



**31%** CSI's revenue growth for fiscal 2014

More than 4,500 patients have been enrolled in CSI clinical studies

# LEADING THE WAY



Cardiovascular Systems, Inc. (CSI) is leading the way in developing and commercializing innovative solutions for treating peripheral and coronary vascular disease. Our primary focus is helping physicians address even the most difficult disease states, including calcium, given the complications it presents for the millions who suffer from peripheral arterial disease (PAD) and coronary artery disease (CAD). We're committed to clinical rigor, constant innovation, and a defining drive to set the standard in safe, effective and economical medical devices that improve patient outcomes.

"Our strong revenue gains demonstrate that we are expanding the vascular interventional market by providing physicians with new tools for patients who were previously difficult to treat."

- David L. Martin. CSI President and Officer

## ABOUT CARDIOVASCULAR SYSTEMS, INC.

CSI is based in St. Paul, Minn. The company's Orbital Atherectomy Systems treat calcified and fibrotic plaque in arterial vessels throughout the leg and heart in a few minutes of treatment time, and address many of the limitations associated with other surgical, catheter and pharmacological treatment alternatives. The U.S. FDA granted 510(k) clearance for the use of the Diamondback Orbital Atherectomy System for the treatment of PAD in August 2007. In October 2013, the company received FDA approval for the use of the Diamondback Orbital Atherectomy System in coronary arteries. To date, over 157,000 of CSI's devices have been sold to leading institutions across the United States.

**156,000** 

The number of CSI PAD devices that have been sold since commercial launch

The number of CSI CAD devices that have been sold since commercial launch

#### FINANCIAL HIGHLIGHTS For the fiscal year ended June 30:



## TO OUR STOCKHOLDERS

CSI had another strong fiscal year. On the top line, we delivered 31 percent growth over the prior year, while making important progress to position the company for further success via product innovations, clinical trials and sales force investments. Our strong revenue gains demonstrate that we are expanding the vascular interventional market by providing physicians with new tools for patients who were previously difficult to treat. Several noteworthy achievements helped drive our results.

David L. Martin, President Chief Executive Officer



Glen D. Nelson, MD Chairman of the Board

#### CORONARY EXCEEDS EXPECTATIONS

In the first half of fiscal 2014, we achieved a best case scenario—FDA approval of our Coronary device within the earliest possible window. We believe this approval

was made possible due to the execution and excellent results of our ORBIT II trial, which evaluated the safety and effectiveness of the Diamondback 360® in treating severely calcified coronary lesions.



## SAVING LIMBS, IMPROVING LIVES: A Physician & Patient Story

#### PHYSICIAN - DR. JIHAD MUSTAPHA

Director of Cardiovascular Catheterization Laboratories, Endovascular Interventions and Cardiovascular Research at Metro Health Hospital—Metro Heart and Vascular

Dr. Jihad Mustapha's passion and purpose is helping those Americans suffering from debilitating vascular disease. As a board-certified interventional cardiologist, Dr. Mustapha at Metro Health Hospital—Metro Heart and Vascular in Wyoming, Mich., is the founder of the AMPutation Prevention Symposium (AMP). He has dedicated his career to helping save the limbs and lives of his patients. An innovator in his field, Dr. Mustapha has used CSI's Orbital Atherectomy Systems (OAS) to treat thousands suffering from Peripheral Arterial Disease (PAD). It was because of this expertise that he met patient David Dilley, PhD.

When Dilley, a former college professor, was referred to Dr. Mustapha, he was facing amputation of both his lower legs. Dilley suffered from serious PAD—with obstructions in the arteries of his legs severely limiting blood flow. Additionally, high levels of calcium combined with tortuous, or extremely small, vessels throughout his legs made conventional therapies impossible. He was told the only option was amputation.



