CARDIOVASCULAR SYSTEMS INC

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The following is a transcript of a conference call hosted by Replidyne, Inc. and Cardiovascular Systems, Inc. on November 4, 2008 at 8:30 a.m. Eastern time.

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**Final Transcript** 

Nov. 04. 2008 / 8:30AM ET, RDYN Replidyne and Cardiovascular Systems Sign Merger Agreement

CORPORATE PARTICIPANTS

**Mark Smith** 

Replidyne CFO

**Ken Collins** 

Replidyne President and CEO

**David Martin** 

Cardiovascular Systems CEO

**Larry Betterley** 

Cardiovascular Systems CFO

CONFERENCE CALL PARTICIPANTS

**Steve Harr** 

Morgan Stanley Analyst

**David Lewis** 

Morgan Stanley Analyst

**PRESENTATION** 

# **Operator**

Good day, ladies and gentlemen, and welcome to the conference call to announce the signing of merger agreement between Replidyne and Cardiovascular Systems. At this time, all lines are in listen-only mode. We will be facilitating a question-and-answer session towards the end of the conference.

(Operator Instructions)

As a reminder, ladies and gentlemen, this conference call is being recorded for replay purposes. I would now like to turn the call over to Mr. Mark Smith, of Replidyne, Chief Financial Officer. Please proceed.

Thank you, [Comma]. I am Mark Smith, Replidyne s Chief Financial Officer, and I would like to welcome you to today s conference call to discuss our merger transaction with Cardiovascular Systems. We appreciate your participation and interest today. The first released announcement in this transaction was issued this morning and the release is available on our website, as is a webcast of today s conference call, at www.replidyne.com.

An overview of the transaction will be given by Ken Collins, President and CEO of Replidyne. Following Ken s presentation, David Martin, CEO of Cardiovascular Systems, will give you an overview of CSI. Following those presentations from Ken and David, we will open the lines to your questions.

As I turn the call over to Ken, I would like to remind everyone that during this call, we will be making forward-looking statements that involve significant risks and uncertainty, including those discussed on this call and others that can be found in the Risk Factors section of Replidyne s Form 10-Q, dated August 5, 2008. We encourage you to review all of our SEC filings. No forward-looking statement can be guaranteed. An actual result and the outcome may differ material from those we project. Information providing during this call represents our current view as of this date. We do not undertake any obligation to update any forward-looking statements made during the call as a result of new information, future events or otherwise. The Safe Harbor language in today s press release regarding forward-looking statements also applies to our comments on this call. I will now turn the call over to Ken Collins.

Ken Collins Replidyne President and CEO

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Nov. 04. 2008 / 8:30AM ET, RDYN Replidyne and Cardiovascular Systems Sign Merger Agreement Thank you, Mark. Over the past several months, we and our advisors have evaluated more than 120 life sciences companies. We looked at biotechnology, at pharmaceutical companies and at medical technology companies, including Molecular Diagnostic and device companies. We didn't just evaluate our strategic alternatives in the context of a merger. We also considered liquidation of Replidyne and operating our company on a reduced scale to develop our earlier stage anti-infector programs and C. difficile and the DNA replication inhibition. Out of this process, we believe we have identified an excellent opportunity for our shareholders to realize future returns and liquidity. As many of you know, we started this process following the nonapproval of our NDA feropenem in 2006 and the termination of our partnership with Forrest Laboratories in May of last year. Feropenem was our lead program and a significant component of our company valuation. The nonapproval of the NDA for feropenem marked a change in the FDA approval requirements for antibiotics. Previously, nonprepriority studies were adequate, but the FDA now requires superiority trials for the important indications of bronchitis and sinusitis. These and other significant changes to the FDA approval process for these products as well as delays in the FDA issuing updated formal guidance increased the perceived execution risk, cost and time for conducting studies. In this environment, despite a substantial effort on our part, we were unable to re-partner feropenem.

