmark study has demonstrated the benefits of endovascular intervention, enhanced medical education and accelerated the adoption of orbital atherectomy in the treatment of patients with PAD.

In addition to anticipated continued growth in our core atherectomy business, we began launching new peripheral products to enhance our revenue per procedure. We now offer a full suite of procedure support products commonly used during peripheral orbital atherectomy cases. These include JADE® peripheral angioplasty balloons, Zilient® peripheral guidewires and the ViperCross™ catheter. Approximately $600-$800 of support products are used in every peripheral atherectomy case. We believe we can capture 50% of that per case revenue opportunity over the next two years with our peripheral support products.

In addition, we recently launched our WIRION® embolic protection device. Embolic protection is a $55 million market and we believe we can capture meaningful share in this market over the next two years.

These new product introductions, combined with continued adoption of our core peripheral atherectomy products, are expected to deliver above market revenue growth in the coming years.

Coronary franchise growth

Momentum in our U.S. Coronary franchise improved throughout fiscal 21 as patient confidence improved and vaccination rates increased. In total, revenue grew 17% driven by above market growth in coronary orbital atherectomy devices sold and a 42% increase in sales of coronary support products.

Our strategy of driving more revenue per procedure is working exceptionally well. Our field sales representatives are present in about 70% of the cases where orbital atherectomy is used. The clinical acumen of our sales organization is a core competitive advantage for the company and enables the opportunity to introduce new, differentiated products for the treatment of these patients. For example, the Sapphire angioplasty balloons and Teleport Microcatheters are increasingly being used by physicians to treat severe coronary artery disease. The demand for these important tools now generates nearly $650 per coronary atherectomy device sold.

On the clinical side, we resumed enrollment in our ECLIPSE trial. This trial was temporarily paused during the pandemic as hospitals struggled with activities beyond critical patient care. This important study compares acute and 1-year outcomes of orbital atherectomy to balloon angioplasty for the treatment of severely calcified lesions. We believe the data presented from this study could lead to guideline changes for these procedures. We anticipate completing enrollment in this 2,000 patient trial within the next 12 months. Following a one-year follow up, we hope to share the results of this important study in the fall of calendar 23.

Environmentally, we are seeing exciting new developments in the field, including the increased use of imaging modalities like Optical Coherence Tomography by our physicians either before or during interventional procedures. This is important because it enables better identification and characterization of calcium in the arteries. With this patient level information, physicians are able to better treat and advance specialized therapy, like CSI's orbital atherectomy, for their patients.

Orbital Atherectomy: Vital tool for complex coronary interventions

Hope for a positive outcome is often at a premium for many patients who arrive at Dr. Ki Park, M.D.'s VA facility after they have seemingly exhausted all their treatment options.

These patients often arrive with complex multivessel disease and calcified lesions in their heart, which can be very difficult to treat effectively. Fortunately, Dr. Park has found the Diamondback 360® Coronary Orbital Atherectomy System (OAS) to be a vital tool to provide these patients with a potential solution.

"They thought they had no other options," said Dr. Park. "Symptom reduction has been dramatic and has truly improved their quality of life."

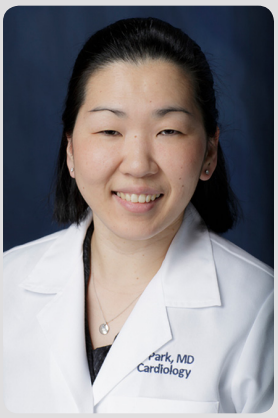
Dr. Park was first introduced to CSI during fellowship training at her VA facility under the guidance of a senior colleague who had adopted orbital atherectomy into the practice.

Now, according to Dr. Park, 25% of all PCIs performed at the facility involve OAS; often times in some of the most complicated cases.

"Due to poor surgical candidacy," she explains, "many of our patients are not deemed to be surgical candidates and are referred to us for high-risk, complex coronary interventions."

OAS has not only become a critical tool to help improve her patients' outcomes, it has also been easy for the staff to integrate this technology into the practice thanks to the straight forward set up and ability to use multiple tools that integrate into one system to facilitate better treatment of calcified lesions.

This has enabled Dr. Park and her team to improve care for patients who had failed PCIs elsewhere with refractory symptoms alleviated by OAS treatment, when they thought they had no other options.

