

CARDIOVASCULAR SYSTEMS INC

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The following is a transcript of a conference call conducted by Cardiovascular Systems, Inc. regarding its second quarter 2009 earnings on February 11, 2009 at 4:00 p.m. Central time.

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Feb 11, 2009 / 10:00PM GMT, CSII Q2 2009 Cardiovascular Systems Inc Earnings Conference Call

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*Cardiovascular Systems Inc. CFO*

**Dave Martin**

*Cardiovascular Systems Inc. President & CEO*

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**Amit Bhalla**

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**Ben Andrew**

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*Caris & Company Analyst*

**Jason Mills**

*Canaccord Adams Analyst*

**Rog Stenhoy**

*Thomas Weisel Partners Analyst*

**Sean Fitz**

*Stephens Incorporated Analyst*

**PRESENTATION**

**Operator**

Good day, ladies and gentlemen. And welcome to the second quarter 2009 Cardiovascular Systems Incorporated earnings conference call. My name is Misall, and I will be your coordinator for today. At this time, all participants are in a listen-only mode. We will be conducting a question and answer session toward the end of this conference.

(Operator Instructions)

As a reminder, this conference is being recorded for replay purposes. I would now like to turn the presentation over to your host for today's call, Mr. Larry Betterley, Chief Financial Officer. Please proceed, sir.

**Larry Betterley Cardiovascular Systems Inc. CFO**

Thank you, Misall. Good afternoon and welcome to our fiscal 2009 second quarter conference call. Before we begin, I'd like to remind you that during the course of this conference call, we'll make forward looking statements that are covered under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Any such statements are subject to risks and uncertainties that could cause actual results to differ materially from those anticipated. Such factors are described in the Company's Form 10 and other reports filed from time to time with the Securities and Exchange Commission.

This conference call also includes non-GAAP financial measures. In accordance with SEC Regulation G, a presentation of the most directly comparable results calculated in accordance with GAAP as well as a reconciliation of the differences between such measures are available on the Company's website at [www.csi360.com](http://www.csi360.com) in the Investors section. I'll now turn the call over to Dave Martin, CSI's President and CEO. Dave?



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**Dave Martin - Cardiovascular Systems Inc. President & CEO**

Thanks, Larry. This is CSI's first quarterly release. We are pleased to announce strong revenue growth as well as product development advancements. I'd also like to provide an update on our pending merger agreement. And Larry will provide a detailed review of the financials.

Second-quarter revenue, driven by the Diamondback 360 Orbital Atherectomy System reached \$14 million, a 200-plus percent increase over \$4.6 million in the year-ago period.

For those of you who may not be familiar with the Diamondback system, let me briefly describe its competitive differentiators. We offer a minimally invasive catheter system for treating peripheral arterial disease or PAD. PAD is blockages in the leg arteries that could adversely affect the quality of life through immobility, pain, and in some circumstances can lead to potential catastrophic risk of limb amputation.

We designed the Diamondback system to give physicians a safer, more effective tool to treat the 8 million to 12 million Americans who suffer from PAD. The Diamondback system is capable of treating a broad range of plaque types and addresses many limitations of other treatments. It's got a short treatment time. It's differential standing minimizes the potential for arterial perforation or dissection. And it's effective in treating calcified lesions.

CSI has conducted three clinical trials involving 207 patients to demonstrate the safety and efficacy of the Diamondback 360. To date, the Diamondback system has helped treat more than 9,000 patients and is quickly becoming a first-line therapy for saving limbs in the battle against PAD.

The Diamondback 360 provides a platform that could be leveraged across multiple market segments. We have plans to launch products to improve our effectiveness in all plaque types and in larger vessels as well as expand our capabilities into coronary applications.

The Company's quarterly revenue has grown consistently since the introduction of the Diamondback in September 2007. Second-quarter growth reflected increases in both hospital counts and physician users. The number of hospital counts rose to 400 from 283 at the end of the first quarter fiscal 2009 and is up from 39 in the year-ago period.

We sold a total of nearly 4,400 Diamondback 360 devices, up from 3,600 at the end of the first quarter fiscal 2009 and more than triple the 1,400 sold in the second quarter of fiscal 2008. Our 90-day disposable reorder rate exceeded 90%. And about 75% of our quarterly revenue was from customer reorders.

Our growth has been driven by our (technical difficulty) sales organization. [And during] second quarter fiscal 2009, we had built our sales team to nearly 90 direct sales professionals versus just 20 a year earlier. The expansion allows us to reach more physicians and more hospitals with our technology and leading products. We have moderately grown this team entering our fiscal third quarter this year with nearly 100 direct sales professionals in the field.

With that overview, let me comment on our pending merger. In early November, CSI signed a definitive merger agreement with Replidyne Incorporated, a biopharmaceutical company in Boulder, CO. A joint proxy statement and prospectus relating to the proposed merger has been mailed to the shareholders of CSI and Replidyne. And both companies special shareholder meetings to vote on the transaction are scheduled for February 24. If approved, the transaction is expected to close on or about the next day.

CSI shareholders will own approximately 83% of the combined company on a fully diluted basis. And we calculate this using treasury method for outstanding stock options and warrants. The combined company's name will be Cardiovascular Systems Inc. And we have applied for listing on the NASDAQ Global Market under the symbol CSII. After an extensive evaluation of our options in exceptionally difficult financial markets that have only gotten worse in the last few months, we concluded that this merger was our best path for raising capital and to become listed on a major US stock exchange. This provides our shareholders the opportunity to realize future value. And through this transaction, we expect to receive \$35 million to \$37 million in net assets, primarily cash, which should bridge us to profitability and positive cash flow. Now Larry will provide a summary of our financial results.