Physician—Dr. Jihad Mustapha,
Director of Cardiovascular
Catheterization Laboratories,
Endovascular Interventions
and Cardiovascular Research
at Metro Health Hospital—
Metro Heart and Vascular

"We brought David into our hospital the same Monday that he was scheduled for his amputation, and he walked out of our hospital less than a week later. Most important, he avoided the amputation. Without the Diamondback, this would not have been possible."

— Dr. Jihad Mustapha

However, Dr. Mustapha and his team had a revolutionary new technology at their disposal. With CSI's Diamondback 360® 60cm Peripheral OAS, Dr. Mustapha performed a minimally invasive procedure, entering Dilley's legs through the foot and avoiding the tortuous vessels in the upper leg—an option not possible before the FDA's recent clearance of the Diamondback.

The result? Dilley's legs were cleared of obstructions and blood flow resumed. Said Dr. Mustapha, "We brought David into our hospital the same Monday that he was scheduled for his amputations, and he walked out of our hospital less than a week later. Most importantly, he avoided the amputation. Without the Diamondback, this would not have been possible."



### PATIENT - DAVID DILLEY, PHD

Professor Emeritus, Michigan State University

David Dilley, PhD, led an active life. As a retired professor of horticulture—now professor emeritus—from Michigan State University, he liked to get outdoors, particularly to fish for trout in the streams locally in Michigan or out in Colorado. But in August 2013 he was diagnosed with congestive heart failure.

Open heart surgery successfully repaired two valves and two arteries in his heart, but another problem soon emerged. Dilley noticed decreased circulation in his legs. He developed a great amount of pain in his feet and open wounds that refused to heal. "My feet hurt so badly that I couldn't do any of the exercises to help rehabilitate my heart," he said.

When the wounds took on the appearance of gangrene a few months later, Dilley went to a surgeon who ordered a double amputation for the following week. Alarmed, Dilley and his family began making phone calls. With the help of his cardiologist Dr. Joel Cohn at the Thoracic Cardiovascular Institute, Lansing, Mich., Dilley was referred to Dr. Jihad Mustapha at Metro Health Hospital.

The morning of Dilley's scheduled amputation, Dr. Mustapha performed the minimally invasive procedure with the Diamondback 360® on his right leg. The results were so successful that they decided to complete the procedure on his left leg, as well. Blood flow returned to normal. Dilley kept both his legs, the pain subsided, and the wounds began to heal.

Now, Dilley is on his way to a full recovery, and he is excited to return to the trout streams. "I spent quite a bit of time out in Colorado before my heart and leg problems—and I'm looking forward to getting back out there. Using the innovative technology from CSI, Dr. Mustapha and his team have given me a new lease on life."



ORBIT II trial results surpassed FDA established endpoints by significant margins, including freedom from MACE of 90 percent. Results continued to be impressive at one year with freedom from target lesion revascularization of 95 percent in this difficult-to-treat patient population. Economic data from ORBIT II is compelling as well, showing cost savings of \$3,200 to more than \$4,000 per patient with our device. We look forward to releasing two-year ORBIT II results later this fiscal year.

The FDA approval of our Coronary device allowed us to launch the product before the end of calendar 2013. In just over six months, in a controlled launch with a small group of dedicated coronary sales professionals, we saw adoption by key opinion leaders and generated \$5 million in device revenue—selling nearly 1,400 units. In the fourth quarter of fiscal 2014, we began preparing for a broader commercial launch, including initial cross training of some of our PAD sales force to sell both coronary and peripheral products in their accounts.

We enter fiscal 2015 with strong momentum, convincing clinical data and a larger sales force to address the \$1.5 billion U.S. calcified coronary arterial disease market.

## NEW PAD ACCESS POINTS HELP PHYSICIANS AND PATIENTS

Also contributing to our success, in February 2014, CSI secured FDA clearance for the Diamondback 360® 60cm Peripheral OAS. This new device, with its low profile and short length, allows physicians to gain access through the foot or ankle to treat peripheral arterial disease (PAD) in the small vessels located below the knee.