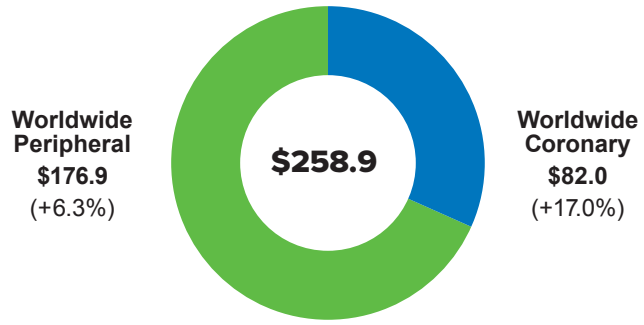


Dr. Ki Park

"Using this system has helped tremendously in advancing care for our patients and has truly allowed us to improve their quality of life," Dr. Park said.

FY21 Revenue Breakdown

Dollars in millions



In fiscal 22, we anticipate continued growth in coronary driven primarily by orbital atherectomy and supported by continued revenue growth from our broadening coronary product offering.

International growth

Internationally, we continue to execute our geographic expansion strategy and orbital atherectomy is now available in 17 countries outside the United States. Despite worldwide travel restrictions throughout the year, international revenues increased 8.3% to $11.3 million in fiscal 21.

Japan is the number two coronary atherectomy market worldwide, and in three years we have captured over 40% market share. Physicians in Japan routinely use imaging to identify and treat severely calcified coronary arteries. The widespread use of imaging supports the use of orbital atherectomy and clearly demonstrates the benefits of its dual mechanism of action – which both removes intimal calcium and fractures medial calcium.

In January, we received CE Mark for the Diamondback 360® Coronary OAS and we are encouraged by the initial enthusiasm for orbital atherectomy in Europe. Using only remote training, we rapidly trained and certified physicians in six countries. Combined, these countries represent a large market where over 25,000 vessel preparation procedures are performed annually. As we have demonstrated in the U.S. and Japan, we expect to grow our market share in Europe as we train and educate physicians throughout this region. Looking ahead, we anticipate that the commercial launch of coronary orbital atherectomy in Europe will accelerate growth in our International Franchise.

Using remote training, education and case support, we intend to launch orbital atherectomy in up to 15 countries in fiscal 22. Simultaneously, we are developing longer-term market entry plans for large, underpenetrated areas like China – where the incidence of CAD and PAD are high, but interventions are, unfortunately, low.

New ventures support sustainable, attractive growth

During fiscal 21, we took several actions to add new growth platforms and to diversify our business in the years ahead:

- In collaboration with an outside partner, we are developing a portfolio of specialty catheters to be used in the treatment of Chronic Total Occlusions (CTO) and complex percutaneous coronary interventions (PCI). These CTO microcatheters will allow CSI to penetrate a $100-$150 million market and will significantly increase our potential revenue per coronary procedure – adding $1,500 in revenue opportunity per coronary case. We are targeting a launch date for these products in fiscal 23.
- CSI entered a partnership with Chansu Vascular Technologies to develop an everolimus-based drug-coated balloon portfolio for peripheral and coronary applications. We are targeting first in-human experience for fiscal 22. If successful, we believe these products will address an estimated $800 million market when commercially available.
- We continue to make progress in our pVAD program, in which we are targeting first in-human experience for fiscal 22. If our development efforts are successful, this product will provide access to an $800 million market in PCI support.
- And finally, we announced an investment and exclusive acquisition option in CarePICS, a telehealth company offering a digital platform designed to accelerate patient access to the appropriate treatment at the right time, resulting in improved care and reduced amputation rates.

Closing

Today, we are poised to execute on an impressive portfolio of initiatives and we believe fiscal 22 will represent an important inflection point for our growth rate, driven by strength in our core orbital atherectomy business, new product introductions and international expansion.

I want to thank all our CSI employees for their extraordinary dedication and commitment to the patients that we serve. Guided by our Mission of *Saving Limbs, Saving Lives, Every Day*, our exceptional team continues to make meaningful progress on our efforts to support our customers, improve patient care, accelerate revenue growth and deliver sustainable, attractive profitability.

Sincerely,

Scott R. Ward
Chairman, President and Chief Executive Officer

September 29, 2021

All product disclosures are available here:
https://csi360.com/product-solutions/

Corporate Information

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Annual Meeting
The annual meeting of the stockholders of Cardiovascular Systems, Inc. will be held November 11, 2021, at 10:00 a.m. CT, as a virtual meeting at www.virtualshareholdermeeting.com/CSII2021.

CSI | CARDIOVASCULAR SYSTEMS, INC.