**Larry Betterley - Cardiovascular Systems Inc. CFO**

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Thank you, Dave. As Dave pointed out, revenue grew to \$14 million, a more than 200% increase from the \$4.6 million in the year-ago period. Currently, all revenue is generated in the United States. We have no international business at this time. Diamondback device revenue was 92% of the total revenue for the quarter versus 90% in second quarter last year.

The gross margin improved to 70% from 53% in the same quarter last year due to higher disposable volumes and greater manufacturing efficiencies. We achieved this improvement even though we implemented a deferred pricing alternative for our controller, the capital equipment portion of our system. Through this program, controllers can be paid for over time to a modest upcharge on the disposable device rather than an upfront payment.

This arrangement reduces the gross margin at the time of the controller's shipment when the cost of the controller is expensed and recovers it in future periods as disposable devices are purchased. In the second quarter, the gross margin on the Diamondback devices alone, excluding controllers and other revenue was over 75%.

SG&A expenses rose 55% to \$14.9 million. Two major factors are behind the increase—the planned buildup of our field sales organization and infrastructure investments to support our growth. A \$3.2 million reduction in stock compensation expense somewhat offset these expense increases.

Last year's fiscal second quarter included a charge for the issuance of stock options to replace expiring options. Those options were fully vested at issuance and immediately expensed in that quarter last year.

R&D expenses grew to \$3.5 million, a 16% increase over the year-ago period. CSI is focused on product development to enhance physicians' ease of use and improve the clinical effectiveness of our technology, both above and below the knee, and with all types of plaque. We're also working to expand our capabilities into coronary applications. Compared to recent quarters, R&D expense run rate has declined this quarter as we completed development projects and coronary safety trials.

The second-quarter operating loss improved by 16% to \$8.6 million, a result of strong revenue growth and gross margin improvements, partially offset by sales, infrastructure, and product development investments.

Interest expense was higher due to outstanding debt in fiscal 2009 versus none in fiscal 2008. Amortization expense of \$472,000 of the value of warrants issued in conjunction with the guarantee of \$5.5 million of debt and a \$179,000 increase in preferred stock warrant accretion.

Interest income increased due to the effect of recording an auction-rate security put option asset of \$2.7 million relating to our acceptance of the UBS offer to repurchase our auction-rate securities at par value beginning in June 2010. This was partially offset by lower averaged cash balances and interest rates.

We also incurred an impairment of \$2.2 million in our auction-rate securities, which must be valued independently of the related put option with UBS. This impairment was more than offset by the gain on that put option this quarter.

The net loss improved by 11% to \$8.7 million. The net loss available to common shareholders was \$11.7 million in the quarter compared with \$10.1 million in the year-ago period, due to an increase in the accretion of redeemable convertible preferred stock of \$2.6 million in the current quarter.

The loss per basic and diluted common share for the quarter was \$1.51 similar to last year's \$1.56. The average common shares outstanding increased by 1.2 million shares between periods with the issuance of restricted stock and exercise of stock options.

For the six months ended December 31, comparisons are more pronounced because we only had one quarter of revenue in last year's first six-month period, due to the September 2007 commercial launch of the Diamondback 360 system.

Revenues rose to \$25.6 million versus \$4.6 million in the same period last year. The gross margin was nearly 69%, slightly lower than the first second fiscal quarter this year due to the effect of the lower gross margin in the first quarter resulting from lower unit volumes.

Operating expenses were \$39.8 million, somewhat higher than the second-quarter run rate, due to a \$1.7 million write-off of capitalized IPO cost in the first quarter and reduced spending on research and development as projects and studies were completed.

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The first half net loss available to common shareholders was \$25.4 million, or \$3.29 per basic and diluted share, versus \$22.4 million, or \$3.50 per share, for the first half of last year. The higher loss was due to increased investments in sales and marketing, infrastructure, and product development, and were not immediately offset by higher revenues.

The loss was reduced by \$2.2 million lower accretion of redeemable convertible preferred stock. The loss per share is slightly less due to the issuance of restricted stock and exercises of stock options, as noted earlier.

Turning now to the balance sheet, we ended the year with \$6.4 million in cash and cash equivalents and have not drawn on our \$5 million accounts receivable line of credit. As Dave noted, we anticipate the merger will add \$35 million to the \$37 million in net assets to our balance sheet consisting primarily of cash, which is expected to be sufficient to bridge us to profitability and positive cash flow.

We are holding auction-rate securities with a par value of \$23 million. The current fair value is \$19.5 million. And the fair value of the auction-rate security put option related to those securities is \$2.7 million for a total fair value of \$22.2 million.

As I mentioned earlier, the put option asset relates to our acceptance of the UBS offer to repurchase our securities at par value beginning in June of 2010. In the meantime, UBS has provided us with a full par-value loan against these securities at an interest rate that matches the interest earned on them.

The remainder of our debt consists of \$8.5 million in term loans from Silicon Valley Bank. Of this amount, \$1.8 million was allocated to the value of warrants issued for guarantees of \$5.5 million of the debt and was recorded as a component of stockholders' equity. The value of the warrants is being amortized to interest expense over the one-year term of that debt, which ends in mid-September 2009. The warrants had a non-amortized balance of \$1.3 million at December 31, 2008.

Upon closing of the merger, all of CSI's stock, including both common and preferred, will be converted into common stock of the combined company. When added to Replidyne's outstanding shares, the combined company's total common shares outstanding are expected to be about 136 million to 142 million shares. This amount, however, will be reduced via a reverse split, the ratio for which will be finalized near the closing date.

