



# Defeating Complex Calcium

2012 ANNUAL REPORT

**CSI** | CARDIOVASCULAR  
SYSTEMS, INC.

## USING SIMPLE PHYSICS

Peripheral Arterial Disease (PAD) affects 8 million to 12 million Americans. When treating it, physicians face a common, under-diagnosed condition and complicating factor — calcium. Cardiovascular Systems has developed a clinically proven, orbital atherectomy technology that addresses this large and unmet need. Our electric-drive Stealth 360°, and pneumatic-driven predecessor Diamondback 360°, Orbital Atherectomy Systems are FDA-cleared to treat calcified and fibrotic plaque in arterial vessels throughout the leg — and they're highly effective. We're also in the final phase of a clinical trial to approve our technology for use in treating calcified coronary arteries. Coronary Artery Disease (CAD) affects 16 million Americans. Using simple physics, we're defeating complex calcium.

"WE SAVE MONEY FOR PHYSICIANS AND PATIENTS BY AVOIDING COMPLICATIONS, REDUCING EXPENSIVE LAB TIME AND LOWERING ADDED COSTS FOR ANCILLARY TECHNOLOGY SUCH AS STENTS."

David L. Martin, CSI President and Chief Executive Officer

**\$3.5 BILLION**

Combined PAD and CAD market opportunity.

**100,000**

Nearly 100,000 CSI PAD devices have been sold life to date.

**225%**

Stealth 360° revenue grew over 225% for the year, 35% quarterly average.

## ABOUT CARDIOVASCULAR SYSTEMS, INC.

Cardiovascular Systems, Inc., based in St. Paul, Minn., is a medical device company focused on developing and commercializing innovative solutions for treating peripheral and coronary vascular disease. The company's electric-drive Stealth 360°, and pneumatic-driven predecessor Diamondback 360°, Orbital Atherectomy Systems treat calcified and fibrotic plaque in arterial vessels throughout the leg in a few minutes of treatment time\*, and address many of the limitations associated with existing surgical, catheter and pharmacological treatment alternatives. The U.S. FDA granted 510(k) clearance for the use of the Diamondback 360° in August 2007 and Stealth 360°

in March 2011. The Stealth 360° has been rapidly adopted and is expected to accelerate the growth of orbital atherectomy in the future. To date, nearly 100,000 PAD orbital atherectomy devices have been sold to leading institutions across the United States. CSI is also in the final phase of its ORBIT II Investigational Device Exemption clinical trial to evaluate the safety and effectiveness of its orbital technology in treating coronary arteries. The coronary system is limited by federal law to investigational use and is currently not commercially available in the United States.

\*Actual treatment times may vary; CSI studies show an average treatment time of less than 2 minutes.





## TO OUR SHAREHOLDERS

We enter fiscal 2013 with momentum. With rising revenues, a large market opportunity and the potential to expand into the coronary space, we're backed by a wealth of clinical data that supports our ability to treat arterial disease and, in particular, disease complicated by calcium.

The prevalence of arterial calcium is vastly underestimated in medicine today. Calcium, even if it isn't visible through angiography, is present in about 65 percent of the 2.5 million people diagnosed annually with peripheral arterial disease (PAD).

The problem is profound. It leads to poor outcomes when traditional balloon and stent therapies are used — including dissection, vessel wall trauma and stent fracture. Moreover, calcified lesions result in higher treatment costs. Also, with obesity and diabetes on the rise, arterial calcium is increasing in prevalence. Successful treatment of calcified lesions requires a different approach than standard balloon or stent therapies.

Our technology is different and effective. It utilizes a scientifically proven orbital mechanism of action that protects healthy vessel tissue, while removing even the most difficult-to-treat calcified plaque throughout the leg. Moreover, it's cost effective. We save money for physicians and patients by avoiding complications, reducing expensive lab time and lowering added costs for ancillary technology such as stents. In addition, our studies indicate that CSI orbital atherectomy avoids early restenosis and thus the cost for reintervention.