This additional access point lets physicians help a broader range of patients who may otherwise face amputation. In addition, use of smaller sheaths has been shown to reduce procedure and access site closure times, reduce radiation exposure, enable faster patient recovery and reduce complications from bleeding. Initial demand has been



strong, comprising 5 percent of peripheral device sales in the first three months after commercial launch.

We believe the current U.S. PAD market is \$2.0 billion with opportunity to expand further. Introducing new, innovative devices, like the Diamondback 360® 60cm Peripheral OAS strengthens our leadership position and provide a sustainable expansion of opportunity in this large and underserved market.

Our low-profile and coronary devices are examples of how our OAS technology is expanding CSI's markets and providing sustainable attractive growth. These systems underscore our commitment to provide physicians new options for treating the most difficult patients who were previously underserved.

#### COMMITMENT TO SCIENCE CONTINUES

CSI's commitment to ongoing clinical science gives physicians and patients the confidence that our innovative and economical solutions are effective treatments, even for calcified arterial disease. Arterial calcium is a significant and underserved problem, often resulting in poor outcomes and higher treatment costs. Our orbital atherectomy technology provides cost-effective and long-term durable outcomes for these difficult-to-treat patients.

In fiscal 2014, we continued to advance our clinical initiatives, including our LIBERTY 360, COAST and ORBIT II studies. These efforts are detailed in the sidebars throughout this letter.

#### RAPID ADOPTION DRIVES FINANCIAL RESULTS

Physicians' rapid adoption of our Peripheral Orbital Atherectomy System, emerging coronary system and mounting clinical data are catalysts for revenue growth. For fiscal 2014, our growing success in the PAD market led to revenue gains of 28 percent or more in each of our four quarters, and we ended the year with \$136.6 million in annual sales. The percentage of revenues from reorders remained robust at 97 percent—reflecting a growing and loyal customer base.

Fiscal 2014 gross margin was strong at 77 percent. Operating expenses rose 36 percent, as we continued to make planned investments in our business to capitalize on the large peripheral and coronary market opportunities. Net loss totaled \$(35.3) million, or \$(1.25) per common share. On an adjusted EBITDA basis, the loss was \$(21.2) million\*; however, excluding net coronary investments, adjusted EBITDA was positive.

In November 2013, CSI raised approximately \$84.4 million in a public offering of common stock. We are using the proceeds to fund growth investments, including commercial expansion, coronary rollout initiatives, clinical studies, product portfolio expansion, education programs, international expansion and facility expansion.

#### WE ARE REDEFINING INTERVENTIONAL VASCULAR SOLUTIONS

CSI is committed to helping physicians successfully address the most difficult vascular disease states. We do this through clinical rigor, constant innovation and a defining drive to improve patient outcomes.

Our fiscal 2015 priorities are to:

- Continue to achieve high growth and increase adoption in the PAD market—expanding that market with our unique, low-profile orbital technology;
- Successfully broaden our commercial launch in the CAD market—methodically adding more physicians and hospitals and expanding the market; and
- Conduct rigorous clinical studies that demonstrate the safety and effectiveness of our technology for very challenging patient populations.

Our ability to expand these markets by treating previously underserved patients is expected to drive adoption of our systems, thereby providing continued attractive growth for CSI. We enter fiscal 2015 with significant momentum and we look forward to updating you on our progress throughout the year.

Sincerely,

David L. Martin
President and Chief Executive Officer

October 3, 2014

G.D. Nelson, MD Chairman of the Board

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<sup>\*</sup> For a reconciliation of the non-GAAP financial measure referred to as adjusted EBITDA, please refer to the table on page 34 of Form 10-K

## CLINICAL RESEARCH

#### ORBIT II ONE-YEAR RESULTS

In February 2014, the company released one-year data from its ORBIT II study of the company's Diamondback 360 Coronary OAS in treating severely calcified lesions. Results demonstrated rates of freedom from major adverse coronary events (MACE) of 84 percent and freedom from target lesion revascularization of 95 percent. Moreover, patients treated with the Diamondback 360 Coronary OAS have been associated with shorter lengths of hospital stay and lower readmission rates, providing an estimated cost savings of \$3,200 to more than \$4,000 per patient for the treating institutions.

