

CARDIOVASCULAR SYSTEMS INC

Form 425

November 04, 2008

Filed by Replidyne, Inc. Pursuant to  
Rule 425

Under the Securities Act of 1933  
And Deemed Filed Pursuant to Rule  
14a-12

Under the Securities Exchange Act  
of 1934

Subject Company: Cardiovascular  
Systems, Inc.

Commission File No. **000-53478**

**CARDIOVASCULAR SYSTEMS SIGNS MERGER AGREEMENT**

***Merger to create NASDAQ-listed medical device company focused on developing and commercializing interventional treatment systems for vascular disease;***

***CSI to be surviving company;***

***\$35 million to \$40 million in cash earmarked to expand CSI sales capability, product development and infrastructure for rapid revenue growth;***

***Conference call scheduled for today, Tuesday, November 4, 2008 at 8:30 AM ET***

**St. Paul, Minn., November 4, 2008** Cardiovascular Systems Inc. (CSI) today announced that it has entered into a definitive merger agreement under which CSI will merge with Replidyne, Inc. (Nasdaq: RDYN) in an all-stock transaction. Under terms of the agreement, Replidyne will issue new shares of its common stock to CSI shareholders whereby former CSI shareholders are expected to own 83 percent of the combined company, and Replidyne shareholders are expected to own 17 percent of the combined company on a fully diluted basis using the treasury stock method, subject to adjustments as described in the merger agreement.

David L. Martin, President and Chief Executive Officer of CSI, said, "Executing this transaction with Replidyne is an expedient way to take our company into the public market and generate a capital infusion for future growth. With an estimated \$35 million to \$40 million in additional cash and investments from the merger, we can further expand our sales and marketing organization and infrastructure to drive revenue growth and continue to invest in product development for future market expansion.

After a diligent process of evaluating strategic alternatives carried out over several months, we believe that a merger with CSI presents our investors with a very good opportunity to realize future value," stated Kenneth J. Collins, President and Chief Executive Officer of Replidyne. "Through our process we have evaluated a broad array of opportunities across the life sciences, molecular diagnostics and medical device industries. After assessing the merger with CSI, we were impressed by the strong launch of the Diamondback 360°, the growth opportunity for treatment of peripheral arterial disease with this product, particularly in calcified lesions, and the quality of the management team driving the company.

The boards of directors of both CSI and Replidyne have unanimously approved the transaction, subject to customary closing conditions, including approval by the shareholders of each of CSI and Replidyne. The merger agreement contains certain termination rights for both CSI and Replidyne. The directors, as well as certain significant shareholders of each of CSI and Replidyne, have executed voting agreements in favor of the transaction.

The transaction is currently expected to close during the first quarter of calendar 2009. Upon consummation of the merger, Replidyne's name will be changed to Cardiovascular Systems Inc. and the combined company will apply for listing on The NASDAQ Global Market® under a new trading symbol.

CSI had filed for an initial public offering in January 2008 but withdrew its registration statement for the initial public offering today. According to Martin, "The current equity market conditions have resulted in the IPO market coming to a standstill. Given the uncertainty regarding timing of a market recovery, we believe



Cardiovascular Systems Inc.

November 4, 2008

Page 2

that this transaction offers the best opportunity at this time for continued growth and for our company to gain access to the public capital markets.

Citi acted as financial advisor to Cardiovascular Systems, and Fredrikson & Byron P.A. served as CSI's legal counsel. Morgan Stanley acted as financial advisor to Replidyne, and Cooley Godward Kronish LLP served as Replidyne's legal counsel.

### **Cardiovascular Systems: Focused on Therapies for Vascular Disease**

CSI is a medical device company focused on developing and commercializing interventional treatment systems for vascular disease. CSI's initial product, the Diamondback 360° Orbital Atherectomy System, is a minimally invasive catheter system for the treatment of peripheral arterial disease, or PAD. PAD affects approximately 8 to 12 million people in the U.S. PAD is caused by the accumulation of plaque in peripheral arteries (commonly the pelvis or leg), reducing blood flow. The plaque deposits range from soft to calcified, with calcified plaque being difficult to treat with traditional interventional procedures. The Diamondback 360° is capable of treating a broad range of plaque types both above and below the knee, including calcified vessel lesions, and addresses many of the limitations associated with existing treatment alternatives.