With that determination, we set about the process of exploring strategic alternatives for Replidyne and retained Morgan Stanley as our advisor. Throughout, we significantly reduced our cost structure to make for an efficient operation while we reviewed strategic alternatives, met our reporting obligations related to studies that were halted, worked with former partners to return licenses and apply diligence and rigor to exploring our alternatives. Our process led us to Cardiovascular Systems or CSI. CSI s Diamondback 360 product for the treatment of peripheral arterial disease has generated impressive early utilization and revenue within a large market opportunity. The management team is experienced in successfully launching and growing products in this arena. And the difficult IPO environment of 2008 has resulted in their initiating the IPO process but being delayed by market conditions. These were among the factors that resulted in our entering into the agreement announced today. Basic terms of the agreement provide for CSI shareholders to receive 83% of the combined company while Replidyne shareholders are expected to receive 17%, calculated using the Treasury stock method for outstanding options and warrants. The final ownership ratio was subject to adjustments detailed in the agreement related to the final contribution of net assets as defined in the agreement by Replidyne. The merger is an all-stock transaction intended to qualify as a tax-free reorganization. The merged Company s board is expected to include two current Replidyne directors, Ned Brown and Gus Lawlor. Consummation of the transaction is subject to approval by the shareholders of Replidyne and CSI, as well as regulatory approvals and customer and closing conditions.

Replidyne shareholders representing approximately 52% of the outstanding common stock have entered into voting agreements for approximately 35% of the outstanding shares. CSI s shareholders representing approximately 32% of the outstanding common stock have entered into voting agreements for approximately 20% of the outstanding shares. As a Minnesota corporation, CSI was limited into entering into shareholder voting agreements with 20% of its shareholders for a transaction requiring issuance of new shares. We anticipate that the transaction will close in the first calendar quarter of 2009. Upon consummation of the merger, the Replidyne name will be changed to Cardiovascular Systems, Inc. and the combined company will reapply for listing on the NASDAQ Global Markets.

Moving forward, the merged company is to be led by the CSI management team, headed by Dave Martin as CEO, with the corporate office in St. Paul, Minnesota. All remaining Replidyne operations will be shut down in the coming months, including disposition, C. difficile and DNA replication inhibition technologies and closure of our Colorado offices.

I would like to take this opportunity to express my appreciation to the team at Replidyne and our advisors, who have worked under difficult circumstances, including a number of organizational restructurings, seek out and evaluate a large number of strategic alternatives that has culminated in our proposed merger with CSI. I would now like to introduce David Martin, the Chief Executive Officer of CSI. Dave has been the CEO of CSI since February 2007 and has served on the CSI board since August of 2006. Previously, Dave held the COO and Executive VP of Sales and Marketing positions with FoxHollow Technologies and directed their commercial plan. In total, he has over 20 years

of medical industry experience. At this time, I would like to turn the call over to Dave.

David Martin Cardiovascular Systems CEO

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Nov. 04. 2008 / 8:30AM ET, RDYN Replidyne and Cardiovascular Systems Sign Merger Agreement Thanks, Ken, and thanks to your team for your hard work and a very diligent selection and process. We really appreciate that. The purpose of my comments are to introduce CSI, our exciting technology, our growth potential in peripheral arterial disease or the PAD market, as well as other market opportunities. For a more comprehensive look at CSI, you are invited to review our Form 10 as filed with the SEC on www.sec.gov or visit our website at www.csi360.com. We are very excited about this transaction. It provides the critical capital for us to continue to grow our business. We will be able to achieve access to public financial markets during these difficult times, and certainly this gives Replidyne investors an attractive opportunity for their investment.

Our company history, since 1997, CSI has devoted its resources to developing the Diamondback 360. It is an atherectomy device based on orbital technology that creates a smooth patent lumen in diseased vessels. The goal of the Diamondback 360 product is to address the growing market need for safer, more effective atherectomy device and shift the treatment paradigm to improve the quality of life for these 8 million to 12 million Americans who suffer from peripheral artery disease or PAD.