I will now turn it back to Dave for an update on our product development accomplishments and plans as well as CSI's outlook for the balance of the fiscal year. Dave?

**Dave Martin Cardiovascular Systems Inc. President & CEO**

Thanks, Larry. We did several product development advancements last quarter. First, we launched the next-generation Diamondback 360 in December 2008 and have received a positive reaction from our customers. The product's new features include the following: a 15-centimeter travel, which is twice the travel in the previous model. That allows us to treat longer lesions twice the length of lesions that we previously treated. It's a significant time-saver for the physician.

The device also improves fluid management. In addition, the device has an easy-use, three-in-one, one-click-connect feature to attach tubing and cables very quickly. And it's got a convenient saline infusion port for the physician.

In addition in December, we introduced two products to supplement the atherectomy device sales and enhance the productivity of our sales staff. First is the ViperSlide lubricant. It increases lubricity and reduces friction in the Diamondback 360 shaft and guidewire. And second is the ViperTrack radiopaque tape that assists the physician with alignment for any procedure, including ours, involving fluoroscopic or radiographic imaging.

And we're committed to actively pursuing additional products to supplement our growing leadership position in the treatment of PAD. Some of these products are expected to be introduced in later calendar 2009.

Now I'd like to discuss our outlook for fiscal 2009. For the last six months of our fiscal year ending June 30, 2009, we expect revenue to range between \$31 million and \$33 million, bringing the expected full fiscal year revenue to between \$56 million and \$58 million. That would be \$56.6 million and \$58.6 million. This is growth of more than 150% over the fiscal 2008 and represents a 21% to 29% increase in the second half of the year over the first half of fiscal year 2009.



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Gross margin is expected to be in the range of 70% to 73% for the six-month period. We expect a net loss for the last six months of fiscal year 2009 ranging from \$17 million to \$19 million. And that compares to \$22.4 million in the first half of the year. The net loss improvement results from increasing revenue and gross profit with lower operating expense growth.

The improvement is more pronounced on an adjusted EBITDA basis, calculated as loss from operations less depreciation and amortization of stock-based compensation expense. The loss range on an adjusted EBITDA basis is expected to be approximately \$10 million to \$12 million, a substantial decline from the \$18.8 million negative adjusted EBITDA in the first half of fiscal 2009.

In conclusion, fiscal 2009 is a milestone year for the Company. Our Diamondback 360 Orbital Atherectomy System has unique utility for any physician dedicated to treating PAD. And physicians' acceptance is demonstrated by our double-digit revenue growth in each consecutive quarter since our initial product line.

We have a highly professional and clinically oriented sales oriented that has capacity for adding new accounts and achieving significant productivity gains. We have an experienced R&D team with a track record of developing new products, both internally and in conjunction with outside organizations. And more products are in the pipeline that are expected to expand our available markets and sales productivity.

We believe PAD is a growing market is growing at a double-digit rate. And we have a uniquely safe and effective device for patients needed revascularization, calcified plaque, and lesions below the knee that were difficult to treat. But with the introduction of our product, their treatment is now safer and easier.

All of these developments in an underserved and growing PAD market are fueling our revenue growth and positioning us for future profitability as we leverage our infrastructure over increasing sales volumes.

With the merger agreement scheduled to close on or about February 25th, we are especially excited about the prospect of the combined company's stock trading under the CSII symbol on the NASDAQ Global Market and to updating you on our progress each quarter.

Now we'd like to open up the call to questions.

**QUESTION AND ANSWER**

**Operator**

(Operator Instructions) Your first question comes from the line of Amit Bhalla with Citi. Please proceed.

**Amit Bhalla Citi Analyst**

Hi, good afternoon. I wanted to start just and ask you a couple of questions about utilization trends. Dave, you started to or you did allude to 75% reorders in your prepared comments. The Diamondback has been on the market for about a year. So maybe you could talk a little bit about utilization trends from some of those earlier accounts. And give us your sense of what you're seeing in the market in terms of procedure volumes for PAD.

**Dave Martin Cardiovascular Systems Inc. President & CEO**

Well, let me start with the last part first. I think procedure volumes are up. The awareness of PAD is growing. The problem is large and growing, unfortunately. And there's more trained physicians than other with specialties, interventional radiologists, vascular surgeons, and interventional cardiologists dedicated to treating. So the market is growing.

As far as utilization in our customers for last year, we did target those physicians dedicated to treating the disease. And we also worked very hard on iterating the device and making it easier and safer to use.

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As we move forward, we are getting into tier II accounts, if that's what you're alluding to. Right now, we're at 400 accounts between just a universe of accounts as high as 1,500 hospitals in the United States.

**Amit Bhalla** *Citi Analyst*

Yes, do you care to put a number on the kind of percentage growth you're seeing in procedure volumes? I have one other follow up.

**Dave Martin** *Cardiovascular Systems Inc. President & CEO*

In general—and some of this revolves around discussions with you and other analysts—but we believe that procedure volume's growing at 15% overall in the market. And we take more for us because of the unique characteristics of the device.

**Amit Bhalla** *Citi Analyst*

And in terms of the guidance, what are your assumptions in your guidance for total sales force by the end of the year? And maybe you could break it down by ASMs versus some of your direct reps as well as your accounts. And then the last question on your guidance—it basically assumes kind of flatish to slightly up in terms of \$14 million that you just reported. Are you just being conservative there? Or is there other trends that we should be aware of in the next few quarters?