Our technology's safety, effectiveness and economic benefits position it as the primary therapy for treating peripheral atherosclerotic arterial disease.

The rapid adoption of CSI's next-generation Stealth 360° and the company's high growth in the rapidly emerging office-based lab market helped drive success in fiscal 2012. In addition, we made significant progress on a number of other fronts, including medical education and clinical research — and we achieved important milestones in preparing for a coronary market application.

### REVENUE (in millions)



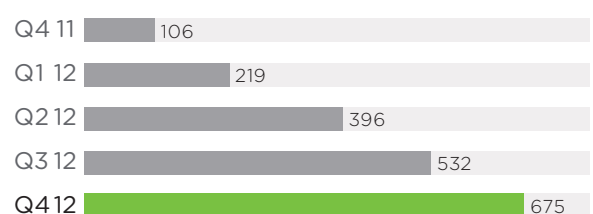
### GROSS MARGIN



### STEALTH 360° REVENUE (by quarter)



### STEALTH 360° CUSTOMERS (by quarter)



**David L. Martin**  
President and  
Chief Executive Officer



**Glen D. Nelson, MD**  
Chairman of the Board



## PHYSICIANS EMBRACE STEALTH 360°

Increasingly, the medical community is becoming aware of the difficulty and high cost of treating arterial calcium. With that comes recognition that our technology is successfully addressing this serious problem. The next-generation Stealth 360° is easy for physicians to use, gives them complete control of device operation and has a high degree of safety in both hospital and office settings.

The simplified and improved Stealth 360° has only six crown configurations versus 13 configurations for its predecessor, the Diamondback 360°, which simplifies crown selection and reduces the amount of inventory the customer needs to have on hand. Reduced inventories and cannibalization of our Diamondback 360° sales limited revenue growth during fiscal 2012; however, as physicians continue to adopt Stealth 360° and perform more procedures, we expect higher usage volumes to drive increased revenue growth in fiscal 2013 and beyond.

Most CSI customers have now converted to the new system, which we launched just over one year ago. During fiscal 2012, our Stealth 360° customer base grew from 106 accounts to nearly 700 accounts. Stealth comprised 86 percent of total device revenues in our fourth quarter.

In the marketplace many physicians are moving their practices from hospitals to office-based labs. As this trend continues, we expect it to broaden access to treatment for the almost 2.5 million people diagnosed annually with PAD. As a result, CSI's office-based lab revenue grew substantially in fiscal 2012. We believe that the strength of our technology — supported by compelling clinical data — will lead to attractive long-term growth in both hospitals and office-based lab settings.

## ORBIT II CORONARY TRIAL IN FINAL PHASE

During fiscal 2012, CSI made substantial progress in the ORBIT II trial, evaluating the safety and effectiveness of CSI's orbital technology in treating severely calcified coronary arteries. We're now in the final phase of enrollment required to approve our technology for coronary use. CSI also received approval from the FDA to include our next-generation electric orbital atherectomy system in the ORBIT II trial. The system is a simpler design that gives physicians complete control of device operation and is the preferred device for commercialization. Including this system in the ORBIT II trial will



## CSI'S ORBITAL TECHNOLOGY



<sup>1</sup>CONFIRM II, CONFIRM III, CALCIUM 360 and COMPLIANCE 360 studies. CSI data on file.

save millions of dollars of clinical trial expense and provide our next-generation technology to patients and their physicians much sooner than with a separate trial.

At the end of August, ORBIT II had over 360 patients enrolled out of a range of 429 to 479 allowed in the trial. We expect to complete enrollment during the fourth quarter of calendar 2012, which may allow commercialization by the end of calendar 2013, subject to approval and timing of approval by the FDA.