The interventional community has waited a long time for a device that is both safe and effective in treating calcified vessels below the knee. The CSI Diamondback 360° fulfills this unmet need and is quickly becoming the first line device for below the knee interventions, stated Dr. Tony Das, Director, Peripheral Vascular Interventions at the Presbyterian Heart Institute in Dallas, Texas.

The Diamondback 360° is being used to pre-treat calcified vessels above the knee due to its ability to safely and effectively change the vessel compliance. This may make current and future adjunctive therapies perform even better, said Dr. Ray Dattilo, Director of Peripheral Vascular Interventions, Kansas Heart and Vascular Center, St. Francis Hospital in Topeka, Kansas.

The Diamondback 360° utilizes the orbital rotation of a diamond grit coated offset crown that is attached to a flexible drive shaft. Physicians position the crown at the site of an arterial plaque lesion and remove the plaque by causing the crown to orbit against it, creating a smooth lumen, or channel, in the vessel. The Diamondback 360° is designed to differentiate between plaque and compliant arterial tissue, a concept known as differential sanding. The particles of plaque resulting from differential sanding are generally smaller than red blood cells and are carried away by the blood stream. As the physician increases the rotational speed of the drive shaft, the crown rotates faster and centrifugal force causes the crown to orbit, creating a lumen with a diameter that is approximately twice the diameter of the device. By giving physicians the ability to create different lumen diameters by changing rotational speed, the Diamondback 360° can reduce the need to use multiple catheters of different sizes to treat a single lesion.

In August 2007, the U.S. FDA granted 510(k) clearance for the use of the Diamondback 360° as a therapy in patients with PAD. The company commenced a limited commercial introduction of the product in the United States in September 2007 and began full commercial launch in the first calendar quarter of 2008. Through September 30, 2008, nearly 11,000 Diamondback devices have been sold to more than 280 hospitals.

### **Clinical Trials Demonstrate Efficacy**

CSI has conducted three clinical trials involving 207 patients to demonstrate the safety and efficacy of the Diamondback 360° in treating PAD. In particular, the pivotal OASIS clinical trial was a prospective 20-center study that enrolled 124 patients with 201 treated lesions and met the study endpoints. CSI was the first, and so far the only, company to conduct a prospective multi-center clinical trial with a prior investigational device exemption, or IDE, in support of a 510(k) clearance for an atherectomy device. The Diamondback 360° provides a platform that can be leveraged across multiple market segments, with plans to launch additional products to treat lesions in larger vessels and to seek premarket approval (PMA) from the FDA to use the Diamondback 360° to treat patients with coronary artery disease.

Cardiovascular Systems Inc.

November 4, 2008

Page 3

**Revenue Progression and Fiscal 2009 Guidance**

CSI revenue has consistently grown on a sequential quarter basis, since the launch of the Diamondback system.

Revenue by quarter follows (in millions):

|                               |        |
|-------------------------------|--------|
| Fiscal Q2 ended December 2007 | \$ 4.6 |
| Fiscal Q3 ended March 2008    | \$ 7.7 |
| Fiscal Q4 ended June 2008     | \$ 9.9 |

|                             |         |
|-----------------------------|---------|
| Fiscal Year ended June 2008 | \$ 22.2 |
|-----------------------------|---------|

|                                |         |
|--------------------------------|---------|
| Fiscal Q1 ended September 2008 | \$ 11.6 |
|--------------------------------|---------|

For the 2009 fiscal year, ending June 30, 2009, CSI expects revenue to more than double over fiscal 2008 revenue of \$22.2 million. CSI anticipates a net loss for fiscal year 2009, due to ongoing investments in sales and marketing, product development, and infrastructure to support company growth, and due to expenses associated with the proposed merger transaction.

**Management and Organization**

The combined company will be headed by CSI's Martin and the CSI executive team. The combined board of directors will consist of 10 members, including two current Replidyne directors, Edward Brown and Augustine Lawlor. The Chairman of the Board will be Glen D. Nelson, M.D., currently Chairman of CSI. The other members of the combined board of directors will be Brent Blackey; John Friedman; Geoffrey Hartzler, M.D.; Roger Howe, Ph.D.; Michael Kallok, Ph.D.; David Martin and Gary Petrucci.