**Dave Martin** *Cardiovascular Systems Inc. President & CEO*

Let me start that. And then Larry will finish. As far as sales model, we do believe that a lot of the building, hiring, and infrastructure build from last year will really pay off. And one example is that sales model. We're at a 100 coming into the quarter. We think the optimal model to serve this market with our product and other products is 120 to 150 sales professionals. Currently, we do have a mix that includes two types of professionals in our field sales force. There's about 80 sales professionals. And the remainder would be a junior sales professional.

**Larry Betterley** *Cardiovascular Systems Inc. CFO*

Okay. In response, Amit, we target about 75 to 100 new accounts per quarter. That's our target going forward. As far as the \$31 million to \$33 million, is that a conservative number? Well, we felt it's reasonably conservative. But in these days, that's appropriately to be.

**Amit Bhalla** *Citi Analyst*

Thank you.

**Operator**

Your next question comes from the line of Ben Andrew with William Blair. Please proceed.

**Ben Andrew** *William Blair Analyst*

Good afternoon. You've got Ben and Matt here actually.

**Dave Martin** *Cardiovascular Systems Inc. President & CEO*

Hi, guys.

**Ben Andrew** *William Blair Analyst*

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A quick couple questions for you David, maybe spend a minute talking about where you are in your clinical work at this point between registry and maybe something a bit more organized and when we might look to see a reasonable set of data that you can use to bolster the position in the market.

**Dave Martin Cardiovascular Systems Inc. President & CEO**

Yes, we're all queued up for two studies. We did hold pending this transaction on enrolling the first patient in our calcium study below the knee. But we're ready to go immediately upon close of the transaction. We think based on our growing customer base we can enroll that very quickly.

And then we have a compliance 360 study, which would be our above-the-knee study. We will follow up on our below-the-knee with that study immediately. And then in addition, as an indicator to the coronary opportunity, we did complete our six-month mark in terms of follow up for the study that we did in India and that we worked closely with the FDA on. So that would be an optional lever that we could push going forward as well in the clinical arena.

**Ben Andrew William Blair Analyst**

Okay. And as you talk to clinicians, you're having a tremendous amount of success. Is there a percentage of people that give you much pushback on the clinical? Or are you targeting better? Or is there just a basic awareness of the benefits of this therapy?

**Dave Martin Cardiovascular Systems Inc. President & CEO**

Well, I think the unmet needs below the knee and particular with calcium and our performance against those against that anatomy and that plaque [pathology] speaks to the physician immediately. We are committed to supporting the physician usage over time with clinical data. And I think that'll need to come. And we'll do that. But initially, physicians that needed a solution for calcium, they needed a way to treat outflow and below the knee. And the product is performing nicely.

**Unidentified Participant**

Okay. And then this is Matt. Just one more quick one any sense for what share you're at, at this point below the knee?

**Dave Martin Cardiovascular Systems Inc. President & CEO**

We don't have any formal data. But we're making great gains. We're certainly into double digits. One reason it's hard to put a number on is because we do two things below the knee. We do take market share immediately not only against other atherectomy devices but against balloons. And we also grow the market (inaudible) our device is low profile and accesses lesions that previously the physicians hadn't accessed. It's uniquely positioned against calcified lesions. 75% of below-the-knee lesions have calcification.

And maybe the most important thing is the safety profile. Now the physician can go down below the knee with the expectation that there won't be a perforation or a dissection. And that's real important for physician outcomes and acute results.

**Unidentified Participant**

Okay. And then just real quick to follow up on that, are you hearing any learning curve as far as physicians with perforation, other complications, hemolysis early in the process of getting up to curve on using Diamondback or any anecdotal comments would be helpful.

**Dave Martin Cardiovascular Systems Inc. President & CEO**

Well, we were really open to whatever may happen, recognizing that we're bringing a new product to market. And we're taking it from bench and FDA clinical data into the commercial setting. So we worked very closely with our physicians on those issues. And we've only gained confidence.

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So at this point in time, we worked last year on iterating the device eight times over the course of five quarters. We feel that we've got a device now that is in a great place to enter into clinical studies. And we're still committed to actually working on iteration schedule. So that's our go-forward plan is to continue to iterate and [enter] (inaudible).

**Unidentified Participant**

All right, thank you.

**Operator**

Your next question comes from the line of [Thomas Cuchicos], Stifel Nicholas. Please proceed.

**Thomas Cuchicos Stifel Nicholas Analyst**

Hey, good afternoon, guys. Thanks for taking the question.

**Dave Martin Cardiovascular Systems Inc. President & CEO**

Hi, Tom.

**Thomas Cuchicos Stifel Nicholas Analyst**

Hey, just wanted to follow up from some comments you made I think in your last conference call. Looking at the split between above- and below-knee treatments, I think you were at maybe roughly 40-60 ratio there with the majority being below the knee. As you've had the product out there for a pretty long time now and as you've had new crown sizes come out to the market, can you talk about maybe the different uses you've seen? And has that ratio changed at all since your last report?

**Dave Martin Cardiovascular Systems Inc. President & CEO**

It probably has changed to 60% above the knee and 40% below the knee. Part of that is there is low-hanging market share for and currently, the market is biased to above-the-knee interventions. One of the opportunities for us this year is to keep a dual message above the knee, below the knee and expand the market. And that's an opportunity for our future success is to continue to take that market share as well as keep a key focus on expanding the market pot.