In September of 2005, we attained an investigational device exemption from the FDA in order to conduct our pivotal Oasis United States clinical trial, which was completed in January of 2007. The Oasis trial was the prospective 20-center study that enrolled 124 patients with 201 treated lesions. The results of this trial met the study endpoints. CSI was the first and, so far, the only company to conduct a prospective multi-center clinical trial, with the prior investigational device exemption in support of a 510K clearance for an atherectomy device.

In August of 2007, we received our 510K clearance for the device and began our commercial launch in September of 2007. We currently have a sales force of nearly 90 sales professionals in the field. We are targeting approximately 1,500 hospitals that routinely perform atherectomy procedures. These hospitals have three potential user groups in each hospital, including the interventional cardiologist, the vascular surgeon and the interventional radiologist. Our product, the Diamondback 360 orbital atherectomy system fills a need for atherectomy technology that is able to treat multiple plaque morphologies, including hard calcified plaque and more safely and efficiently overall in the peripheral arteries. The system s offset crown creates a unique orbital mechanism of action through the principles of centrifugal force as it rotates, creating a device to lumen ratio of about one to two for maximal luminal gain without requiring a catheter upsizing. So, it is a small device that creates a larger hole.

The Diamond coating on the crown sands away the plaque while preserving healthy tissue of the arterial wall, which we refer to as differential sanding. The degree from the sanding is typically smaller than red blood cells and is easily absorbed by the body.

Our industry. Our current industry focus is the peripheral arterial disease market. There are 8 million to 12 million people who are affected with PAD in the US. The market is nearly as large as coronary artery disease and diabetes. Both of these groups have overlap with patients in the PAD market. PAD is underdiagnosed at 2.5 million cases per year. 1.5 million of those are treated, 0.5 million by surgery and 1 million with endovascular procedures, including angioplasty, stenting and atherectomy. Nearly half of all these cases have these interventional cases have hard, calcified plaque, which is very, very difficult to treat. Reimbursement for this procedure is available for PAD and it is very similar to the reimbursement received for coronary artery disease.

The other treatments currently available to the physicians do have their shortfalls. Surgery, which includes bypass and amputation, is traumatic to the patient and has many complications. Stents. Stents can fracture the movement of the peripheral vessels lead to a high incidence of [brief] stenosis. Balloons can damage arterial walls and plaque rebound does reduce lumen size with balloon technology. Other atherectomy products can damage arterial walls, they can produce large debris and they can clog that clog arteries downstream and are not effective in calcium. As well, they can require lengthy treatments and multiple device insertions.

The Diamondback 360 has unique benefits. It has got a very strong safety profile. It differentiates between plaque and the arterial tissue, the healthy tissue on the vessel wall. It generates small particle debris the body can absorb and it reduces complications of adjunctive therapies. It is extremely effective on calcified plaque, which is present in almost 50% of the cases. We have supported our technology with rigorous clinical studies, including the only PAD-related atherectomy prospective multi-center clinical trial. From this trial, we know the device is faster and we know that the

device is more cost-effective. A single insertion treats multiple vessels or lesions and the average treatment time was three to nine minutes. The result of treatment is a smooth lumen that often doesn t require additional therapy. Our product development. Our platform is a broad foundation from which we can create product iterations without starting from scratch. Some of the things that we are able to work with are rotational speed, crown characteristics like mass and the shape of the crown, as well as grit size, and shaft characteristics like shape and construction. We have got a robust product pipeline. We focus on ease of use, we focus on large orbits for

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Nov. 04. 2008 / 8:30AM ET, RDYN Replidyne and Cardiovascular Systems Sign Merger Agreement larger lumens above the knee, which may eliminate the need for adjunctive therapy. And we are looking for enhanced removal of soft plaque above the knee as well. These initiatives are targeted at expanding the available market for our products and their rate of adoption.