#### LIBERTY 360°

CSI continued enrolling patients in its post-market study, LIBERTY 360°, during fiscal 2014. The study is evaluating the acute and long-term clinical and economic outcomes of the company's orbital atherectomy system in treating PAD. It is the first study of its kind to compare orbital atherectomy to any other PAD interventional treatment option in a difficult-to-treat patient population. As a prospective, observational, multicenter post-market study, LIBERTY 360° will enroll up to 1,200 patients at up to 100 sites across the United States, including patients with claudication (painful circulatory problems), critical limb ischemia (a severe form of PAD) or are scheduled for amputation.

#### COAST

In June 2014, CSI enrolled its first patients in the Coronary Orbital Atherectomy System Trial (COAST). This investigational study will assess the safety and efficacy, as well as economic outcomes, of CSI's new micro crown OAS in treating severely calcified coronary lesions in patients suffering from coronary disease. In total, 100 patients will be enrolled in the COAST study at up to 15 sites in the United States and five sites in Japan. If the trial is successful, the results may help secure commercial approval for the second generation Coronary OAS device in Japan. This would be significant as Japan is both a large and underserved CAD market.



#### **EXECUTIVE OFFICERS**

#### David L. Martin

President and Chief Executive Officer

#### Laurence L. Betterley

Chief Financial Officer

#### Kevin J. Kenny

Executive Vice President, Sales and Marketing

#### Paul Koehn

Senior Vice President, Quality and Operations

#### Robert J. Thatcher

Chief Healthcare Policy Officer

#### **HEADQUARTERS**

Cardiovascular Systems, Inc. 651 Campus Drive St. Paul, Minnesota 55112

#### **BOARD OF DIRECTORS**

#### Glen D. Nelson, MD

Chairman Chairman, GDN Holdings Vice Chairman (retired) Medtronic, Inc.

#### **Scott Bartos**

President and Chief Executive Officer Rural/Metro Corporation

#### **Brent Blackey**

President and Chief Operating Officer Holiday Companies

#### **Edward Brown**

Senior Advisor Health Evolution Partners

#### **Augustine Lawlor**

Managing Partner HealthCare Ventures

#### David L. Martin

President and Chief Executive Officer Cardiovascular Systems, Inc.

#### Leslie L. Trigg

Executive-in-Residence Warburg Pincus

#### Scott R. Ward

Managing Director SightLine Partners President Raymond Holdings

## TRANSFER AGENT AND REGISTRAR

For change of name, address, or to replace lost stock certificates, contact:

American Stock Transfer & Trust Company, LLC 6201 15th Avenue Brooklyn, New York 11219 info@amstock.com www.amstock.com 800.937.5449

#### INDEPENDENT ACCOUNTANTS

PricewaterhouseCoopers LLP Minneapolis, Minnesota

#### **CORPORATE COUNSEL**

Fredrikson & Byron, P.A. Minneapolis, Minnesota

#### **INVESTOR RELATIONS**

Jack Nielsen 651.202.4919 j.nielsen@csi360.com

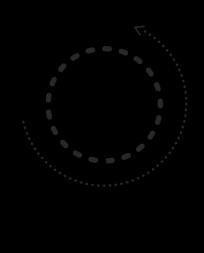
#### ANNUAL MEETING

The annual meeting of the shareholders of Cardiovascular Systems, Inc., will be held November 12, 2014, at 10:00 a.m. CT at:

Cardiovascular Systems, Inc. 651 Campus Drive St. Paul, Minnesota 55112

#### FORWARD-LOOKING STATEMENT

Certain statements in this annual report 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 in this document regarding (i) the market expansion from CSI's Orbital Atherectomy Systems; (ii) CSI's clinical trials, including the expected number of patients expected to be enrolled in the LIBERTY 360° and COAST trials; (iii) the broader coronary launch; (iv) the size of the U.S. calcified CAD and PAD markets; (v) the potential to secure commercial approval in Japan; (vi) the size of the Japanese CAD market; (vii) the use of proceeds from CSI's public stock offering; (viii) CSI's priorities in fiscal 2015; and (ix) potential future growth of CSI, 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, regulatory developments in the U.S. and foreign countries; the experience of physicians regarding the effectiveness and reliability of the PAD and CAD Systems; the potential for unanticipated delays in enrolling medical centers and patients for clinical trials; actual clinical trial results; dependence on market growth; the reluctance of physicians to accept new products; the difficulty of successfully managing operating costs; FDA and similar foreign clearances and approvals; the impact of competitive products and pricing; approval of products for reimbursement and the level of reimbursement; unanticipated delays or costs related to construction of CSI's new corporate headquarters; unanticipated developments affecting CSI's estimates regarding expenses, future revenues and capital requirements; fluctuations in results and expenses based on new product introductions, sales mix, unanticipated warranty claims, and the timing of project expenditures; CSI's inability to expand its sales and marketing organization and research and development efforts; CSI's ability to obtain and maintain intellectual property protection for product candidates; CSI's actual financial resources; 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 in this annual report. 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 in this annual report. The forward-looking statements made in this annual report are made only as of the date of this report, and CSI undertakes no obligation to update them to reflect subsequent events or circumstances.





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#### **Product Disclosures:**

#### **Peripheral Products**

The Stealth 360° PAD System, Diamondback 360° PAD System and Predator 360° PAD System are percutaneous orbital atherectomy systems indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and stenotic material from artificial arteriovenous dialysis fistulae. The systems are contraindicated for use in coronary arteries, bypass grafts, stents or where thrombus or dissections are present. Although the incidence of adverse events is rare, potential events that can occur with atherectomy include: pain, hypotension, CVA/TIA, death, dissection, perforation, distal embolization, thrombus formation, hematuria, abrupt or acute vessel closure, or arterial spasm.

#### **Coronary Product**

Indications: The Diamondback 360° Coronary Orbital Atherectomy System (OAS) is a percutaneous orbital atherectomy system indicated to facilitate stent delivery in patients with coronary artery disease (CAD) who are acceptable candidates for PTCA or stenting due to de novo, severely calcified coronary artery lesions.

**Contraindications:** The OAS is contraindicated when the ViperWire guide wire cannot pass across the coronary lesion or the target lesion is within a bypass graft or stent. The OAS is contraindicated when the patient is not an appropriate candidate for bypass surgery, angioplasty, or atherectomy therapy, or has angiographic evidence of thrombus, or has only one open vessel, or has angiographic evidence of significant dissection at the treatment site and for women who are pregnant or children.

Warnings/Precautions: Performing treatment in excessively tortuous vessels or bifurcations may result in vessel damage; The OAS was only evaluated in severely calcified lesions, A temporary pacing lead may be necessary when treating lesions in the right coronary and circumflex arteries; On-site surgical back-up should be included as a clinical consideration; Use in patients with an ejection fraction (EF) of less than 25 percent has not been evaluated. See the instructions for use before performing Diamondback 360 Coronary OAS procedures for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information call CSI at 1-877-274-0901 and/or consult CSI's website at www.csi360.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

#### Micro Crown OAS

CSI has commenced its COAST Investigational Device Exemption clinical trial to evaluate the safety and effectiveness of its new micro crown orbital technology in treating coronary arteries. This new system is limited by federal law to investigational use and is currently not commercially available in the United States or Japan.