CSI's technology has an established track record of safety and effectiveness in treating small calcified lesions. In addition, CSI's ORBIT I coronary feasibility study demonstrated safety, procedural success and compelling long-term clinical outcomes in treating calcified lesions in coronary arteries. Based on that success, we believe that our orbital technology is well-suited for removing calcific and fibrocalcific plaque in coronary lesions. A coronary application would open up a large, underserved market opportunity for CSI, estimated to exceed \$1.5 billion annually.

## DATA CONFIRMS ORBITAL TECHNOLOGY'S SAFETY AND EFFECTIVENESS

With 13 peripheral clinical trials studying nearly 4,000 patients completed, we are an industry leader in clinical data support for our physician customers. During fiscal 2012, presentations of clinical data at key conferences, including Transcatheter Cardiovascular Therapeutics (TCT), American College of Cardiology (ACC), Society for Interventional Radiology (SIR), New Cardiovascular Horizons (NCVH) and C3, among others, continued to demonstrate the proven safety and effectiveness of CSI's orbital technology in treating patients with PAD. Of particular note:

⇒ Twelve-month data from CSI's COMPLIANCE 360° study of calcified above-the-knee lesions demonstrated that avoiding stents and reducing restenosis lowers cost. The cost effectiveness of the CSI orbital atherectomy system group versus the percutaneous transluminal angioplasty (PTA) group at six months was substantial. The PTA arm required bailout stenting in 84 percent of the procedures, compared to 8 percent for orbital atherectomy.

## CSI'S MARKET OPPORTUNITY

**12 MILLION**

people in U.S. with lower extremity PAD

**700,000**

PAD procedures annually, 65% with calcified lesions

**\$2 BILLION**

PAD market opportunity and growing

**16 MILLION**

people in U.S. with CAD

**1.4 MILLION**

CAD procedures annually, nearly 40% with calcified lesions

**\$1.5 BILLION<sup>2</sup>**

Potential coronary market opportunity

<sup>2</sup>CSI's ORBIT II Investigational Device Exemption clinical trial is evaluating the safety and effectiveness of its orbital technology in treating coronary arteries. The coronary system is limited by federal law to investigational use and is currently not commercially available in the United States.

⇒ Twelve-month data from our CALCIUM 360° study of calcified, below-the-knee lesions showed significantly favorable outcomes of the orbital atherectomy system group versus PTA alone, including freedom from death and freedom from major serious adverse events (major amputation, death and target lesion revascularization/target vessel revascularization) of 93 percent versus 58 percent.

⇒ Our CONFIRM Registry Series, three studies of over 3,100 real-world patients, with no exclusion criteria, showed predictable and reproducible results of orbital atherectomy in calcified peripheral arterial disease. Results demonstrated excellent acute safety and procedural efficacy (98 percent freedom from flow-limiting dissection, 94 percent freedom from stenting, 99 percent freedom from perforation and 90 percent freedom from stenosis immediately post procedure).

⇒ Two studies of orbital atherectomy in the office-based lab setting showed similar favorable results when used in the physician's office compared to the hospital, including high procedure success and low complication rates that were comparable to the CONFIRM series results.

## FINANCIAL RESULTS

The strength of our Stealth 360° and clinical data are catalysts for revenue growth. For fiscal 2012, after a slow first quarter affected by our product transition to Stealth 360° and initial surge of physicians leaving hospitals to establish office-based labs, revenues rebounded in the following quarters and rose to \$82.5 million for the fiscal year, up 5 percent from the prior year. The percentage of revenues from reorders increased to 96 percent — reflecting a strong and loyal customer base.