Intellectual property. Our IT position is extensive with over 90 patents issued or applications filed. And the longer term potential of our platform exists for the use of this technology in the coronary arteries. Many similarities exist between peripheral disease and coronary disease. We have completed a successful human feasibility trial in India this summer. We work very closely with the FDA to work on the design of this study in order that they accept this data to support an ID submission in the US

Financial overview. We began generating revenue in September 2007 after FDA clearance in August of 2007. Revenue has consistently risen in each sequential quarter since product introduction, growing from \$4.6 million in our fiscal Q2 ended December 2007. The very next quarter, we followed that up with \$7.7 million, followed immediately by \$9.9 million in our fiscal Q4 for a total of \$22.2 million in our first fiscal year of sales. We have continued that growth in our first fiscal quarter of this year, which ended September 30, by reaching \$11.6 million in revenue. Since commencing sales, we have sold nearly 11,000 devices to over 280 hospitals. Reorder rates are very strong at over 70% on a 30-day basis and over 90% reorder rate on a 90-day basis. This typically reorder typically represents over 70% of our revenue in a period.

We expect growth will continue and revenue to more than double in our fiscal year ending June 30, 2009 from fiscal year 2008. We did incur net losses in fiscal 08 and expect to continue to do so in fiscal 09 as we invest in our sales and marketing organization and we invest in our robust product development pipeline and infrastructure to support the growth. The cash provided from this merger should be sufficient to bring us to profitability and deposit cash flow under our current business strategy for PAD.

Management. To [accommodate] strategy, we have put together a senior management team with extensive industry and public company experience. More importantly, they do share a passion to succeed improving the lives of those patients with PAD. One member of the team is Larry Betterley, our CFO, who is with me today. Larry joined the company earlier this year and has nearly 15 years of experience as a CFO and more than 25 years of experience in finance and accounting, most of which has been with public companies.

There are other key executive leaders, including Dr. Mike Kallok, who is with us today. He is our Chief Scientific Officer. He spent over 16 years with Medtronic. He was the previous CEO and he has been with our company since 2002. Also, Bob Thatcher, our Executive Vice President, leads R&D and operations. John Borrell, with extensive experience in this space, is our Vice President of Sales. Brian Doughty is our Vice President of Marketing. Jim Flaherty, our Chief Administrative Officer, Paul Keane, our Vice President of Manufacturing, and Paul Tyska, our VP of Business Development. We are also very accomplished and we have an extremely experienced Board to guide us, led by Dr. Glenn Nelson. Glenn Nelson has been CSI s Chairman for over a year and he was formerly Vice Chairman of Medtronic for 14 years.

In summary, CSI has highly differentiated products that address a large underserved peripheral vascular disease market opportunity, with the ability to leverage this core technology to expand our market potential with not only PAD but also in the coronary arteries. We have got a proven experienced management team with which to implement our strategy. And we really appreciate this merger opportunity, which provides us the capital and access to public markets critical to continued growth and implementation of our strategy. We look forward to working on your behalf to achieve the full potential and value of CSI. We Il now open up this call for your questions and turn this over to Ken Collins to facilitate.

## **QUESTION AND ANSWER**

### **Operator**

(Operator Instructions) And the first question comes from the line of Steve Harr from Morgan Stanley. Please proceed.

Steve Harr Morgan Stanley Analyst

Hi, it is Steve Harr. How are you?

David Martin Cardiovascular Systems CEO

Hey, Steve.

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#### Steve Harr Morgan Stanley Analyst

So, could you help us understand what the 09 burn rate is likely to look like and when the company, CSI, you guys think you need to come back to the markets for capital? Or is what you are getting adequate to fund yourself to profitability?

## Larry Betterley Cardiovascular Systems CFO

Yes, this is Larry Betterley, the CFO of CSI. We expect, as Dave said, we expect revenue to grow throughout 2009 and be double that of our fiscal year 2008 or more. We do expect losses to continue. We are not in a position to give specific guidance on that, although we would expect that the loss rate would continue to improve by quarter. But at this point, we are not in a position to give specific guidance on the loss progression.

Regarding the cash situation, we believe that with our current PAD strategy that the cash will be sufficient to bring us to profitability and cash flow positive.

#### Steve Harr Morgan Stanley Analyst

And then, what type of lockups are in place? Because both companies have pretty conscious rate ownerships. What type of lockups are in place around current shareholders for both companies?

#### Ken Collins Replidyne President and CEO

This is Ken. Mark I am going to let Mark Smith address that, our CFO.

