Cardiovascular Systems Inc
Form DEFA14A
January 26, 2010

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

SCHEDULE 14A

Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934 (Amendment No.)

Filed by the Registrant þ

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Check the appropriate box:

o Preliminary Proxy Statement
o Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))
o Definitive Proxy Statement
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CARDIOVASCULAR SYSTEMS, INC.
(Name of Registrant as Specified In Its Charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

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(1) Title of each class of securities to which transaction applies:

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o Fee paid previously with preliminary materials.

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(1) Amount Previously Paid:

(2) Form, Schedule or Registration Statement No.:

(3) Filing Party:

(4) Date Filed:

David L. Martin
President and
Chief Executive Officer

Glen D. Nelson, MD
Chairman of the Board

To Our Shareholders:

The opportunity for Cardiovascular Systems is clear: saving legs saves lives. By restoring blood flow in the leg, we can significantly improve outcomes for patients and their families. CSI offers a system with a demonstrated safety profile for treating peripheral arterial disease, or PAD blockages in leg arteries that lead to pain, immobility, non-healing wounds and eventually loss of limbs and increased mortality. In a few minutes of treatment time, our Diamondback 360® PAD System helps physicians treat patients to bring back their ability to walk pain free, remain productive and live independently.

We are addressing a large, underserved medical need and market opportunity. In the United States alone, as many as 12 million patients suffer from PAD, and up to 180,000 PAD-related amputations are performed annually. Remarkably, approximately half occur without a complete diagnostic vascular evaluation.

We launched the Diamondback 360° in September 2007. Our mission is to introduce this device to more doctors and establish this product as a first-line interventional treatment for effectively treating PAD. As of the fiscal 2009 year-end, nearly 600 hospitals had adopted our system, with more than 15,000 procedures performed.

CSI s Diamondback 360° PAD System offers:

- **Patients and their families** a new option for recapturing quality of life and returning to independent living and favored activities;

- **Physicians** an easy-to-use treatment solution resulting in improved, durable long-term patient outcomes; and

- **Healthcare providers** a cost-effective procedure that can reduce amputations and the related costly extended recovery and long-term care.

Fiscal 2009 was a milestone year for CSI in many respects:

- Revenue increased sequentially every quarter and operating profitability improved throughout the year.

- We expanded our product portfolio with new products, as well as distribution partnerships.

- We initiated clinical trials evaluating our Diamondback 360°.

- We became a publicly traded company.

Financial Highlights: Solid Revenue Growth, Gross Margin

On February 25, 2009, we closed a reverse merger allowing CSI to gain a listing on the Nasdaq Global Market® under the symbol CSII. Through this transaction, we received $37 million in net assets (primarily cash), which we are using to expand our commercial organization, develop new products and support clinical trials key initiatives to grow our business. We anticipate that these funds from the reverse merger and available debt financing can carry CSI to

profitability and positive cash flow. With the reverse merger, our capital structure changed substantially, by conversion of all our preferred stock to common stock. As of June 30, 2009, we had 14.1 million common shares outstanding, as well as many new shareholders whom we d like to formally welcome to CSI.

With the Diamondback 360°, our team has achieved clinical success in the most complex lesions, including highly calcified vessels below the knee a territory often ignored due to high complication rates.

Tony S. Das, MD, FACC, *Director,*
Peripheral Vascular Interventions,
Presbyterian Hospital of Dallas,
Dallas, Texas

CSI is conducting the rigorous clinical trials needed to support the use of a new therapy. I have used various tools to treat PAD, and the Diamondback 360° offers both safety and positive outcomes.

Raymond Dattilo, MD, *Director,*
Peripheral Interventions,
St. Francis Hospital,
Topeka, Kansas

I have used the Diamondback 360° to treat many patients thought to be untreatable. This therapy has the potential to prevent amputations and gives patients another chance to live an active life.

Jihad Mustapha, MD, FACC, FSCAI
Metro Health Hospital, Grand
Rapids, Michigan

Fiscal 2009 was our first full year with a product on the market. Revenue grew sequentially each quarter, while we limited operating expense increases. As a result, the bottom line improved dramatically, and we achieved significant progress toward our goal of profitability.