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Scott R. Ward
Chairman of the Board, President and CEO
Cardiovascular Systems, Inc.

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Augustine Lawlor
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Managing Partner
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St. Jude Children's Research Hospital

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Chairman of the Board, President and CEO

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Vice President and General Manager, Coronary Sales

Ryan D. Egeland, M.D., Ph.D.
Chief Medical Officer

John M. Hastings
Executive Vice President, Operations and Technology

Matthew P. Muscari
Vice President and General Manager, Peripheral Sales

Jack E. Nielsen
Vice President, Investor Relations and Corporate Communications

Jeffrey S. Points
Chief Financial Officer

Stephen J. Rempe
Chief Human Resources Officer

Rhonda J. Robb
Chief Operating Officer

Alexander Rosenstein
General Counsel and Corporate Secretary

Sandra M. Sedo
Chief Compliance Officer

Christopher R. Volker
Vice President and General Manager, International

David S. Whitescarver
Vice President, Corporate Development and Intellectual Property

Forward-Looking Statement
Certain statements herein are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and are provided under the protection of the safe harbor for forward-looking statements provided by that Act. For example, statements herein regarding (i) CSI's strategy and goals;(ii) markets, market share and market leadership; (iii) future growth and profitability; (iv) our clinical trials, including enrollment, results and the announcement of results; (v) the development and introduction of new products, including the specific products, the number of new products, the anticipated timing thereof, and the anticipated revenue generated therefrom; (vi) international expansion, including the anticipated timing thereof; and (vii) new growth platforms, including the anticipated timing and revenue opportunity thereof, are forward-looking statements. These statements involve risks and uncertainties that could cause results to differ materially from those projected, including, but not limited to, the ongoing COVID-19 pandemic and the impact and scope thereof on us, our distribution partners, the supply chain and physicians and facilities, including government actions related to the COVID-19 outbreak, material delays and cancellations of procedures, delayed spending by healthcare providers, and distributor and supply chain disruptions; regulatory developments, clearances and approvals; approval of our products for distribution outside of the United States; approval of products for reimbursement and the level of reimbursement in the U.S., Japan and other foreign countries; dependence on market growth; agreements with third parties to sell their products; the ability of us and our distribution partners to successfully launch our products outside of the United States; our ability to maintain third-party supplier relationships and renew existing purchase agreements; our ability to maintain our relationships with distribution partners; the experience of physicians regarding the effectiveness and reliability of the products we sell; the reluctance of physicians, hospitals and other organizations to accept new products; the potential for unanticipated delays in enrolling medical centers and patients for clinical trials; actual clinical trial and study results; the impact of competitive products and pricing; our ability to comply with the financial covenants in our loan and security agreement and to make payments under and comply with the lease agreement for our corporate headquarters; unanticipated developments affecting our estimates regarding expenses, future revenues and capital requirements; the difficulty of successfully managing operating costs; our ability to manage our sales force strategy; actual research and development efforts and needs, including the timing of product development programs; our ability to obtain and maintain intellectual property protection for product candidates; fluctuations in results and expenses based on new product introductions, sales mix, unanticipated warranty claims, and the timing of project expenditures; our ability to manage costs; our actual financial resources and our ability to obtain additional financing; investigations or litigation threatened or initiated against us; court rulings and future actions by the FDA and other regulatory bodies; international trade developments; the effects of hurricanes, flooding, and other natural disasters on our business; the impact of federal corporate tax reform on our business, operations and financial statements; shutdowns of the U.S. federal government; the potential impact of any future strategic transactions; and general economic conditions; and other factors detailed from time to time in CSI's SEC reports, including its most recent annual report on Form 10-K and subsequent quarterly reports on Form 10-Q. CSI encourages you to consider all of these risks, uncertainties and other factors carefully in evaluating the forward-looking statements contained herein. As a result of these matters, changes in facts, assumptions not being realized or other circumstances, CSI's actual results may differ materially from the expected results discussed in the forward-looking statements contained herein. The forward-looking statements made herein are made only as of the date of hereof, and CSI undertakes no obligation to update them to reflect subsequent events or circumstances.

About CSI
Cardiovascular Systems, Inc., based in St. Paul, Minn., is a medical device company focused on developing and commercializing innovative solutions for treating vascular and coronary disease. The company's orbital atherectomy system treats calcified and fibrotic plaque in arterial vessels throughout the leg and heart and addresses many of the limitations associated with existing surgical, catheter and pharmacological treatment alternatives. For additional information, please visit www.csi360.com and connect on Twitter @csi360.