## Mark Smith Replidyne CFO

Currently, Steve, we have lockups on the Replidyne side. We have lockups covering that 35% of the voting shares. However, that represents shareholdings from shareholders who hold about 52% of Replidyne s outstanding shares. As Ken mentioned, on the CSI side, there is lockups in place covering about 20% of the outstanding shares, although that represents again an ownership holding of approximately 32% of CSI s outstanding shares. Recall, as Ken mentioned in his remarks, that CSI s overall ability to lock up both the entry [debugging] requirements is limited to approximately 20% of outstanding shareholdings by Minnesota law.

#### Steve Harr Morgan Stanley Analyst

Great, thank you.

## **Operator**

(Operator Instructions) And the next question comes from the line of David Lewis from Morgan Stanley. Please proceed.

#### David Lewis Morgan Stanley Analyst

Good morning. Can you hear me?

#### Ken Collins Replidyne President and CEO

Yes, David.

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## David Lewis Morgan Stanley Analyst

Dave, I wonder if you could give us kind of an overview of the market size and what you see out there in the peripheral artery disease marketplace? We have seen several companies report here over the last couple of weeks. We have seen different companies talking about different growth rates. What do you think is the growth rate right now for the PAD marketplace and maybe talk about your specific sub segment, either below-the-knee or above-the-knee and how you think that segment is growing or expanding?

#### David Martin Cardiovascular Systems CEO

Yes, I think some of the reports are tagging it maybe at around 15% per year. Certainly, there is way more opportunity beyond that with 10 million to 12 million in patients with the disease. And new technologies open up markets. Our ability to uniquely treat calcium, which is a big problem with our call point, really gives us some opportunity and has been an indicator in our past success in both below-the-knee and above-the-knee. So, we think we lead and are above that 15% overall generalization for the atherectomy category. And we do it in two places, below-the-knee and above-the-knee.

#### David Lewis Morgan Stanley Analyst

So, David, you talk about your existing growth for this year and as you head about your expectations for next year. Can you give us a sense of what of that growth is predicated on the below-the-knee market versus the above-the-knee market?

#### David Martin Cardiovascular Systems CEO

Yes, currently, we believe in our 290 to 300 customers that we ve got just over half to 60% of our devices are used below the knee, and that is based on our safety profile and our unique ability to treat calcium, which exists 75% of the time below the knee. And then the other 30% to 40% of our business is above the knee, where 40% of the time, the physician encounters a calcium and the ability to get a smooth tubular lumen is desirable. So we think it is about 60-40.

#### David Lewis Morgan Stanley Analyst

And, Dave, what would you expect that to be at the end of fiscal 09? That mix?

## David Martin Cardiovascular Systems CEO

That mix, as we continue the development pipeline, will edge towards 50-50 as we continue to contribute more and more in the above-the-knee market.

## David Lewis Morgan Stanley Analyst

Great. Thank you very much.

#### **Operator**

(Operator Instructions) I would now like to turn the call back over to Mr. Mark Smith for closing remarks. Please proceed.

## Mark Smith Replidyne CFO

Thank you very much, Comma. Well, we would like to thank you for your time today and your interest in both Replidyne and CSI. A replay of the conference call will be available approximately one hour after completion of the call through Tuesday, November 11, 2008 at midnight. Callers may access the replay by dialing 888-286-010 for US participants or 617-801-6888 for international participants. The audio replay

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Nov. 04. 2008 / 8:30AM ET, RDYN Replidyne and Cardiovascular Systems Sign Merger Agreement passcode is 13353327. To access the replay of the webcast, please visit the Investor Relations section of our website at www.replidyne.com. Thank you very much.

# **Operator**

This concludes the presentation for today. Ladies and gentlemen, you may now disconnect. Have a wonderful day.

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#### Safe Harbor

This communication 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, and the anticipated benefits of the transaction. 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 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. 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 in 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 <a href="www.sec.gov">www.sec.gov</a>. 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 <a href="mailto:ir@replidyne.com">ir@replidyne.com</a> 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.