**Thomas Cuchicos Stifel Nicholas Analyst**

Okay. And then to follow up on the last question from the previous caller, it might be difficult to quantify. But could you provide some sort of measure of how much your growth is coming from expanding the market because you can treat calcium more effectively versus what maybe competitive wins in the market place?

**Dave Martin Cardiovascular Systems Inc. President & CEO**

I lost you on the beginning of that. Will you repeat the beginning of that question?

**Thomas Cuchicos Stifel Nicholas Analyst**

Sure, just some sense of is the bulkier growth coming from expanding the market because you can expand the treatment population due to the device's capacity in calcium? Or is it more on the competitive win front?





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**Dave Martin** *Cardiovascular Systems Inc. President & CEO*

Well, we do both when we're out at a hospital. We compete not only against other atherectomy devices, but we compete very well against balloons and stents because we make smooth tubular lumens. We've got a unique safety profile and the toughest plaque [morphology]. We're finding our physicians are picking us up first. And the Diamondback is great for starting a case and sometimes ending it. So that's the place that we're in right now. Does that begin to answer your question?

**Thomas Cuchicos** *Stifel Nicholas Analyst*

Yes, I think so. I mean, you've had your sequential growth was pretty impressive and just trying to get a sense of market dynamics and share position. And you said it might be tough to quantify. But one of your early messages was that you would expand the market because you have a device that others haven't been able to really get to places in calcium and things like that. I'm just curious. Have you seen I guess it's tough to quantify but how much incremental procedure volume do you think you're getting because of that ability to reach places where others can't?

**Dave Martin** *Cardiovascular Systems Inc. President & CEO*

Yes, we do see that. And we're looking at quantifying that. Just some examples calcified below the knee, that's a trouble area. A lot of physicians won't go there with devices that were previously available. But they do go down there routinely. And we're seeing market expansion in physician practices, both the vascular surgeon and the interventional cardiologist.

We do have accounts where when we arrive, they've got the traditional three-to-one split between above-the-knee and below-the-knee interventions. And six months, they will have doubled or tripled their below-the-knee interventions. We do have some examples of that in our customer base. And we'll continue to look at that as we go forward.

**Thomas Cuchicos** *Stifel Nicholas Analyst*

Okay. That's really helpful. And then finally, one last one could you talk a little bit about your early efforts in the coronary space because that sounds like you might be getting more aggressive going towards the heart?

**Dave Martin** *Cardiovascular Systems Inc. President & CEO*

Well, we did work very closely with the FDA on a feasibility trial that we conducted last year in India. It was 50 patients. And the low profile of the device, its ability to access small vessels and the unique safety profile were indicators for us that this will be a great device in the coronaries. And in fact, that's turned out to be true. We completed the 50 cases by June of calendar year last year. And we've got the six-month follow up on nearly all of them at this point in time. We will be meeting with the FDA shortly to review those results and really look forward to giving you updates over time on that coronary opportunity.

**Thomas Cuchicos** *Stifel Nicholas Analyst*

Great. Thanks so much, guys.

**Operator**

Your next question comes from Christopher Warren with Caris & Company. Please proceed.

**Christopher Warren** *Caris & Company Analyst*

Thanks so much. I appreciate it taking the question. I wanted to ask you over the last two to four quarters have you in your opinion seen any market procedure deceleration in terms of growth?

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**Dave Martin** *Cardiovascular Systems Inc. President & CEO*

We keep our eyes open. With the economy in the state that it is, we haven't observed any hard data. Unfortunately, a lot of the patients who need treatment are at end stage. And they're looking at immobility, pain, or amputation. So we haven't seen a trend towards less cases in PAD intervention. But we're open to looking for it.

**Christopher Warren** *Caris & Company Analyst*

Thanks. That's helpful. And just another question on the competitive landscape - there are two primary competitors that you go head to head with, both of which I cover. And my question for you would be is there any change there? Do you perceive you're taking more share from one than the other?

**Dave Martin** *Cardiovascular Systems Inc. President & CEO*

It's hard to tell. I don't have a definitive answer. We compete well against both atherectomy and non-atherectomy solutions, compete very well against balloons of all kinds as well. And we compete well against non-treatment once the physician gets comfortable with our safety profile. We definitely have taken some market share. Physicians needed a solution for calcium. And I think we have taken market share from some of the companies out there. But it's hard to determine because we do grow the market pie as well.

**Christopher Warren** *Caris & Company Analyst*

Understood. And just one last question on inventories - have you seen any change in what the hospitals are stocking or destocking, anything there?

**Dave Martin** *Cardiovascular Systems Inc. President & CEO*

Well, it's been pretty stringent. When we entered the market five quarters ago, the hospitals have been in pretty good control. And we also have some stringent policies here. We don't give away free product. We don't consign. We sell only enough devices on an initial stocking order for the physician to be ready for the next couple of cases. And then when physicians or hospitals reorder, we'll sell them one or two or whatever their need is for their ordering patterns. So we're not seeing any unusual practices other than continued control of inventories, both from the hospital side and from the CSI side.

**Christopher Warren** *Caris & Company Analyst*

Okay. Thanks so much. Great growth on the quarter.

**Larry Betterley** *Cardiovascular Systems Inc. CFO*

Thank you.

**Dave Martin** *Cardiovascular Systems Inc. President & CEO*

Thanks.

**Operator**

And the next question comes from the line of Jason Mills with Canaccord Adams. Please proceed.