Full-year revenue grew over 150 percent to $56.5 million. Gross margin improved to 71 percent from 60 percent in fiscal 2008, a result of higher product volumes, manufacturing efficiencies and product cost reductions. In fiscal 2009, the net loss was $(31.9) million, lower than last fiscal year, due to higher revenue, partially offset by important investments in sales and marketing, infrastructure to support growth and product development.

Next-Generation Diamondback 360° Launched

In December 2008, we introduced the next generation of the Diamondback 360°, which reflects CSI s commitment to continuous performance gains in efficacy, speed, safety and ease of use. We continuously work with physicians to understand their needs and respond with improved and innovative solutions. These interactions led to major enhancements, including a new handle for treating longer lesions without repositioning the device; improved fluid management; advanced shafts and crowns; a one-click-connect feature to attach tubing and cables; and a convenient saline infusion port. Our engineering team is focused on iterating our devices to advance ergonomics and performance.

Providing Comprehensive Endovascular Tools

We are committed to providing physicians with a comprehensive and synergistic set of tools to treat PAD. Our product offerings were enhanced significantly in fiscal 2009.

We added several products to our Viper line products to supplement or enhance Diamondback 360° performance. Current offerings include:

- ViperSlide Lubricant for smooth operation of the Diamondback 360°;
- ViperTrack Radiopaque Tape to assist in measuring the treatment parameters;
- ViperWire Guide Wire with flexible and firm stiffness profiles for exclusive use with the Diamondback 360°; and
- ViperCaddy Guide Wire Management, a system designed to make interventional procedures more efficient.

We also expanded our product portfolio by signing a U.S. distribution agreement in early fiscal 2010, with Asahi-Intecc Co., Ltd., to market its peripheral guide wire line. These guide wires are especially well suited for addressing chronic occlusions and long, complex lesions above or below the knee, and facilitate lesion access with the Diamondback 360°.

A Focused Sales and Marketing Organization

Currently, we have a clinically oriented sales team of over 100 domestic sales professionals, up from 55 at the end of fiscal 2008. They are becoming increasingly productive as they gain product and procedure experience and increase customers within their territories. With our marketing professionals and national direct sales force in place, we have an efficient avenue to bring our existing and new products to the marketplace.

Sound Scientific Research Supports Innovation

Physicians need scientifically sound data to support using a certain technology and make therapeutic decisions. We are committed to providing that data for the Diamondback 360°, including specific application techniques, to make it the benchmark device for PAD treatment.

In April 2009, we named Dr. Nabil Dib, MSc, FACC, a renowned interventional cardiologist and researcher, a medical advisor to CSI. He has assembled a world-class science task force to guide CSI in how best to provide scientifically sound and clinically useful data to the physician community. This task force also provides input for the continuous improvement of our devices and usage techniques.

We initiated two prospective, randomized, post-market clinical trials during 2009:

- The COMPLIANCE 360° study will compare the benefits of first modifying calcified plaque with the Diamondback 360° plus low-pressure balloon inflation, if desired, versus the use of traditional balloon angioplasty alone in non-compliant vessels above the knee. Initial treatment with the Diamondback 360° could reduce the level of balloon pressure required to open the

Revenue *(in millions) for fiscal year ended June 30* Gross Margins *for fiscal year ended June 30* Number of Accounts *for fiscal year ended June 30* Reorder Revenue as % of Total Revenue *for fiscal year ended June 30*

vessel. We believe that balloon angioplasty alone can injure large vessels above the knee resulting in restenosis. This study calls for enrolling 50 patients at five U.S. medical centers and following them for 12 months.

- The CALCIUM 360° clinical trial will compare the effectiveness of the Diamondback 360° to balloon dilation angioplasty in non-compliant lesions in vessels behind and below the knee, which are especially difficult to treat with stents, balloons or other devices. Calcified lesions occur in up to 70 percent of lesions below the knee. At the end of fiscal 2009, hospital internal review board (IRB) submissions were in progress for this trial.