Fiscal 2012 gross margin remained strong at 77 percent, even with higher initial costs associated with our product transition and expansion of our manufacturing capacity to meet future demand. Operating expenses rose 9 percent as we continued to invest in our business to capitalize on our large peripheral and coronary market opportunities and accelerate revenue growth in the future. Net loss totaled \$(16.8) million, or \$(0.93) per common share, versus \$(11.1) million, or \$(0.70) per common share, in fiscal 2011. On an adjusted EBITDA basis, the loss was \$(8.4) million.<sup>3</sup>

In May, we raised approximately \$15 million in a public offering of common stock, resulting in a cash and cash equivalent balance of \$35.5 million at fiscal year end. We will use the proceeds to accelerate growth in the company's existing PAD business and prepare for our coronary application.

## FISCAL 2013: FOCUS ON DRIVING ACCELERATED GROWTH

With unique products and a wealth of market opportunity, this is a very exciting time for CSI's employees and shareholders. In fiscal 2013, investments in science, our commercial organization and medical education should accelerate and drive our next stage of growth in the PAD market, and prepare us for a large potential coronary market application.

While these strategies will increase operating expenses in the near term, we expect them to set the stage for attractive revenue growth in 2013 and beyond and profitability long term. We have a great future and look forward to updating you on our progress.

Sincerely,



David L. Martin

President and Chief Executive Officer



G.D. Nelson, MD

Chairman of the Board

August 30, 2012

<sup>3</sup>For a reconciliation of the non-GAAP financial measure referred to as adjusted EBITDA, please refer to the table on page 41 of Form 10-K.

## EXECUTIVE OFFICERS AND ADVISORS

**David L. Martin**  
President and Chief Executive Officer

**Laurence L. Betterley**  
Chief Financial Officer

**James E. Flaherty**  
Chief Administrative Officer

**Kevin J. Kenny**  
Executive Vice President,  
Sales and Marketing

**Paul Koehn**  
Vice President, Manufacturing,  
Quality and Operations

**Robert J. Thatcher**  
Executive Vice President

**Nabil Dib, MD, MSc, FACC**  
Medical Advisor

## 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.

**Brent Blackey**  
President and Chief Operating Officer  
Holiday Companies

**Edward Brown**  
Senior Advisor  
Health Evolution Partners

**John Friedman**  
Managing Partner  
Easton Capital Investment

**Augustine Lawlor**  
Managing Partner  
HealthCare Ventures

**Leslie L. Trigg**  
Executive-in-Residence  
Warburg Pincus

**David L. Martin**  
President and Chief Executive Officer  
Cardiovascular Systems, Inc.

## TRANSFER AGENT AND REGISTRAR

For change of name, address, or to replace lost stock certificates, contact: American Stock Transfer & Trust Company, LLC  
6201 15<sup>th</sup> 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

Padilla Speer Beardsley Inc.  
Minneapolis, Minnesota

## ANNUAL MEETING

The annual meeting of the shareholders of Cardiovascular Systems, Inc., will be held on October 31, 2012, 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) CSI's expectations regarding Stealth 360° and acceleration of the growth of orbital atherectomy; (ii) the increasing prevalence of arterial calcium in the general public; (iii) higher usage volumes for the Stealth 360° and increased revenue growth in fiscal 2013 and beyond; (iv) long-term growth in both hospitals and office-based lab settings; (v) clinical trial expense and timing expectations; (vi) commercialization timing expectations; (vii) the benefits of and market opportunity for a coronary application; (viii) use of proceeds from CSI's May 2012 public offering; and (ix) near-term increases in operating expenses and long-term profitability expectations, are forward-looking statements. These statements involve risks and uncertainties which could cause results to differ materially from those projected, including but not limited to the potential for unanticipated delays in enrolling medical centers and patients for clinical trials; dependence on market growth; the reluctance of physicians to accept new products; the effectiveness of the Stealth 360°; actual clinical trial results; the impact of competitive products and pricing; the difficulty to successfully manage operating costs; fluctuations in quarterly results; FDA clearances and approvals; approval of products for reimbursement and the level of reimbursement; 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 DISCLOSURE

The Diamondback® Orbital Atherectomy System is indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and stenotic material from artificial arteriovenous dialysis fistulae. The system is 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.