**Jason Mills** *Canaccord Adams Analyst*

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**Final Transcript**

**Feb 11, 2009 / 10:00PM GMT, CSII Q2 2009 Cardiovascular Systems Inc Earnings Conference Call**

Hi, David. Thanks for taking the question. David, first of all, you and your team at Foxhollow did really the best initial and perhaps the best job of developing the referral channel in this market. But yet in our due diligence, it's still amazing to me the number of physician podiatrists especially out there that are either ignorant or not as aware as others about the interventional treatments such as yours. I'm wondering what your current company's doing - CSI's doing - to continue the referral development and how that's going. What inning do you kind of see us being in, in terms of awareness among the specific diagnosticians, whether they be podiatrists or general care practitioners out there?

**Dave Martin Cardiovascular Systems Inc. President & CEO**

Yes, we're in the first three innings still. But we're not in the first inning. We're in the third inning. We've seen in general some increased awareness and dramatic increase in the number of physicians dedicated to intervening here. So maybe in the study in 2004 it was interventional cardiology that got into the leg space in spades and necessarily so for the size of the problem. And now we're seeing vascular surgeons doing a great getting that endo-training.

In terms of what we do and how we spend and invest, at this point in time, we're in 400 accounts. We need to be in 1,500. We've got a chance to take market share and build the market pie without really expanding into the referral marketing activities. We're for them. But at this stage of the game, we're going to focus one physician at a time and support those physicians.

But there is a ground swell. There are hospitals now who are getting behind their physician operators and with marketing and awareness campaigns. And physician operators with the continued success of their leg interventions are calling up their referral physicians to make them aware of what they can do. And certainly a great reason for them to do that right now is the new technology that treats calcium uniquely and has a unique safety profile. So some of that work is being done for us and for patients by the hospitals and the physicians themselves.

**Jason Mills Canaccord Adams Analyst**

That's helpful. To a question a little bit ago with respect to the clinical trial update, you mentioned the calcium trial. I'm wondering if you could just update me - and perhaps I missed it - with the details. If you've already gone over them, I apologize for making you repeat them, but details in terms of number of centers you plan to be involved in that trial and the specific endpoints you'll be targeting.

**Dave Martin Cardiovascular Systems Inc. President & CEO**

Yes, we're going to look at acute and long-term results. It's going to be a below-the-knee study. We know that calcium is prevalent in 75% of those cases. So we will look at acute and long-term results. As far as the number of patients, that's a bough that we could touch. We will likely start with ten centers and then expand if necessary. And we look forward to updating you over time.

**Jason Mills Canaccord Adams Analyst**

Okay. Just a few final ones, and I'll get back in queue. Is there any way, David, you could assign any nominal benefit vis-a-vis Spectranetics federal investigation and perhaps some clinicians losing faith, be it right or wrong - I'm not here to judge - but in that technology or in that company vis-a-vis the federal investigation? Is there any way that you could quantify or speak to that?

**Dave Martin Cardiovascular Systems Inc. President & CEO**

No. I think that the big issues important is just the number. You have 8 million to 12 million patients who need the treatment. We need more tools. And I think that's where the physicians' heads are right now is just needing new tools to treat this large patient population.

**Jason Mills Canaccord Adams Analyst**

Okay. And then lastly, just with respect, you mentioned a bit ago your practices with respect to inventory and in the hospitals. When a new center starts, has there been any change or could you just remind us what your sort of normal center's upfront investment would be when they start a CSI practice?

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**Dave Martin** *Cardiovascular Systems Inc. President & CEO*

Sure. Yes, it's about \$40,000. We have five different sizes. And we think to prepare for the next couple of cases, we like them to have up to two devices per size. So I'd say the average number of devices would be six to ten, not all of them ordered, two of each size. And then for the pole and the scoreboard, we don't give that away. But we also don't get a big margin off of that. So we think that's the way we've installed every account today.

**Larry Betterley** *Cardiovascular Systems Inc. CFO*

Just I'll point out that the numbers Dave said we had \$40,000 that would be assuming that they were buying the controller as well. But oftentimes, they choose to pay for that with a modest uplift in the device.

**Jason Mills** *Canaccord Adams Analyst*

Okay. Thanks, guys. Congratulations on a good quarter.

**Larry Betterley** *Cardiovascular Systems Inc. CFO*

Thank you.

**Dave Martin** *Cardiovascular Systems Inc. President & CEO*

Thanks.

**Operator**

Your next question comes from [Rog Stenhoy] with Thomas Weisel Partners. Please proceed.

**Rog Stenhoy** *Thomas Weisel Partners Analyst*

Hi, good evening. I just wonder if I could just ask a question. I know you've covered this a little bit. But I just wanted to reconcile one of your larger competitors in this market has made comments that they don't think this market is growing and that it requires additional clinical data to really get the market moving. And yet you are making comments that the market is still very healthy. And is it simply a case of your ability to treat areas they can't? Or are you seeing something in the marketplace that they're missing?

**Dave Martin** *Cardiovascular Systems Inc. President & CEO*

Yes, I think you're exactly right. We treat areas that other devices can't. So we're not limited to just the traditional and visible two atherectomy companies. We apply to literally anytime a physician's looking at the above the knee or below the knee. They can and often do start with the Diamondback 360. So we do have more opportunity. And we're seeing that in our usage and uptake.

**Rog Stenhoy** *Thomas Weisel Partners Analyst*

Well, then could you even hazard a guess at the growth you're putting up, the revenue numbers you're putting up, how much of that is coming from new areas that couldn't be treated versus competitive wins you're taking from devices which are already on the market?