**Conference Call Today at 8:30 AM ET**

CSI and Replidyne will host a joint conference call Tuesday, November 4, 2008 at 8:30 AM ET (7:30 AM CT, 5:30 AM PT) to discuss this transaction. Callers may participate in the conference call by dialing (800) 329-9097 (domestic) or (617) 614-4929 (international), and providing the passcode 89012165. To access the live webcast, log onto Replidyne's website at [www.Replidyne.com](http://www.Replidyne.com) and go to the Investor Relations section.

A replay of the conference call will be available approximately one hour after the completion of the call through Tuesday, November 11, 2008 at midnight. Callers may access the replay by dialing (888) 286-8010 (U.S. participants) or (617) 801-6888 (international participants). The audio replay passcode is 13353327. To access a replay of the webcast, visit the Investor Relations section of Replidyne's website at [www.Replidyne.com](http://www.Replidyne.com).

Additional information about this transaction is available online at [www.Replidyne.com](http://www.Replidyne.com) or [www.csi360.com](http://www.csi360.com).

**Safe Harbor**

*This press release contains plans, intentions, objectives, estimates and expectations that constitute forward-looking statements about Replidyne and CSI that involve significant risks and uncertainties. Examples of such statements include, but are not limited to, the anticipated closing date of the merger, the expected cash that will be available to CSI at the closing of the merger, the expected ownership of the stockholders of Replidyne and CSI after the closing of the merger, the anticipated benefits of the transaction, and CSI's expectation for revenues and loss for the fiscal year ending June 30, 2009. Actual results could differ materially from those discussed in the forward-looking statements due to a number of factors including, the outcome of the shareholder vote for the proposed merger, the outcome of Replidyne's efforts to wind up its business including the disposition of its research pipeline programs; regulatory developments in the U.S. and foreign countries; the accuracy of Replidyne's or CSI's estimates regarding expenses, future revenues and capital requirements; and CSI's ability to obtain and maintain intellectual property protection for product candidates. These and additional risks and uncertainties are described more fully in CSI's registration statement on Form 10 filed with the Securities and Exchange Commission (SEC) on October 28, 2008 and Replidyne's most recent Form 10-Q filed with the SEC*



Cardiovascular Systems Inc.

November 4, 2008

Page 4

*under the Securities Exchange Act of 1934. Copies of filings made with the SEC are available through the SEC's electronic data gathering analysis and retrieval system (EDGAR) at [www.sec.gov](http://www.sec.gov). All forward-looking statements made in the press release are made as of the date hereof and neither Replidyne nor CSI assumes any obligation to update the forward-looking statements in the document.*

**Additional Information About the Merger and Where to Find It**

This communication may be deemed to be solicitation material with respect to the proposed transaction between CSI and Replidyne. In connection with the transaction, Replidyne intends to file a registration statement on Form S-4 with the SEC containing a related proxy statement/prospectus. The proxy statement/prospectus will be mailed to the stockholders of Replidyne and CSI. Investors and security holders of Replidyne and CSI are urged to read the proxy statement/prospectus when it becomes available because it will contain important information about Replidyne, CSI and the proposed transaction. The proxy statement/prospectus (when it becomes available), and any other documents filed by Replidyne or CSI with the SEC, may be obtained free of charge at the SEC web site at [www.sec.gov](http://www.sec.gov). In addition, investors and security holders may obtain free copies of the documents filed with the SEC by Replidyne by contacting Replidyne Investor Relations by email at [ir@replidyne.com](mailto:ir@replidyne.com) or by telephone at (303) 996-5522. Investors and security holders may obtain free copies of the documents filed with the SEC by CSI by contacting CSI by telephone at (651) 259-1000. Investors and security holders are urged to read the proxy statement/prospectus and the other relevant materials when they become available before making any voting decision with respect to the proposed transaction.

Replidyne and CSI and their respective directors and executive officers may be deemed to be participants in the solicitation of proxies from their shareholders in favor of the proposed transaction. Information about the directors and executive officers of Replidyne and CSI and their respective interests in the proposed transaction will be available in the proxy statement/prospectus.

This communication shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

###

**Contacts:**

**For Cardiovascular Systems Inc.**

Padilla Speer Beardsley:

Marian Briggs

(612) 455-1742

[mbriggs@psbpr.com](mailto:mbriggs@psbpr.com)

Nancy A. Johnson

(612) 455-1745

[njohnson@psbpr.com](mailto:njohnson@psbpr.com)

**Replidyne**

Mark Smith

Chief Financial Officer

(303) 996-5535