These studies build on our pivotal OASIS clinical trial the first-ever prospective multi-center study evaluating a plaque removal system. In this 20-center trial:

- 94.5 percent of lesions treated were located below the knee, where lesions have traditionally gone untreated until they require bypass surgery or amputation;
- 55 percent of lesions consisted of calcified plaque a challenge for balloons and stents; and
- 48 percent of lesions were greater than 3 cm in length, which typically require multiple balloon expansions or stent placements.

Outcomes for the 124 patients enrolled exceeded the safety and efficacy endpoint targets, that is:

- 59.4 percent plaque reduction versus a 55 percent target;
- 4.8 percent device-related serious adverse events compared to a target of less than 16 percent; and
- 2.4 percent target lesion revascularization (TLR) rate through six months versus a target of less than or equal to 20 percent.

In addition, long-term follow up of about half of the OASIS patients showed a TLR rate at a mean of 29 months of 13.6 percent better than data available for any other endovascular treatment method.

Study for Coronary Indication Planned

Treating blocked coronary arteries with our Diamondback 360° would provide additional applications for our technology and significantly expand our market potential. We have received conditional FDA approval of an IDE application for a U.S. pivotal trial to begin in calendar 2010. The small diameter of our device, its abilities to both navigate small vessels and treat calcium, as well as its unique safety characteristics, are all factors that could make the Diamondback 360° an effective treatment option for coronary arteries. The results from our 2008 ORBIT 1 trial in India showed positive outcomes with regard to the safety and efficacy of the device in the coronary arteries, and we have confidence this outcome will be supported in the U.S. trial.

Raising the Standard of Care for PAD Patients

People in their 60s, 70s and older are more active than ever often working and engaged with their families, friends and communities. At CSI, we are dedicated to raising the standard of care for PAD patients by providing physicians with the tools to treat PAD, enabling them to save limbs, lives and restore patients quality of life. We are redefining the treatment of vascular disease by focusing on:

- Continually improving the Diamondback 360° and expanding our product portfolio to provide a comprehensive PAD solution to physicians, while leveraging our U.S. sales force; and
- Bringing the Diamondback 360° to more hospitals and training physicians in the optimal use of the technology;
- Conducting clinical studies to provide physicians with sound, useful data;
- Managing our growth toward profitability and positive cash flow.

The CSI team s accomplishments in fiscal 2009 have laid the groundwork for the coming fiscal year and for our future. We look forward to updating you on our progress. Thank you for your support.
Sincerely,

David L. Martin
President and Chief Executive Officer

G.D. Nelson, MD
Chairman of the Board

January 6, 2010

Executive Officers and Advisors
David L. Martin
President and Chief Executive Officer
Laurence L. Betterley
Chief Financial Officer
James E. Flaherty
Chief Administrative Officer
Robert J. Thatcher
Executive Vice President
Brian Doughty
Vice President,
Commercial Operations
Paul Koehn
Vice President,
Manufacturing
Scott Kraus
Vice President, Sales
Paul Tyska
Vice President,
Business Development
Nabil Dib, MD, MSc, FACC
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Chief Operating Officer
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Stemedica Cell Technologies, Inc.
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Chief Executive Officer
Cardiovascular Systems, Inc.
Gary Petrucci
Senior Vice President -
Financial Consultant
RBC Wealth Management

Headquarters
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For change of name, address, or
to replace lost stock certificates, contact:
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New York, New York 10038
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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 March 5, 2010 at noon 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) sufficiency of existing funds and available debt to carry CSI to profitability and positive cash flow; (ii) CSI s expectations for its two clinical trials initiated in calendar 2009; and (iii) CSI s IDE submission for a U.S. pivotal trial treating coronary arteries in calendar 2010 and anticipated expansion into the interventional coronary market, 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 difficulty in accurately predicting product, customer and geographic sales mix; product development delays; the reluctance of physicians to accept new products; the impact of competitive products and pricing; dependence on major customers and distribution partners; the difficulty to successfully manage operating costs; fluctuations in quarterly results; 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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