**Dave Martin** *Cardiovascular Systems Inc. President & CEO*



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**Final Transcript**

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Yes, and we don't have great detail on that. Last year, we invested in infrastructure. We had new sales hires. We installed and trained new physicians in hospitals. We did take the low-hanging fruit market share. But we've got a number of examples in our customer base of situations where they've doubled or more the amount of below-the-knee cases that they've done. And they've changed their approach completely to any case where they think they're encountering calcification.

**Rog Stenhoy** *Thomas Weisel Partners Analyst*

Okay. And then just lastly, you mentioned you haven't expanded yet internationally. Do you have any update on your timing or plans to start moving overseas?

**Dave Martin** *Cardiovascular Systems Inc. President & CEO*

Well, we've got a great margin and a great business in the United States. And we're going to focus our precious dollars on the U.S. market first. We're open to technologies from any part of the world that would help us at our user base or with our hospitals. So we do engage in that dialogue. But for right now, we're going to be a U.S.-focused company.

**Rog Stenhoy** *Thomas Weisel Partners Analyst*

Great. Thank you.

**Operator**

Your next question comes from the line of Sean Fitz with Stephens Incorporated. Please proceed.

**Sean Fitz** *Stephens Incorporated Analyst*

Yes, great. Thank you. Congratulations on the quarter and a strong 12 months. This is a bit of a follow up to Rog's questions. But I guess as we look around at the atherectomy space and some of the technologies that have addressed this market, there seems to be kind of a track record here where you see some very dramatic growth initially and then a period where there appears to be kind of a glass ceiling and a deterioration into negative growth.

So just as an analyst trying to understand this industry, could you kind of help me understand what it is about your technology or your sales force that would make that not a reliable predictor of kind of future growth trends for CSI?

**Dave Martin** *Cardiovascular Systems Inc. President & CEO*

Sure. In terms of market share, balloons, stents, surgical alternatives, we make smooth tubular lumens. And we're very safe. And we're easy to use and getting easier to use. So that in terms of just market share allows us to compete with anything that's used right now.

In addition to that, we do access anatomy that previously couldn't be accessed routinely and safely. And a great example of that is below the knee. There's a three-to-one bias for above-the-knee versus below-the-knee treatment. And that's not because the disease doesn't exist. Unfortunately, the disease is diffuse. If you've got it above the knee, you've got it below the knee. If you've got it in one leg, you've got it in the other leg. It's just the limitations of technologies that allow the physicians to get to some anatomy, especially below the knee, routinely. Our device allows physicians to do that.

**Sean Fitz** *Stephens Incorporated Analyst*

And so when we think, again, about just the composition of the blockage, it sounds like you all are particularly strong with calcified lesions. Just as we think about focal versus diffuse lesions, do you feel like you've got a competitive advantage from that standpoint?

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**Dave Martin** *Cardiovascular Systems Inc. President & CEO*

We do because one device will treat both. And that's unique. Now with the longer throw, the 15-centimeter treatment length that we can now have available to the doctor, that allows the physician to go in and treat multiple focal lesions or diffuse lesions. And with the safety profile, the device does differentiate between healthy and organized plaque. We're great on all plaque morphologies, particularly calcium. And the reason that when you talk to the physicians you'll hear about calcium a lot is there just hasn't been a device in the past that allows them to routinely treat it.

**Sean Fitz** *Stephens Incorporated Analyst*

Okay. So below the knee, is it fair to assume that that's roughly 40% of all atherectomy procedures in the marketplace now?

**Dave Martin** *Cardiovascular Systems Inc. President & CEO*

Well, no, for us, it is. For us, it is. But I think other technologies have difficulty getting down there routinely. So I don't think that that mix would be as high.

**Sean Fitz** *Stephens Incorporated Analyst*

Okay. And so then if we think about calcified lesions below the knee, what percentage of the atherectomy procedures below the knee do you think encounter are to address a calcified lesion?

**Dave Martin** *Cardiovascular Systems Inc. President & CEO*

Physicians tell us that 75% of the time they are below the knee, there is calcium.

**Sean Fitz** *Stephens Incorporated Analyst*

Okay. Thanks, David. Appreciate you guys' time.

**Dave Martin** *Cardiovascular Systems Inc. President & CEO*

Sure. Thank you.

**Operator**

At this time, we have no additional questions in the queue. I would now turn the call back over to Mr. Dave Martin for any further remarks. Please proceed.

**Dave Martin** *Cardiovascular Systems Inc. President & CEO*

Well, thanks for attending the call. We believe [the numbers] established in the first half of fiscal 2009 will carry us into the rest of the year. And our Diamondback 360 system is making an impact on the treatment of patients with PAD. And we have the team and the brand for a superior execution for the remainder of the year and beyond. Thank you.

**Operator**

Ladies and gentlemen, thank you for your participation in today's conference. This concludes the presentation. You may now disconnect. And have a wonderful day.

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### **Forward-looking Statements**

*This communication contains plans, intentions, objectives, estimates and expectations that constitute forward-looking statements about Replidyne, Inc. ( Replidyne ) and Cardiovascular Systems, Inc. ( 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 anticipated benefits of the transaction, including the sufficiency of Replidyne's net assets to bridge CSI to profitability and a positive cash flow, the expected ownership of CSI shareholders in the combined company, the number of shares outstanding following the merger, and CSI's expectation for revenues, gross margin, loss and EBITDA for the last six months of 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; Replidyne's actual net assets at the closing of the merger; the number of outstanding shares of CSI and Replidyne immediately prior to the closing of the merger; regulatory developments in the U.S. and foreign countries; the experience of physicians regarding the effectiveness and reliability of the Diamondback 360°; competition from other devices; unanticipated developments affecting 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 December 17, 2008, Replidyne's Form S-4 filed with the SEC on January 26, 2009, and Replidyne's most recent Form 10-Q filed with the SEC. 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 this communication 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 has filed a registration statement on Form S-4 with the SEC containing a related proxy statement/prospectus. The proxy statement/prospectus has been mailed to the stockholders of Replidyne and CSI. Investors and security holders of Replidyne and CSI are urged to read the proxy statement/prospectus because it contains important information about Replidyne, CSI and the proposed transaction. The proxy statement/prospectus, 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 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

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and executive officers of Replidyne and CSI and their respective interests in the proposed transaction is 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.

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

#### **Non-GAAP Financial Measures**

To supplement CSI's consolidated condensed financial statements prepared in accordance with GAAP, CSI uses certain non-GAAP financial measures in this communication. These non-GAAP financial measures include Adjusted EBITDA.

Reconciliations of the non-GAAP financial measures used in this communication to the most comparable U.S. GAAP measures for the respective periods can be found in the tables below. In addition, an explanation of the manner in which CSI's management uses these non-GAAP measures to conduct and evaluate its business, the economic substance behind management's decision to use these non-GAAP measures, the substantive reasons why management believes that these non-GAAP measures provide useful information to investors, the material limitations associated with the use of these non-GAAP measures and the manner in which management compensates for those limitations is included following the reconciliation table below.

**Cardiovascular Systems, Inc.**  
**Adjusted EBITDA (unaudited)**  
**(Dollars in Thousands)**

|                                    | <b>Projected Range<br/>Six Months Ending<br/>June 30, 2009</b> |             |
|------------------------------------|--|-------------|
|                                    | <b>High</b>  | <b>Low</b>  |
| Loss from operations               | \$ (16,000)  | \$ (18,000) |
| Add: Stock-based compensation      | 5,700  | 5,700       |
| Add: Depreciation and amortization | 300  | 300         |
| Adjusted EBITDA                    | \$ (10,000)  | \$ (12,000) |

#### **Use and Economic Substance of Non-GAAP Financial Measures Used by CSI and Usefulness of Such Non-GAAP Financial Measures to Investors**

CSI uses the non-GAAP financial measures described above as supplemental measures of performance and believes these measures facilitate operating performance comparisons from period to period and company to company by factoring out potential differences caused by non-recurring, unusual or infrequent charges not related to CSI's regular, ongoing business, depreciation, non-cash charges and certain large and unpredictable charges. CSI's management uses the non-GAAP financial measures used in this communication to analyze the underlying trends in CSI's business, assess the performance of CSI's core operations, establish operational goals and forecasts that are used in allocating resources and evaluate CSI's performance period over period and in relation to its competitors' operating results. Additionally, CSI's management is evaluated on the basis of some of these non-GAAP financial measures when determining achievement of their incentive compensation performance targets.

CSI believes that presenting the non-GAAP financial measures used in this communication provides investors greater transparency to the information used by CSI's management for its financial and operational decision-making and allows investors to see CSI's results through the eyes of management. CSI also believes that providing this information better enables CSI's investors to understand CSI's operating performance and evaluate the methodology





used by CSI's management to evaluate and measure such performance. CSI's management believes that non-GAAP financial measures are useful to investors to evaluate CSI's performance period over period and in relation to its competitors' operating results.

The following is an explanation of each of the items that management excluded from one or more of the non-GAAP financial measures used in this communication and the reasons for excluding each of these individual items:

**Stock-based compensation.** CSI excludes stock-based compensation expense from its non-GAAP financial measures primarily because such expense, while constituting an ongoing and recurring expense, is not an expense that requires cash settlement. CSI's management also believes that excluding this item from CSI's non-GAAP results is useful to investors to understand the application of SFAS 123R and its impact on CSI's operational performance, liquidity and its ability to make additional investments in the company, and it allows for greater transparency to certain line items in CSI's financial statements.

**Depreciation and amortization expense.** CSI excludes depreciation and amortization expense from its non-GAAP financial measures primarily because such expenses, while constituting ongoing and recurring expenses, are not an expense that requires cash settlement and is not used by CSI's management to assess the core profitability of CSI's business operations. CSI's management also believes that excluding these items from CSI's non-GAAP results is useful to investors to understand CSI's operational performance, liquidity and its ability to make additional investments in the company.

**Material Limitations Associated with the Use of Non-GAAP Financial Measures and Manner in which CSI Compensates for these Limitations**

Non-GAAP financial measures have limitations as analytical tools and should not be considered in isolation or as a substitute for CSI's financial results prepared in accordance with GAAP. Some of the limitations associated with CSI's use of these non-GAAP financial measures are:

Items such as stock-based compensation do not directly affect CSI's cash flow position; however, such items reflect economic costs to CSI and are not reflected in CSI's Adjusted EBITDA and therefore these non-GAAP measures do not reflect the full economic effect of these items.

Non-GAAP financial measures are not based on any comprehensive set of accounting rules or principles and therefore other companies may calculate similarly titled non-GAAP financial measures differently than CSI, limiting the usefulness of those measures for comparative purposes.

CSI's management exercises judgment in determining which types of charges or other items should be excluded from the non-GAAP financial measures CSI uses.

CSI compensates for these limitations by relying primarily upon its GAAP results and using non-GAAP financial measures only supplementally. CSI provides full disclosure of each non-GAAP financial measure CSI uses and detailed reconciliations of each non-GAAP measure to its most directly comparable GAAP measure. CSI encourages investors to review these reconciliations. CSI qualifies its use of non-GAAP financial measures with cautionary statements as set forth above.